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Paroxetine (Hydrochloride Hemihydrate)
GlaxoSmithKline

Consolidated Response Document

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Paroxetine EMEA LOQs

EMEA LOQs Table 1.01
Incidence of Possibly Suicide-Related AEs During First 2 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	13/7892 (0.2%)	17/5207 (0.3%)	0.5 (0.24, 1.04)	0.06
Depression	n/N (%)	12/3360 (0.4%)	9/2053 (0.4%)	0.81 (0.34, 1.94)	0.66
GAD	n/N (%)	0/904 (0.0%)	0/697 (0.0%)		
OCD	n/N (%)	0/542 (0.0%)	3/265 (1.1%)		0.04
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
PTSD	n/N (%)	1/698 (0.1%)	2/510 (0.4%)	0.36 (0.03, 4.03)	0.58
Panic	n/N (%)	0/920 (0.0%)	2/780 (0.3%)		0.21
SAD	n/N (%)	0/708 (0.0%)	1/523 (0.2%)		0.42

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.01a
Incidence of Possibly Suicide-Related AEs During First 2 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials, Study 057
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Depression	n/N (%)	4/131 (3.1%)	7/136 (5.1%)	0.58 (0.17, 2.03)	0.54

Paroxetine EMEA LOQs

EMEA LOQs Table 1.02
Incidence of Possibly Suicide-Related AEs During First 4 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	35/7892 (0.4%)	28/5207 (0.5%)	0.82 (0.5, 1.36)	0.44
Depression	n/N (%)	33/3360 (1.0%)	18/2053 (0.9%)	1.12 (0.63, 2)	0.77
GAD	n/N (%)	0/904 (0.0%)	1/697 (0.1%)		0.44
OCD	n/N (%)	0/542 (0.0%)	3/265 (1.1%)		0.04
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
PTSD	n/N (%)	2/698 (0.3%)	3/510 (0.6%)	0.49 (0.08, 2.92)	0.66
Panic	n/N (%)	0/920 (0.0%)	2/780 (0.3%)		0.21
SAD	n/N (%)	0/708 (0.0%)	1/523 (0.2%)		0.42

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.02a
Incidence of Possibly Suicide-Related AEs During First 4 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials, Study 057
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Depression	n/N (%)	14/131 (10.7%)	11/136 (8.1%)	1.36 (0.59, 3.12)	0.53

Paroxetine EMEA LOQs

EMEA LOQs Table 1.03

Incidence of Possibly Suicide-Related AEs During First 2 Weeks of Treatment by Treatment Group and Control Medication Class

Excluding Relapse Prevention Studies

Adult Active Control Trials

On-Therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	18/6522 (0.3%)	24/4969 (0.5%)	0.57 (0.31, 1.05)	0.09
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
SSRI	n/N (%)	4/1200 (0.3%)	13/1218 (1.1%)	0.31 (0.1, 0.95)	0.05
TETRACYCLIC	n/N (%)	0/527 (0.0%)	0/518 (0.0%)		
TRICYCLIC	n/N (%)	9/2953 (0.3%)	10/2754 (0.4%)	0.84 (0.34, 2.07)	0.82
OTHER	n/N (%)	5/1766 (0.3%)	1/402 (0.2%)	1.14 (0.13, 9.77)	1.00

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.04

Incidence of Possibly Suicide-Related AEs During First 4 Weeks of Treatment by Treatment Group and Control Medication Class

Excluding Relapse Prevention Studies

Adult Active Control Trials

On-Therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	38/6522 (0.6%)	44/4969 (0.9%)	0.66 (0.42, 1.01)	0.06
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
SSRI	n/N (%)	10/1200 (0.8%)	18/1218 (1.5%)	0.56 (0.26, 1.22)	0.18
TETRACYCLIC	n/N (%)	2/527 (0.4%)	3/518 (0.6%)	0.65 (0.11, 3.93)	0.68
TRICYCLIC	n/N (%)	17/2953 (0.6%)	21/2754 (0.8%)	0.75 (0.4, 1.43)	0.42
OTHER	n/N (%)	9/1766 (0.5%)	2/402 (0.5%)	1.02 (0.22, 4.76)	1.00

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.05
Incidence of Possibly Suicide-Related AEs During First 2 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Paediatric Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	2/642 (0.3%)	1/549 (0.2%)	1.71 (0.15, 18.94)	1.00
Depression	n/N (%)	2/378 (0.5%)	1/285 (0.4%)	1.51 (0.14, 16.74)	1.00
OCD	n/N (%)	0/99 (0.0%)	0/107 (0.0%)		
SAD	n/N (%)	0/165 (0.0%)	0/157 (0.0%)		

Includes studies 329, 377, 676, 701 and 704

Paroxetine EMEA LOQs

EMEA LOQs Table 1.06
Incidence of Possibly Suicide-Related AEs During First 4 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Paediatric Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	6/642 (0.9%)	2/549 (0.4%)	2.58 (0.52, 12.83)	0.30
Depression	n/N (%)	4/378 (1.1%)	2/285 (0.7%)	1.51 (0.28, 8.32)	0.70
OCD	n/N (%)	1/99 (1.0%)	0/107 (0.0%)		0.48
SAD	n/N (%)	1/165 (0.6%)	0/157 (0.0%)		1.00

Includes studies 329, 377, 676, 701 and 704

Paroxetine EMEA LOQs

EMEA LOQs Table 1.07
Incidence of Self Harm During First 2 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	8/7892 (0.1%)	11/5207 (0.2%)	0.48 (0.19, 1.19)	0.16
Depression	n/N (%)	7/3360 (0.2%)	7/2053 (0.3%)	0.61 (0.21, 1.74)	0.41
GAD	n/N (%)	0/904 (0.0%)	0/697 (0.0%)		
OCD	n/N (%)	0/542 (0.0%)	1/265 (0.4%)		0.33
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
PTSD	n/N (%)	1/698 (0.1%)	1/510 (0.2%)	0.73 (0.05, 11.7)	1.00
Panic	n/N (%)	0/920 (0.0%)	1/780 (0.1%)		0.46
SAD	n/N (%)	0/708 (0.0%)	1/523 (0.2%)		0.42

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.07a
Incidence of Self Harm During First 2 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials, Study 057
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Depression	n/N (%)	4/131 (3.1%)	7/136 (5.1%)	0.58 (0.17, 2.03)	0.54

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.08
Incidence of Self Harm During First 4 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	23/7892 (0.3%)	17/5207 (0.3%)	0.89 (0.48, 1.67)	0.75
Depression	n/N (%)	22/3360 (0.7%)	13/2053 (0.6%)	1.03 (0.52, 2.06)	1.00
GAD	n/N (%)	0/904 (0.0%)	0/697 (0.0%)		
OCD	n/N (%)	0/542 (0.0%)	1/265 (0.4%)		0.33
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
PTSD	n/N (%)	1/698 (0.1%)	1/510 (0.2%)	0.73 (0.05, 11.7)	1.00
Panic	n/N (%)	0/920 (0.0%)	1/780 (0.1%)		0.46
SAD	n/N (%)	0/708 (0.0%)	1/523 (0.2%)		0.42

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.08a
Incidence of Self Harm During First 4 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Adult Placebo Controlled Trials, Study 057
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Depression	n/N (%)	13/131 (9.9%)	11/136 (8.1%)	1.25 (0.54, 2.9)	0.67

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.09
Incidence of Self Harm During First 2 Weeks of Treatment by Treatment Group and Control Medication Class
Excluding Relapse Prevention Studies
Adult Active Control Trials
On-Therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	7/6522 (0.1%)	6/4969 (0.1%)	0.89 (0.3, 2.65)	1.00
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
SSRI	n/N (%)	2/1200 (0.2%)	1/1218 (0.1%)	2.03 (0.18, 22.44)	0.62
TETRACYCLIC	n/N (%)	0/527 (0.0%)	0/518 (0.0%)		
TRICYCLIC	n/N (%)	4/2953 (0.1%)	5/2754 (0.2%)	0.75 (0.2, 2.78)	0.75
OTHER	n/N (%)	1/1766 (0.1%)	0/402 (0.0%)		1.00

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.10
Incidence of Self Harm During First 4 Weeks of Treatment by Treatment Group and Control Medication Class
Excluding Relapse Prevention Studies
Adult Active Control Trials
On-Therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	17/6522 (0.3%)	19/4969 (0.4%)	0.68 (0.35, 1.31)	0.31
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
SSRI	n/N (%)	4/1200 (0.3%)	4/1218 (0.3%)	1.02 (0.25, 4.07)	1.00
TETRACYCLIC	n/N (%)	2/527 (0.4%)	1/518 (0.2%)	1.97 (0.18, 21.79)	1.00
TRICYCLIC	n/N (%)	10/2953 (0.3%)	13/2754 (0.5%)	0.72 (0.31, 1.64)	0.53
OTHER	n/N (%)	1/1766 (0.1%)	1/402 (0.2%)	0.23 (0.01, 3.64)	0.34

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.11
Incidence of Self Harm During First 2 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Paediatric Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	2/642 (0.3%)	1/549 (0.2%)	1.71 (0.15, 18.94)	1.00
Depression	n/N (%)	2/378 (0.5%)	1/285 (0.4%)	1.51 (0.14, 16.74)	1.00
OCD	n/N (%)	0/99 (0.0%)	0/107 (0.0%)		
SAD	n/N (%)	0/165 (0.0%)	0/157 (0.0%)		

Includes studies 329, 377, 676, 701 and 704

Paroxetine EMEA LOQs

EMEA LOQs Table 1.12
Incidence of Self Harm During First 4 Weeks of Treatment by Treatment Group and Indication
Excluding Relapse Prevention Studies
Paediatric Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	4/642 (0.6%)	2/549 (0.4%)	1.71 (0.31, 9.4)	0.69
Depression	n/N (%)	4/378 (1.1%)	2/285 (0.7%)	1.51 (0.28, 8.32)	0.70
OCD	n/N (%)	0/99 (0.0%)	0/107 (0.0%)		
SAD	n/N (%)	0/165 (0.0%)	0/157 (0.0%)		

Includes studies 329, 377, 676, 701 and 704

Paroxetine EMEA LOQs

EMEA LOQs Table 1.13
Incidence of Possibly Suicide-Related AEs by Treatment Group and Suicidality Design Criteria
Adult Placebo Controlled Trials
On-Therapy

Suicidality Design Criteria		Paroxetine	Placebo	Odds Ratio (95% CI)	P-Value
Overall	n/N (%)	66/8481 (0.8%)	55/5808 (0.9%)	0.82 (0.57, 1.18)	0.31
Global Criteria					
Suicidal behaviour required	n/N (%)	27/131 (20.6%)	29/136 (21.3%)	0.96 (0.53, 1.73)	1.00
No specific criteria	n/N (%)	0/21 (0.0%)	0/10 (0.0%)		
Severe or serious risks excluded	n/N (%)	34/6180 (0.6%)	22/3984 (0.6%)	1 (0.58, 1.71)	1.00
Known, established or current risk excluded	n/N (%)	5/2149 (0.2%)	4/1678 (0.2%)	0.98 (0.26, 3.64)	1.00
Method Criteria					
Suicidal behaviour required	n/N (%)	27/131 (20.6%)	29/136 (21.3%)	0.96 (0.53, 1.73)	1.00
No specific criteria	n/N (%)	0/21 (0.0%)	0/10 (0.0%)		
Severe or serious risks excluded (Investigator's opinion)	n/N (%)	34/6180 (0.6%)	22/3984 (0.6%)	1 (0.58, 1.71)	1.00
Known, established or current risk excluded	n/N (%)	5/2149 (0.2%)	4/1678 (0.2%)	0.98 (0.26, 3.64)	1.00

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.14
Incidence of Possibly Suicide-Related AEs by Treatment Group and Suicidality Design Criteria
Adult Active Control Trials
On-Therapy

Suicidality Design Criteria		Paroxetine	Comparator	Odds Ratio (95% CI)	P-Value
Overall	n/N (%)	55/6522 (0.8%)	63/4969 (1.3%)	0.66 (0.46, 0.95)	0.03
Global Criteria					
No specific criteria	n/N (%)	3/857 (0.4%)	5/850 (0.6%)	0.59 (0.14, 2.49)	0.51
Severe or serious risks excluded	n/N (%)	37/4318 (0.9%)	35/2790 (1.3%)	0.68 (0.43, 1.08)	0.11
Known, established or current risk excluded	n/N (%)	15/1347 (1.1%)	23/1329 (1.7%)	0.64 (0.33, 1.23)	0.19
Method Criteria					
No specific criteria	n/N (%)	3/857 (0.4%)	5/850 (0.6%)	0.59 (0.14, 2.49)	0.51
Severe or serious risks excluded (HAMD item 3 = 4)	n/N (%)	1/126 (0.8%)	1/125 (0.8%)	0.99 (0.06, 16.04)	1.00
Severe or serious risks excluded (Investigator's opinion)	n/N (%)	36/4192 (0.9%)	34/2665 (1.3%)	0.67 (0.42, 1.07)	0.11
Known, established or current risk excluded	n/N (%)	15/1347 (1.1%)	23/1329 (1.7%)	0.64 (0.33, 1.23)	0.19

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.15
Incidence of Possibly Suicide-Related AEs by Treatment Group and Suicidality Design Criteria
Paediatric Placebo Controlled Trials
On-Therapy

Suicidality Design Criteria		Paroxetine	Placebo	Odds Ratio (95% CI)	P-Value
Overall	n/N (%)	18/738 (2.4%)	7/647 (1.1%)	2.29 (0.95, 5.51)	0.07
Global Criteria					
Severe or serious risks excluded	n/N (%)	16/535 (3.0%)	6/438 (1.4%)	2.22 (0.86, 5.72)	0.13
Known, established or current risk excluded	n/N (%)	2/203 (1.0%)	1/209 (0.5%)	2.07 (0.19, 23)	0.62
Method Criteria					
Severe or serious risks excluded (Investigator's opinion)	n/N (%)	16/535 (3.0%)	6/438 (1.4%)	2.22 (0.86, 5.72)	0.13
Known, established or current risk excluded	n/N (%)	2/203 (1.0%)	1/209 (0.5%)	2.07 (0.19, 23)	0.62

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.16
Incidence of Self Harm by Treatment Group and Suicidality Design Criteria
Adult Placebo Controlled Trials
On-Therapy

Suicidality Design Criteria		Paroxetine	Placebo	Odds Ratio (95% CI)	P-Value
Overall	n/N (%)	51/8481 (0.6%)	38/5808 (0.7%)	0.92 (0.6, 1.4)	0.75
Global Criteria					
Suicidal behaviour required	n/N (%)	26/131 (19.8%)	28/136 (20.6%)	0.96 (0.53, 1.74)	1.00
No specific criteria	n/N (%)	0/21 (0.0%)	0/10 (0.0%)		
Severe or serious risks excluded	n/N (%)	21/6180 (0.3%)	10/3984 (0.3%)	1.35 (0.64, 2.88)	0.47
Known, established or current risk excluded	n/N (%)	4/2149 (0.2%)	0/1678 (0.0%)		0.14
Method Criteria					
Suicidal behaviour required	n/N (%)	26/131 (19.8%)	28/136 (20.6%)	0.96 (0.53, 1.74)	1.00
No specific criteria	n/N (%)	0/21 (0.0%)	0/10 (0.0%)		
Severe or serious risks excluded (Investigator's opinion)	n/N (%)	21/6180 (0.3%)	10/3984 (0.3%)	1.35 (0.64, 2.88)	0.47
Known, established or current risk excluded	n/N (%)	4/2149 (0.2%)	0/1678 (0.0%)		0.14

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.17
Incidence of Self Harm by Treatment Group and Suicidality Design Criteria
Adult Active Control Trials
On-Therapy

Suicidality Design Criteria		Paroxetine	Comparator	Odds Ratio (95% CI)	P-Value
Overall	n/N (%)	29/6522 (0.4%)	32/4969 (0.6%)	0.69 (0.42, 1.14)	0.16
Global Criteria					
No specific criteria	n/N (%)	2/857 (0.2%)	4/850 (0.5%)	0.49 (0.09, 2.71)	0.45
Severe or serious risks excluded	n/N (%)	15/4318 (0.3%)	13/2790 (0.5%)	0.74 (0.35, 1.57)	0.44
Known, established or current risk excluded	n/N (%)	12/1347 (0.9%)	15/1329 (1.1%)	0.79 (0.37, 1.69)	0.57
Method Criteria					
No specific criteria	n/N (%)	2/857 (0.2%)	4/850 (0.5%)	0.49 (0.09, 2.71)	0.45
Severe or serious risks excluded (HAMD item 3 = 4)	n/N (%)	0/126 (0.0%)	1/125 (0.8%)		0.50
Severe or serious risks excluded (Investigator's opinion)	n/N (%)	15/4192 (0.4%)	12/2665 (0.5%)	0.79 (0.37, 1.7)	0.56
Known, established or current risk excluded	n/N (%)	12/1347 (0.9%)	15/1329 (1.1%)	0.79 (0.37, 1.69)	0.57

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.18
Incidence of Self Harm by Treatment Group and Suicidality Design Criteria
Paediatric Placebo Controlled Trials
On-Therapy

Suicidality Design Criteria		Paroxetine	Placebo	Odds Ratio (95% CI)	P-Value
Overall	n/N (%)	15/738 (2.0%)	5/647 (0.8%)	2.66 (0.96, 7.37)	0.07
Global Criteria					
Severe or serious risks excluded	n/N (%)	14/535 (2.6%)	4/438 (0.9%)	2.92 (0.95, 8.92)	0.06
Known, established or current risk excluded	n/N (%)	1/203 (0.5%)	1/209 (0.5%)	1.03 (0.06, 16.57)	1.00
Method Criteria					
Severe or serious risks excluded (Investigator's opinion)	n/N (%)	14/535 (2.6%)	4/438 (0.9%)	2.92 (0.95, 8.92)	0.06
Known, established or current risk excluded	n/N (%)	1/203 (0.5%)	1/209 (0.5%)	1.03 (0.06, 16.57)	1.00

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.19
Incidence of Possibly Suicide-Related AEs by Treatment Group and Dose
Adult Placebo Controlled Trials
On-Therapy

Dose		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
5 mg	n/N (%)	0/11 (0.0%)	0/9 (0.0%)		
10 mg	n/N (%)	3/775 (0.4%)	1/737 (0.1%)	2.86 (0.3, 27.55)	0.62
20 mg	n/N (%)	9/1405 (0.6%)	9/1324 (0.7%)	0.94 (0.37, 2.38)	1.00
30 mg	n/N (%)	1/150 (0.7%)	0/101 (0.0%)		1.00
40 mg	n/N (%)	27/874 (3.1%)	32/810 (4.0%)	0.78 (0.46, 1.31)	0.36
50 mg	n/N (%)	0/57 (0.0%)	0/60 (0.0%)		
60 mg	n/N (%)	0/182 (0.0%)	1/184 (0.5%)		1.00

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.19a
Incidence of Possibly Suicide-Related AEs by Treatment Group and Dose (Excluding Study 057)
Adult Placebo Controlled Trials
On-Therapy

Dose		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
5 mg	n/N (%)	0/11 (0.0%)	0/9 (0.0%)		
10 mg	n/N (%)	3/775 (0.4%)	1/737 (0.1%)	2.86 (0.3, 27.55)	0.62
20 mg	n/N (%)	9/1405 (0.6%)	9/1324 (0.7%)	0.94 (0.37, 2.38)	1.00
30 mg	n/N (%)	1/150 (0.7%)	0/101 (0.0%)		1.00
40 mg	n/N (%)	0/743 (0.0%)	3/674 (0.4%)		0.11
50 mg	n/N (%)	0/57 (0.0%)	0/60 (0.0%)		
60 mg	n/N (%)	0/182 (0.0%)	1/184 (0.5%)		1.00

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.20
Incidence of Self Harm by Treatment Group and Dose
Adult Placebo Controlled Trials
On-Therapy

Dose		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
5 mg	n/N (%)	0/11 (0.0%)	0/9 (0.0%)		
10 mg	n/N (%)	1/775 (0.1%)	0/737 (0.0%)		1.00
20 mg	n/N (%)	9/1405 (0.6%)	5/1324 (0.4%)	1.7 (0.57, 5.09)	0.43
30 mg	n/N (%)	1/150 (0.7%)	0/101 (0.0%)		1.00
40 mg	n/N (%)	26/874 (3.0%)	28/810 (3.5%)	0.86 (0.5, 1.47)	0.58
50 mg	n/N (%)	0/57 (0.0%)	0/60 (0.0%)		
60 mg	n/N (%)	0/182 (0.0%)	0/184 (0.0%)		

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.20a
Incidence of Self Harm by Treatment Group and Dose (Excluding Study 057)
Adult Placebo Controlled Trials
On-Therapy

Dose		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
5 mg	n/N (%)	0/11 (0.0%)	0/9 (0.0%)		
10 mg	n/N (%)	1/775 (0.1%)	0/737 (0.0%)		1.00
20 mg	n/N (%)	9/1405 (0.6%)	5/1324 (0.4%)	1.7 (0.57, 5.09)	0.43
30 mg	n/N (%)	1/150 (0.7%)	0/101 (0.0%)		1.00
40 mg	n/N (%)	0/743 (0.0%)	0/674 (0.0%)		
50 mg	n/N (%)	0/57 (0.0%)	0/60 (0.0%)		
60 mg	n/N (%)	0/182 (0.0%)	0/184 (0.0%)		

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.21
Summary of Age by Treatment Group and Study
Paediatric Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Overall	N	738	647	1385
	SD	2.97	3.01	2.99
	Mean	13.3	13.2	13.3
	Median	14	14	14
	Mode	15	14	14
	Minimum	6	6	6
	Maximum	19	18	19
Study 329	N	93	88	181
	SD	1.66	1.65	1.66
	Mean	14.8	15.1	15
	Median	15	15	15
	Mode	16	16	16
	Minimum	11	12	11
	Maximum	18	18	18
Study 377	N	181	95	276
	SD	1.63	1.6	1.62
	Mean	15.5	15.8	15.6
	Median	16	16	16
	Mode	17	17	17
	Minimum	12	13	12
	Maximum	19	18	19
Study 453	N	96	98	194
	SD	2.59	2.92	2.75
	Mean	11.8	11.7	11.8
	Median	11	12	12
	Mode	11	9	12
	Minimum	7	6	6
	Maximum	17	18	18
Study 676	N	165	157	322
	SD	2.83	2.72	2.77
	Mean	13.1	13.3	13.2
	Median	13	14	14
	Mode	14	14	14
	Minimum	7	7	7
	Maximum	17	17	17
Study 701	N	104	102	206
	SD	3	2.95	2.97
	Mean	11.9	12.2	12.1
	Median	12	12	12
	Mode	9	10	10

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.21
Summary of Age by Treatment Group and Study
Paediatric Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 701	Minimum	7	7	7
	Maximum	17	17	17
Study 704	N	99	107	206
	SD	3.02	2.98	3
	Mean	11.1	11.6	11.3
	Median	11	11	11
	Mode	7	11	11
	Minimum	6	6	6
	Maximum	17	17	17

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.22

Incidence of Possibly Suicide-Related AEs by Treatment Group, Indication and Modified Age Group

Paediatric Placebo Controlled Trials

On-Therapy

Indication	Modified Age Group		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	18/738 (2.4%)	7/647 (1.1%)	2.29 (0.95, 5.51)	0.07
	< 12 years	n/N (%)	0/205 (0.0%)	0/194 (0.0%)		
	12-15 years	n/N (%)	10/329 (3.0%)	5/269 (1.9%)	1.66 (0.56, 4.9)	0.44
	>=16 years	n/N (%)	8/204 (3.9%)	2/184 (1.1%)	3.71 (0.78, 17.72)	0.11
Depression	Overall	n/N (%)	14/378 (3.7%)	7/285 (2.5%)	1.53 (0.61, 3.84)	0.50
	< 12 years	n/N (%)	0/51 (0.0%)	0/46 (0.0%)		
	12-15 years	n/N (%)	7/184 (3.8%)	5/120 (4.2%)	0.91 (0.28, 2.93)	1.00
	>=16 years	n/N (%)	7/143 (4.9%)	2/119 (1.7%)	3.01 (0.61, 14.77)	0.19
OCD	Overall	n/N (%)	1/195 (0.5%)	0/205 (0.0%)		0.49
	< 12 years	n/N (%)	0/107 (0.0%)	0/103 (0.0%)		
	12-15 years	n/N (%)	1/66 (1.5%)	0/76 (0.0%)		0.46
	>=16 years	n/N (%)	0/22 (0.0%)	0/26 (0.0%)		
SAD	Overall	n/N (%)	3/165 (1.8%)	0/157 (0.0%)		0.25
	< 12 years	n/N (%)	0/47 (0.0%)	0/45 (0.0%)		
	12-15 years	n/N (%)	2/79 (2.5%)	0/73 (0.0%)		0.50
	>=16 years	n/N (%)	1/39 (2.6%)	0/39 (0.0%)		1.00

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

EMEA LOQs Table 1.22a
Incidence of Hostility by Treatment Group, Indication and Modified Age Group
Paediatric Placebo Controlled Trials
On-Therapy

Indication	Modified Age Group		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	27/738 (3.7%)	4/647 (0.6%)	6.1 (2.12, 17.54)	<0.001
	< 12 years	n/N (%)	15/205 (7.3%)	1/194 (0.5%)	15.24 (1.99, 116.49)	<0.001
	12-15 years	n/N (%)	10/329 (3.0%)	3/269 (1.1%)	2.78 (0.76, 10.2)	0.16
	>=16 years	n/N (%)	2/204 (1.0%)	0/184 (0.0%)		0.50
Depression	Overall	n/N (%)	7/378 (1.9%)	1/285 (0.4%)	5.36 (0.66, 43.8)	0.15
	< 12 years	n/N (%)	1/51 (2.0%)	0/46 (0.0%)		1.00
	12-15 years	n/N (%)	5/184 (2.7%)	1/120 (0.8%)	3.32 (0.38, 28.81)	0.41
	>=16 years	n/N (%)	1/143 (0.7%)	0/119 (0.0%)		1.00
OCD	Overall	n/N (%)	15/195 (7.7%)	1/205 (0.5%)	17 (2.22, 129.97)	<0.001
	< 12 years	n/N (%)	11/107 (10.3%)	1/103 (1.0%)	11.69 (1.48, 92.25)	0.005
	12-15 years	n/N (%)	4/66 (6.1%)	0/76 (0.0%)		0.04
	>=16 years	n/N (%)	0/22 (0.0%)	0/26 (0.0%)		
SAD	Overall	n/N (%)	5/165 (3.0%)	2/157 (1.3%)	2.42 (0.46, 12.67)	0.45
	< 12 years	n/N (%)	3/47 (6.4%)	0/45 (0.0%)		0.24
	12-15 years	n/N (%)	1/79 (1.3%)	2/73 (2.7%)	0.46 (0.04, 5.13)	0.61
	>=16 years	n/N (%)	1/39 (2.6%)	0/39 (0.0%)		1.00

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

EMEA LOQs Table 1.23
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Adult Placebo Controlled Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
001	PAROXETINE	25	1.16	0.62	0	2
	PLACEBO	25	1.24	0.78	0	2
002	PAROXETINE	170	1.48	0.90	0	4
	PLACEBO	171	1.42	0.81	0	3
003	PAROXETINE	241	0.97	0.81	0	3
	PLACEBO	244	1.00	0.81	0	3
007	PAROXETINE	13	2.00	0.82	0	3
	PLACEBO	12	2.25	0.75	1	3
009	PAROXETINE	421	1.11	0.83	0	3
	PLACEBO	53	1.06	0.74	0	2
076	PAROXETINE	4	0.25	0.50	0	1
	PLACEBO	4	0.00	0.00	0	0
083	PAROXETINE	68	0.01	0.12	0	1
	PLACEBO	67	0.01	0.12	0	1
108	PAROXETINE	60	0.02	0.13	0	1
	PLACEBO	60	0.02	0.13	0	1
115	PAROXETINE	283	1.13	0.91	0	3
	PLACEBO	117	1.13	0.92	0	3
116	PAROXETINE	259	0.24	0.55	0	3
	PLACEBO	89	0.21	0.46	0	2
118	PAROXETINE	82	0.21	0.49	0	2
	PLACEBO	77	0.16	0.43	0	2
128	PAROXETINE	357	1.12	0.95	0	3
	PLACEBO	140	1.15	0.89	0	3
190	PAROXETINE	61	0.00	0.00	0	0
	PLACEBO	64	0.03	0.18	0	1
201	PAROXETINE	57	0.04	0.19	0	1
	PLACEBO	60	0.07	0.25	0	1
251	PAROXETINE	125	0.94	0.80	0	2
	PLACEBO	129	0.94	0.80	0	3
274	PAROXETINE	22	0.86	0.89	0	2

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.23
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Adult Placebo Controlled Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
274	PLACEBO	23	1.09	0.85	0	2
275	PAROXETINE	4	1.25	0.96	0	2
	PLACEBO	3	1.67	1.53	0	3
276	PAROXETINE	20	1.50	0.95	0	3
	PLACEBO	21	1.67	1.02	0	3
279	PAROXETINE	21	1.62	1.02	0	3
	PLACEBO	10	1.30	1.06	0	3
327	PAROXETINE	81	0.44	0.61	0	2
	PLACEBO	85	0.42	0.59	0	2
352	PAROXETINE	35	1.03	1.07	0	3
	PLACEBO	43	1.02	0.94	0	3
448	PAROXETINE	212	1.09	0.87	0	3
	PLACEBO	103	1.03	0.81	0	3
449	PAROXETINE	223	1.01	0.91	0	3
	PLACEBO	110	1.15	1.03	0	3
487	PAROXETINE	214	0.80	0.76	0	3
	PLACEBO	109	0.78	0.81	0	3
595	PAROXETINE	162	0.05	0.22	0	1
	PLACEBO	161	0.07	0.30	0	2
790	PAROXETINE	186	0.01	0.07	0	1
	PLACEBO	184	0.05	0.23	0	1
810	PAROXETINE	306	0.74	0.73	0	3
	PLACEBO	148	0.89	0.77	0	3

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.24
Summary Statistics for Baseline Level of Suicidal Risk (MADRS item 10) By Treatment Group and Study
Adult Placebo Controlled Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
001	PAROXETINE	25	1.56	0.82	0	3
	PLACEBO	25	1.80	0.96	0	3
002	PAROXETINE	170	2.03	0.96	0	5
	PLACEBO	171	2.00	0.96	0	5
003	PAROXETINE	241	1.76	1.09	0	4
	PLACEBO	244	1.79	1.09	0	4
007	PAROXETINE	13	3.00	1.08	1	4
	PLACEBO	11	2.55	0.82	2	4
009	PAROXETINE	421	1.54	1.06	0	4
	PLACEBO	53	1.47	1.05	0	3
057	PAROXETINE	128	1.94	1.41	0	6
	PLACEBO	127	1.91	1.55	0	6
106	PAROXETINE	16	2.63	1.78	0	6
	PLACEBO	17	2.47	1.37	0	6
120	PAROXETINE	209	0.52	0.79	0	4
	PLACEBO	69	0.36	0.64	0	3
136	PAROXETINE	201	0.67	0.94	0	5
	PLACEBO	99	0.67	0.89	0	4
187	PAROXETINE	123	0.37	0.61	0	3
	PLACEBO	123	0.39	0.64	0	3
223	PAROXETINE	76	0.34	0.68	0	3
	PLACEBO	71	0.44	0.84	0	4
625	PAROXETINE	112	1.16	1.04	0	4
	PLACEBO	117	1.02	1.03	0	4
627	PAROXETINE	157	0.92	1.07	0	4
	PLACEBO	161	1.00	1.12	0	4
637	PAROXETINE	187	0.20	0.44	0	2
	PLACEBO	185	0.20	0.44	0	2
641	PAROXETINE	386	0.16	0.39	0	2
	PLACEBO	180	0.16	0.41	0	2
642	PAROXETINE	164	0.14	0.38	0	2
	PLACEBO	166	0.16	0.40	0	2

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.24
Summary Statistics for Baseline Level of Suicidal Risk (MADRS item 10) By Treatment Group and Study
Adult Placebo Controlled Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
646	PAROXETINE	278	0.03	0.17	0	1
	PLACEBO	288	0.01	0.12	0	1
648	PAROXETINE	163	0.72	1.01	0	4
	PLACEBO	160	0.66	0.85	0	4
650	PAROXETINE	88	0.14	0.46	0	3
	PLACEBO	88	0.13	0.40	0	2
651	PAROXETINE	375	0.96	0.99	0	4
	PLACEBO	187	0.90	0.89	0	4
785	PAROXETINE	197	1.61	1.07	0	4
	PLACEBO	105	1.49	1.08	0	4
791	PAROXETINE	167	0.17	0.41	0	2
	PLACEBO	166	0.19	0.47	0	2

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.25
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Adult Active Control Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
003	PAROXETINE	241	0.97	0.81	0	3
	COMPARATOR	241	1.02	0.79	0	4
006	PAROXETINE	33	1.18	0.81	0	3
	COMPARATOR	33	1.33	0.89	0	3
007	PAROXETINE	13	2.00	0.82	0	3
	COMPARATOR	13	2.46	0.52	2	3
011	PAROXETINE	103	0.83	0.77	0	3
	COMPARATOR	103	0.81	0.78	0	3
019	PAROXETINE	31	1.52	1.12	0	3
	COMPARATOR	35	1.60	1.12	0	4
020	PAROXETINE	24	1.17	0.76	0	2
	COMPARATOR	24	0.96	0.69	0	2
022	PAROXETINE	16	1.25	1.18	0	3
	COMPARATOR	17	1.29	1.10	0	3
025	PAROXETINE	4	2.00	1.15	1	3
	COMPARATOR	4	1.25	1.50	0	3
026	PAROXETINE	30	1.23	0.68	0	3
	COMPARATOR	30	1.17	0.70	0	2
027	PAROXETINE	17	1.06	0.83	0	2
	COMPARATOR	15	1.27	1.22	0	3
028	PAROXETINE	8	0.88	0.64	0	2
	COMPARATOR	6	1.00	0.89	0	2
029	PAROXETINE	4	1.00	0.82	0	2
	COMPARATOR	5	1.00	0.71	0	2
030	PAROXETINE	21	0.90	0.94	0	3
	COMPARATOR	19	0.79	0.85	0	3
032	PAROXETINE	30	1.00	1.02	0	3
	COMPARATOR	30	1.20	1.13	0	3
035	PAROXETINE	3	1.00	1.00	0	2
	COMPARATOR	4	1.00	1.41	0	3
038	PAROXETINE	32	1.75	0.76	0	3

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.25
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Adult Active Control Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
038	COMPARATOR	29	1.76	0.64	0	3
043	PAROXETINE	15	0.20	0.56	0	2
	COMPARATOR	18	0.50	0.79	0	3
046	PAROXETINE	21	0.33	0.73	0	2
	COMPARATOR	22	0.50	0.74	0	2
047	PAROXETINE	46	0.43	0.83	0	3
	COMPARATOR	48	0.25	0.64	0	3
049	PAROXETINE	62	0.24	0.50	0	2
	COMPARATOR	32	0.31	0.78	0	4
059	PAROXETINE	72	1.07	0.84	0	4
	COMPARATOR	71	1.13	0.89	0	4
060	PAROXETINE	43	1.07	0.91	0	4
	COMPARATOR	47	0.89	0.91	0	4
061	PAROXETINE	54	1.20	0.74	0	3
	COMPARATOR	52	1.23	0.88	0	4
063	PAROXETINE	21	0.90	0.83	0	3
	COMPARATOR	19	0.74	0.81	0	2
064	PAROXETINE	49	1.04	0.76	0	3
	COMPARATOR	50	1.20	0.86	0	3
065	PAROXETINE	28	1.57	1.03	0	4
	COMPARATOR	32	0.78	0.75	0	3
069	PAROXETINE	45	1.93	0.99	0	4
	COMPARATOR	46	1.70	0.89	0	3
071	PAROXETINE	9	1.56	1.01	0	3
	COMPARATOR	9	1.11	1.05	0	3
073	PAROXETINE	6	1.83	1.47	0	4
	COMPARATOR	4	1.00	2.00	0	4
074	PAROXETINE	20	1.50	1.28	0	4
	COMPARATOR	19	1.37	1.42	0	4
076	PAROXETINE	4	0.25	0.50	0	1
	COMPARATOR	4	1.00	1.41	0	3

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.25
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Adult Active Control Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
077	PAROXETINE	46	1.80	1.15	0	4
	COMPARATOR	46	1.83	0.97	0	4
078	PAROXETINE	46	1.30	0.81	0	3
	COMPARATOR	45	1.00	0.85	0	3
079	PAROXETINE	45	1.13	0.76	0	3
	COMPARATOR	45	1.20	0.76	0	3
080	PAROXETINE	10	1.40	1.07	0	3
	COMPARATOR	13	1.62	1.12	0	4
082	PAROXETINE	37	0.95	0.78	0	3
	COMPARATOR	34	0.91	0.51	0	2
086	PAROXETINE	271	0.59	0.73	0	3
	COMPARATOR	274	0.67	0.71	0	3
088	PAROXETINE	15	1.53	1.06	0	4
	COMPARATOR	15	1.13	0.74	0	2
089	PAROXETINE	26	1.27	0.78	0	3
	COMPARATOR	34	1.74	0.99	0	4
090	PAROXETINE	77	1.06	0.71	0	2
	COMPARATOR	75	0.97	0.75	0	2
095	PAROXETINE	134	1.05	0.84	0	3
	COMPARATOR	68	1.03	0.91	0	4
112	PAROXETINE	55	1.42	0.92	0	3
	COMPARATOR	65	1.42	1.03	0	4
115	PAROXETINE	283	1.13	0.91	0	3
	COMPARATOR	288	1.14	0.91	0	3
118	PAROXETINE	82	0.21	0.49	0	2
	COMPARATOR	82	0.17	0.41	0	2
128	PAROXETINE	357	1.12	0.95	0	3
	COMPARATOR	351	1.09	0.99	0	3
131	PAROXETINE	100	0.85	0.99	0	3
	COMPARATOR	99	0.76	0.96	0	3
135	PAROXETINE	60	0.70	0.93	0	3

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.25
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Adult Active Control Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
135	COMPARATOR	62	1.00	1.01	0	4
184	PAROXETINE	14	1.07	0.62	0	2
	COMPARATOR	14	1.14	0.77	0	2
239	PAROXETINE	1727	0.94	1.06	0	4
	COMPARATOR	393	0.89	0.99	0	3
256	PAROXETINE	39	1.82	1.19	0	4
	COMPARATOR	34	1.56	1.13	0	4
260	PAROXETINE	21	1.33	1.06	0	3
	COMPARATOR	23	1.61	0.99	0	3
261	PAROXETINE	62	1.21	1.06	0	4
	COMPARATOR	58	1.21	0.95	0	4
272	PAROXETINE	5	1.20	0.84	0	2
	COMPARATOR	3	0.33	0.58	0	1
275	PAROXETINE	4	1.25	0.96	0	2
	COMPARATOR	4	0.50	1.00	0	2
279	PAROXETINE	21	1.62	1.02	0	3
	COMPARATOR	16	2.06	1.18	0	3
281	PAROXETINE	104	1.01	0.99	0	4
	COMPARATOR	96	0.99	0.97	0	3
289	PAROXETINE	37	2.05	1.37	0	4
	COMPARATOR	39	2.00	1.49	0	4
290	PAROXETINE	40	2.03	1.07	0	4
	COMPARATOR	38	1.84	1.03	0	4
292	PAROXETINE	44	1.48	1.15	0	4
	COMPARATOR	43	1.49	1.24	0	4
308	PAROXETINE	10	2.00	1.25	0	4
	COMPARATOR	12	1.83	0.94	0	3
309	PAROXETINE	10	1.20	0.63	0	2
	COMPARATOR	10	2.00	1.15	1	4
310	PAROXETINE	9	2.00	1.12	0	3
	COMPARATOR	10	1.90	1.20	0	3

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.25
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Adult Active Control Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
312	PAROXETINE	2	1.50	0.71	1	2
	COMPARATOR	2	0.50	0.71	0	1
314	PAROXETINE	9	1.11	0.33	1	2
	COMPARATOR	8	0.88	0.64	0	2
316	PAROXETINE	9	1.89	0.93	0	3
	COMPARATOR	8	1.38	1.06	0	3
318	PAROXETINE	9	1.67	1.32	0	4
	COMPARATOR	12	1.42	1.00	0	3
319	PAROXETINE	1	1.00		1	1
	COMPARATOR	1	2.00		2	2
331	PAROXETINE	41	1.15	0.82	0	3
	COMPARATOR	40	1.08	0.97	0	3
352	PAROXETINE	35	1.03	1.07	0	3
	COMPARATOR	39	0.95	0.97	0	3

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.26
Summary Statistics for Baseline Level of Suicidal Risk (MADRS item 10) By Treatment Group and Study
Adult Active Control Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
003	PAROXETINE	241	1.76	1.09	0	4
	COMPARATOR	241	1.85	1.00	0	4
006	PAROXETINE	33	1.88	1.17	0	4
	COMPARATOR	33	1.91	1.28	0	5
007	PAROXETINE	13	3.00	1.08	1	4
	COMPARATOR	13	3.15	1.14	1	5
011	PAROXETINE	101	1.32	0.73	0	4
	COMPARATOR	101	1.51	0.94	0	4
059	PAROXETINE	72	1.96	1.11	0	4
	COMPARATOR	71	1.80	1.12	0	6
060	PAROXETINE	43	1.72	1.10	0	5
	COMPARATOR	47	1.45	1.02	0	4
061	PAROXETINE	54	2.30	1.06	1	4
	COMPARATOR	52	2.12	1.11	0	4
063	PAROXETINE	21	1.48	1.12	0	4
	COMPARATOR	19	1.58	1.26	0	4
064	PAROXETINE	49	1.61	1.04	0	4
	COMPARATOR	50	1.68	1.22	0	4
065	PAROXETINE	28	2.14	1.43	0	4
	COMPARATOR	32	1.72	0.85	1	4
069	PAROXETINE	45	2.56	1.41	1	6
	COMPARATOR	46	2.54	1.15	1	6
070	PAROXETINE	32	1.53	0.92	0	4
	COMPARATOR	30	1.77	1.36	0	5
073	PAROXETINE	6	3.00	1.55	1	5
	COMPARATOR	4	1.75	1.50	1	4
079	PAROXETINE	45	1.49	0.66	1	3
	COMPARATOR	45	1.62	0.68	1	3
080	PAROXETINE	10	2.10	0.99	1	4
	COMPARATOR	11	2.55	1.21	1	4
082	PAROXETINE	37	1.59	0.96	0	4
	COMPARATOR	34	1.62	0.55	1	3

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.26
Summary Statistics for Baseline Level of Suicidal Risk (MADRS item 10) By Treatment Group and Study
Adult Active Control Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
084	PAROXETINE	6	2.33	1.21	1	4
	COMPARATOR	5	2.00	1.00	1	3
089	PAROXETINE	26	2.31	1.09	0	4
	COMPARATOR	34	2.65	1.12	1	5
136	PAROXETINE	201	0.67	0.94	0	5
	COMPARATOR	99	0.51	0.64	0	2
187	PAROXETINE	123	0.37	0.61	0	3
	COMPARATOR	122	0.44	0.69	0	3
197	PAROXETINE	99	1.23	1.07	0	4
	COMPARATOR	99	1.17	1.05	0	4
223	PAROXETINE	76	0.34	0.68	0	3
	COMPARATOR	76	0.45	0.91	0	4
245	PAROXETINE	516	1.57	1.10	0	6
	COMPARATOR	510	1.42	1.08	0	6
291	PAROXETINE	41	1.59	1.32	0	5
	COMPARATOR	42	1.40	1.11	0	4
785	PAROXETINE	197	1.61	1.07	0	4
	COMPARATOR	205	1.56	1.05	0	5

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.27
Summary Statistics for Baseline Level of Suicidal Risk (HAMD item 3) By Treatment Group and Study
Paediatric Placebo Controlled Trials

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
329	PAROXETINE	93	0.82	0.94	0	3
	PLACEBO	88	1.13	0.96	0	3
453	PAROXETINE	96	0.08	0.35	0	2
	PLACEBO	98	0.09	0.38	0	2

Includes studies 329 and placebo controlled phase of 453

EMEA LOQs Table 1.28
Summary Statistics for Baseline Level of Suicidal Risk (MADRS item 10) By Treatment Group and Study
Paediatric Placebo Controlled Trials, Study 377

Study number	Treatment group	Number in analysis	Mean	S.D.	Min.	Max.
377	PAROXETINE	181	1.76	1.38	0	5
	PLACEBO	95	1.66	1.48	0	5

Paroxetine EMEA LOQs

EMEA LOQs Table 1.29
Emergent Suicidal Ideation (MADRS item 10) by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
PAROXETINE	44/2387	1.8	0.64	[0.43, 0.97]	0.03
PLACEBO	52/1834	2.8			

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.30
Emergent Suicidal Ideation (MADRS item 10) by Treatment Group
Adult Active Control Trials
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
PAROXETINE	22/1111	2.0			
COMPARATOR	25/1044	2.4	1.21	[0.68, 2.17]	0.51

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.31
Emergent Suicidal Ideation (MADRS item 10) by Treatment Group
Paediatric Placebo Controlled Trials, Study 377
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
PAROXETINE	4/82	4.9	0.41	[0.10, 1.61]	0.20
PLACEBO	5/45	11.1			

EMEA LOQs Table 1.32
Incidence of Possibly Suicide-Related AEs by Treatment Group and Study
Adult Placebo Controlled Trials - Depression Studies Only
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	58/3421 (1.7%)	41/2117 (1.9%)	0.87 (0.58, 1.31)	0.53
Study 276(02DEC1982)	n/N (%)	0/20 (0.0%)	0/21 (0.0%)		
Study 279(02JUN1983)	n/N (%)	0/21 (0.0%)	0/10 (0.0%)		
Study 274(20JUN1983)	n/N (%)	0/22 (0.0%)	0/23 (0.0%)		
Study 275(24AUG1983)	n/N (%)	0/4 (0.0%)	0/3 (0.0%)		
Study 001(03APR1984)	n/N (%)	0/25 (0.0%)	0/25 (0.0%)		
Study 002(25APR1985)	n/N (%)	1/170 (0.6%)	0/171 (0.0%)		0.50
Study 009(25APR1985)	n/N (%)	3/421 (0.7%)	0/53 (0.0%)		1.00
Study 003(01MAY1985)	n/N (%)	0/241 (0.0%)	0/244 (0.0%)		
Study 007(01NOV1986)	n/N (%)	0/13 (0.0%)	0/12 (0.0%)		
Study 201(30NOV1988)	n/N (%)	0/57 (0.0%)	0/60 (0.0%)		
Study 083(17DEC1988)	n/N (%)	0/68 (0.0%)	2/67 (3.0%)		0.24
Study 076(04JUL1989)	n/N (%)	0/4 (0.0%)	0/4 (0.0%)		
Study 057(19MAY1990)	n/N (%)	27/131 (20.6%)	29/136 (21.3%)	0.96 (0.53, 1.73)	1.00
Study 106(25JUN1990)	n/N (%)	7/18 (38.9%)	5/18 (27.8%)	1.65 (0.41, 6.71)	0.72
Study 115(20MAR1991)	n/N (%)	4/283 (1.4%)	2/117 (1.7%)	0.82 (0.15, 4.56)	1.00
Study 128(17MAY1991)	n/N (%)	4/357 (1.1%)	2/140 (1.4%)	0.78 (0.14, 4.32)	0.68
Study 251(20MAY1992)	n/N (%)	1/125 (0.8%)	0/129 (0.0%)		0.49
Study 190(22SEP1993)	n/N (%)	0/61 (0.0%)	0/64 (0.0%)		
Study 327(01MAR1994)	n/N (%)	1/81 (1.2%)	0/85 (0.0%)		0.49
Study 352(05APR1994)	n/N (%)	0/35 (0.0%)	0/43 (0.0%)		
Study 448(10SEP1996)	n/N (%)	3/212 (1.4%)	0/103 (0.0%)		0.55
Study 449(26SEP1996)	n/N (%)	1/223 (0.4%)	0/110 (0.0%)		1.00
Study 487(24OCT1996)	n/N (%)	2/214 (0.9%)	0/109 (0.0%)		0.55

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.32
Incidence of Possibly Suicide-Related AEs by Treatment Group and Study
Adult Placebo Controlled Trials - Depression Studies Only
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Study 625(29AUG1998)	n/N (%)	1/112 (0.9%)	0/117 (0.0%)		0.49
Study 785(11APR2001)	n/N (%)	1/197 (0.5%)	0/105 (0.0%)		1.00
Study 810(28AUG2001)	n/N (%)	2/306 (0.7%)	1/148 (0.7%)	0.97 (0.09, 10.75)	1.00

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.33
Incidence of Possibly Suicide-Related AEs by Treatment Group and Study
Adult Active Control Trials - Depression Studies Only
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	54/6040 (0.9%)	59/4589 (1.3%)	0.69 (0.48, 1)	0.06
Study 260(17OCT1980)	n/N (%)	0/21 (0.0%)	0/23 (0.0%)		
Study 310(17SEP1981)	n/N (%)	0/9 (0.0%)	1/10 (10.0%)		1.00
Study 308(30SEP1981)	n/N (%)	1/10 (10.0%)	0/12 (0.0%)		0.45
Study 309(13MAR1982)	n/N (%)	1/11 (9.1%)	0/10 (0.0%)		1.00
Study 319(25AUG1982)	n/N (%)	0/1 (0.0%)	0/1 (0.0%)		
Study 318(22SEP1982)	n/N (%)	0/9 (0.0%)	0/12 (0.0%)		
Study 316(05OCT1982)	n/N (%)	1/9 (11.1%)	1/8 (12.5%)	0.87 (0.05, 16.74)	1.00
Study 314(07MAR1983)	n/N (%)	0/10 (0.0%)	0/8 (0.0%)		
Study 281(14MAR1983)	n/N (%)	0/106 (0.0%)	0/98 (0.0%)		
Study 279(02JUN1983)	n/N (%)	0/21 (0.0%)	0/16 (0.0%)		
Study 275(24AUG1983)	n/N (%)	0/4 (0.0%)	0/4 (0.0%)		
Study 312(08OCT1983)	n/N (%)	0/2 (0.0%)	0/2 (0.0%)		
Study 256(21OCT1983)	n/N (%)	0/39 (0.0%)	0/34 (0.0%)		
Study 022(04NOV1983)	n/N (%)	0/16 (0.0%)	0/17 (0.0%)		
Study 272(19JAN1984)	n/N (%)	0/5 (0.0%)	0/3 (0.0%)		
Study 020(19JUN1984)	n/N (%)	0/24 (0.0%)	0/24 (0.0%)		
Study 289(25JUN1984)	n/N (%)	0/42 (0.0%)	0/44 (0.0%)		
Study 292(14AUG1984)	n/N (%)	0/46 (0.0%)	0/44 (0.0%)		
Study 035(20AUG1984)	n/N (%)	0/3 (0.0%)	0/4 (0.0%)		
Study 261(17APR1985)	n/N (%)	0/62 (0.0%)	0/58 (0.0%)		
Study 003(01MAY1985)	n/N (%)	0/241 (0.0%)	0/241 (0.0%)		
Study 027(05JUN1985)	n/N (%)	0/17 (0.0%)	0/15 (0.0%)		
Study 038(18JUN1985)	n/N (%)	0/32 (0.0%)	0/29 (0.0%)		

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.33
Incidence of Possibly Suicide-Related AEs by Treatment Group and Study
Adult Active Control Trials - Depression Studies Only
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Study 028(20JUN1985)	n/N (%)	0/8 (0.0%)	0/6 (0.0%)		
Study 030(09JUL1985)	n/N (%)	0/21 (0.0%)	0/19 (0.0%)		
Study 026(10JUL1985)	n/N (%)	0/30 (0.0%)	0/30 (0.0%)		
Study 032(19JUL1985)	n/N (%)	0/30 (0.0%)	0/30 (0.0%)		
Study 025(27AUG1985)	n/N (%)	0/4 (0.0%)	0/4 (0.0%)		
Study 029(11SEP1985)	n/N (%)	0/4 (0.0%)	0/5 (0.0%)		
Study 043(09DEC1985)	n/N (%)	0/15 (0.0%)	0/18 (0.0%)		
Study 088(19DEC1985)	n/N (%)	0/16 (0.0%)	1/15 (6.7%)		0.48
Study 019(24JAN1986)	n/N (%)	0/31 (0.0%)	0/35 (0.0%)		
Study 007(01NOV1986)	n/N (%)	0/13 (0.0%)	0/13 (0.0%)		
Study 006(19NOV1986)	n/N (%)	0/33 (0.0%)	0/33 (0.0%)		
Study 089(28JAN1987)	n/N (%)	2/26 (7.7%)	3/34 (8.8%)	0.86 (0.13, 5.57)	1.00
Study 290(17FEB1987)	n/N (%)	0/40 (0.0%)	0/39 (0.0%)		
Study 071(09APR1987)	n/N (%)	0/9 (0.0%)	0/9 (0.0%)		
Study 291(23JUN1987)	n/N (%)	0/41 (0.0%)	0/42 (0.0%)		
Study 011(08SEP1987)	n/N (%)	0/103 (0.0%)	0/103 (0.0%)		
Study 046(16SEP1987)	n/N (%)	1/21 (4.8%)	0/22 (0.0%)		0.49
Study 047(30SEP1987)	n/N (%)	2/46 (4.3%)	1/49 (2.0%)	2.18 (0.19, 24.91)	0.61
Study 184(30SEP1987)	n/N (%)	0/14 (0.0%)	0/14 (0.0%)		
Study 049(04DEC1987)	n/N (%)	0/62 (0.0%)	0/32 (0.0%)		
Study 060(29APR1988)	n/N (%)	2/44 (4.5%)	0/47 (0.0%)		0.23
Study 059(30APR1988)	n/N (%)	5/72 (6.9%)	5/71 (7.0%)	0.99 (0.27, 3.56)	1.00
Study 069(16MAY1988)	n/N (%)	0/45 (0.0%)	1/46 (2.2%)		1.00
Study 077(09JUL1988)	n/N (%)	1/46 (2.2%)	0/46 (0.0%)		1.00

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.33
Incidence of Possibly Suicide-Related AEs by Treatment Group and Study
Adult Active Control Trials - Depression Studies Only
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Study 070(13JUL1988)	n/N (%)	0/32 (0.0%)	0/30 (0.0%)		
Study 065(01OCT1988)	n/N (%)	0/28 (0.0%)	1/32 (3.1%)		1.00
Study 090(04OCT1988)	n/N (%)	1/79 (1.3%)	1/78 (1.3%)	0.99 (0.06, 16.07)	1.00
Study 078(24OCT1988)	n/N (%)	0/155 (0.0%)	0/153 (0.0%)		
Study 074(28OCT1988)	n/N (%)	0/20 (0.0%)	1/20 (5.0%)		1.00
Study 063(14NOV1988)	n/N (%)	0/21 (0.0%)	0/19 (0.0%)		
Study 073(24JAN1989)	n/N (%)	0/6 (0.0%)	0/4 (0.0%)		
Study 064(01FEB1989)	n/N (%)	0/49 (0.0%)	0/50 (0.0%)		
Study 061(14FEB1989)	n/N (%)	3/54 (5.6%)	2/52 (3.8%)	1.47 (0.24, 9.18)	1.00
Study 079(16FEB1989)	n/N (%)	0/45 (0.0%)	0/45 (0.0%)		
Study 076(04JUL1989)	n/N (%)	0/4 (0.0%)	0/4 (0.0%)		
Study 080(17JUL1989)	n/N (%)	0/10 (0.0%)	0/13 (0.0%)		
Study 082(24NOV1989)	n/N (%)	0/37 (0.0%)	0/34 (0.0%)		
Study 086(31MAR1990)	n/N (%)	2/271 (0.7%)	3/275 (1.1%)	0.67 (0.11, 4.07)	1.00
Study 095(01OCT1990)	n/N (%)	0/134 (0.0%)	0/68 (0.0%)		
Study 115(20MAR1991)	n/N (%)	4/283 (1.4%)	1/288 (0.3%)	4.11 (0.46, 37.04)	0.21
Study 084(03APR1991)	n/N (%)	0/6 (0.0%)	0/5 (0.0%)		
Study 128(17MAY1991)	n/N (%)	4/357 (1.1%)	10/351 (2.8%)	0.39 (0.12, 1.24)	0.11
Study 112(11JUL1991)	n/N (%)	0/55 (0.0%)	1/65 (1.5%)		1.00
Study 135(27SEP1991)	n/N (%)	0/60 (0.0%)	2/62 (3.2%)		0.50
Study 131(27DEC1991)	n/N (%)	2/100 (2.0%)	5/99 (5.1%)	0.38 (0.07, 2.03)	0.28
Study 109(03JUL1992)	n/N (%)	1/65 (1.5%)	1/67 (1.5%)	1.03 (0.06, 16.84)	1.00
Study 245(28OCT1992)	n/N (%)	6/517 (1.2%)	10/510 (2.0%)	0.59 (0.21, 1.63)	0.33
Study 239(20NOV1992)	n/N (%)	13/1766 (0.7%)	3/402 (0.7%)	0.99 (0.28, 3.48)	1.00

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.33
Incidence of Possibly Suicide-Related AEs by Treatment Group and Study
Adult Active Control Trials - Depression Studies Only
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Study 197(29DEC1993)	n/N (%)	1/99 (1.0%)	2/99 (2.0%)	0.49 (0.04, 5.55)	1.00
Study 331(11MAR1994)	n/N (%)	0/41 (0.0%)	0/40 (0.0%)		
Study 352(05APR1994)	n/N (%)	0/35 (0.0%)	0/39 (0.0%)		
Study 785(11APR2001)	n/N (%)	1/197 (0.5%)	3/206 (1.5%)	0.35 (0.04, 3.35)	0.62

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.34
Incidence of Possibly Suicide-Related AEs by Treatment Group and Study
Paediatric Placebo Controlled Trials - Depression Studies Only
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	14/378 (3.7%)	7/285 (2.5%)	1.53 (0.61, 3.84)	0.50
Study 329(20APR1994)	n/N (%)	6/93 (6.5%)	2/88 (2.3%)	2.97 (0.58, 15.1)	0.28
Study 377(18MAY1995)	n/N (%)	7/181 (3.9%)	4/95 (4.2%)	0.92 (0.26, 3.21)	1.00
Study 701(20MAR2000)	n/N (%)	1/104 (1.0%)	1/102 (1.0%)	0.98 (0.06, 15.89)	1.00

Includes studies 329, 377 and 701

EMEA LOQs Table 1.35
Change from Baseline in HAMD Individual Items and Total Score by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Total score	PAROXETINE	3420	-7.98	0.11	-2.60	(-2.96,-2.24)	<0.001
	PLACEBO	2172	-5.39	0.14			
Item 1: Depressed Mood	PAROXETINE	3114	-1.16	0.02	-0.46	(-0.51,-0.40)	
	PLACEBO	1982	-0.71	0.02			
Item 2: Feelings of Guilt	PAROXETINE	3114	-0.73	0.01	-0.25	(-0.29,-0.20)	
	PLACEBO	1982	-0.49	0.02			
Item 3: Suicide	PAROXETINE	3114	-0.53	0.01	-0.17	(-0.21,-0.13)	
	PLACEBO	1982	-0.36	0.01			
Item 4: Insomnia Early	PAROXETINE	3114	-0.42	0.01	-0.09	(-0.13,-0.05)	
	PLACEBO	1982	-0.34	0.02			
Item 5: Insomnia Middle	PAROXETINE	3114	-0.46	0.01	-0.09	(-0.13,-0.05)	
	PLACEBO	1982	-0.36	0.02			
Item 6: Insomnia Late	PAROXETINE	3114	-0.45	0.01	-0.14	(-0.17,-0.10)	
	PLACEBO	1982	-0.31	0.02			
Item 7: Work and Activities	PAROXETINE	3114	-1.03	0.02	-0.32	(-0.38,-0.26)	
	PLACEBO	1982	-0.71	0.02			
Item 8: Retardation	PAROXETINE	3114	-0.46	0.01	-0.15	(-0.18,-0.11)	
	PLACEBO	1982	-0.31	0.01			
Item 9: Agitation	PAROXETINE	3114	-0.42	0.01	-0.11	(-0.15,-0.07)	
	PLACEBO	1982	-0.31	0.02			
Item 10: Anxiety Psychic	PAROXETINE	3114	-0.84	0.02	-0.35	(-0.40,-0.30)	
	PLACEBO	1981	-0.49	0.02			
Item 11: Anxiety Somatic	PAROXETINE	3114	-0.55	0.01	-0.12	(-0.16,-0.07)	
	PLACEBO	1981	-0.43	0.02			
Item 12: Somatic Symptoms Gastrointestinal	PAROXETINE	3114	-0.22	0.01	-0.04	(-0.07,-0.01)	
	PLACEBO	1982	-0.18	0.01			
Item 13: Somatic Symptoms General	PAROXETINE	3114	-0.56	0.01	-0.16	(-0.21,-0.12)	
	PLACEBO	1982	-0.40	0.02			
Item 14: Genital Symptoms	PAROXETINE	3114	-0.25	0.01	-0.02	(-0.06, 0.02)	

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.35
Change from Baseline in HAMD Individual Items and Total Score by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Item 14: Genital Symptoms	PLACEBO	1982	-0.23	0.02			
Item 15: Hypochondriasis	PAROXETINE	3114	-0.34	0.01	-0.11	(-0.14,-0.07)	
	PLACEBO	1982	-0.23	0.01			
Item 16: Loss of Weight	PAROXETINE	3114	-0.07	0.01	-0.01	(-0.04, 0.01)	
	PLACEBO	1982	-0.06	0.01			
Item 17: Insight	PAROXETINE	3113	-0.08	0.01	-0.02	(-0.03,-0.00)	
	PLACEBO	1981	-0.06	0.01			

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.36
Change from Baseline in HAMD Individual Items and Total Score by Treatment Group
Adult Active Control Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Total score	PAROXETINE	4056	-12.22	0.12	-0.97	(-1.33,-0.61)	<0.001
	COMPARATOR	2949	-11.25	0.14			
Item 1: Depressed Mood	PAROXETINE	4056	-1.58	0.02	-0.12	(-0.17,-0.07)	
	COMPARATOR	2949	-1.46	0.02			
Item 2: Feelings of Guilt	PAROXETINE	4058	-0.92	0.01	-0.09	(-0.12,-0.05)	
	COMPARATOR	2949	-0.83	0.01			
Item 3: Suicide	PAROXETINE	4057	-0.78	0.01	-0.06	(-0.09,-0.03)	
	COMPARATOR	2949	-0.72	0.01			
Item 4: Insomnia Early	PAROXETINE	4056	-0.64	0.01	0.01	(-0.03, 0.04)	
	COMPARATOR	2948	-0.64	0.01			
Item 5: Insomnia Middle	PAROXETINE	4057	-0.67	0.01	-0.03	(-0.06, 0.01)	
	COMPARATOR	2947	-0.65	0.01			
Item 6: Insomnia Late	PAROXETINE	4056	-0.67	0.01	-0.06	(-0.09,-0.03)	
	COMPARATOR	2947	-0.61	0.01			
Item 7: Work and Activities	PAROXETINE	4058	-1.43	0.02	-0.14	(-0.19,-0.08)	
	COMPARATOR	2949	-1.30	0.02			
Item 8: Retardation	PAROXETINE	4058	-0.69	0.01	-0.04	(-0.07,-0.00)	
	COMPARATOR	2949	-0.65	0.01			
Item 9: Agitation	PAROXETINE	4046	-0.65	0.01	-0.10	(-0.14,-0.06)	
	COMPARATOR	2940	-0.55	0.02			
Item 10: Anxiety Psychic	PAROXETINE	4057	-1.11	0.02	-0.16	(-0.21,-0.12)	
	COMPARATOR	2949	-0.95	0.02			
Item 11: Anxiety Somatic	PAROXETINE	4058	-0.78	0.01	-0.11	(-0.15,-0.07)	
	COMPARATOR	2949	-0.67	0.02			
Item 12: Somatic Symptoms Gastrointestinal	PAROXETINE	4057	-0.42	0.01	-0.04	(-0.06,-0.01)	
	COMPARATOR	2948	-0.38	0.01			
Item 13: Somatic Symptoms General	PAROXETINE	4055	-0.66	0.01	-0.07	(-0.11,-0.04)	
	COMPARATOR	2948	-0.59	0.01			
Item 14: Genital Symptoms	PAROXETINE	4041	-0.38	0.01	0.00	(-0.03, 0.03)	

Includes paroxetine and active control data from multiple arm trials with placebo
Treatment differences are Paroxetine minus Comparator
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.36
Change from Baseline in HAMD Individual Items and Total Score by Treatment Group
Adult Active Control Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Item 14: Genital Symptoms	COMPARATOR	2941	-0.38	0.01			
Item 15: Hypochondriasis	PAROXETINE	4057	-0.52	0.01	-0.07	(-0.10,-0.04)	
	COMPARATOR	2949	-0.46	0.01			
Item 16: Loss of Weight	PAROXETINE	4054	-0.25	0.01	-0.01	(-0.03, 0.01)	
	COMPARATOR	2946	-0.24	0.01			
Item 17: Insight	PAROXETINE	4054	-0.11	0.01	0.01	(-0.01, 0.03)	
	COMPARATOR	2948	-0.12	0.01			

Includes paroxetine and active control data from multiple arm trials with placebo
Treatment differences are Paroxetine minus Comparator
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.37
Change from Baseline in HAMD Individual Items and Total Score by Treatment Group
Paediatric Placebo Controlled Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Total score	PAROXETINE	177	-4.41	0.44	-1.05	(-2.28, 0.17)	0.09
	PLACEBO	180	-3.35	0.44			
Item 1: Depressed Mood	PAROXETINE	177	-0.67	0.08	-0.24	(-0.48,-0.01)	
	PLACEBO	180	-0.42	0.08			
Item 2: Feelings of Guilt	PAROXETINE	177	-0.19	0.05	0.01	(-0.12, 0.15)	
	PLACEBO	180	-0.20	0.05			
Item 3: Suicide	PAROXETINE	177	-0.27	0.04	0.01	(-0.11, 0.13)	
	PLACEBO	180	-0.28	0.04			
Item 4: Insomnia Early	PAROXETINE	177	-0.33	0.05	-0.14	(-0.29, 0.00)	
	PLACEBO	180	-0.19	0.05			
Item 5: Insomnia Middle	PAROXETINE	177	-0.21	0.04	-0.03	(-0.13, 0.08)	
	PLACEBO	180	-0.18	0.04			
Item 6: Insomnia Late	PAROXETINE	177	-0.18	0.03	0.01	(-0.07, 0.08)	
	PLACEBO	180	-0.19	0.03			
Item 7: Work and Activities	PAROXETINE	177	-0.58	0.07	-0.06	(-0.25, 0.13)	
	PLACEBO	180	-0.52	0.07			
Item 8: Retardation	PAROXETINE	177	-0.37	0.05	-0.06	(-0.18, 0.07)	
	PLACEBO	180	-0.32	0.05			
Item 9: Agitation	PAROXETINE	177	-0.21	0.06	-0.04	(-0.20, 0.12)	
	PLACEBO	180	-0.17	0.06			
Item 10: Anxiety Psychic	PAROXETINE	177	-0.20	0.07	-0.11	(-0.32, 0.10)	
	PLACEBO	180	-0.09	0.07			
Item 11: Anxiety Somatic	PAROXETINE	177	-0.24	0.05	-0.07	(-0.22, 0.07)	
	PLACEBO	180	-0.17	0.05			
Item 12: Somatic Symptoms Gastrointestinal	PAROXETINE	177	-0.10	0.03	-0.01	(-0.11, 0.09)	
	PLACEBO	180	-0.09	0.03			
Item 13: Somatic Symptoms General	PAROXETINE	177	-0.43	0.05	-0.18	(-0.32,-0.04)	
	PLACEBO	180	-0.25	0.05			
Item 14: Genital Symptoms	PAROXETINE	176	-0.07	0.02	-0.01	(-0.05, 0.04)	

Includes studies 329 and placebo controlled phase of 453
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.37
Change from Baseline in HAMD Individual Items and Total Score by Treatment Group
Paediatric Placebo Controlled Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Item 14: Genital Symptoms	PLACEBO	179	-0.06	0.02			
Item 15: Hypochondriasis	PAROXETINE	177	-0.19	0.04	-0.09	(-0.20, 0.02)	
	PLACEBO	180	-0.10	0.04			
Item 16: Loss of Weight	PAROXETINE	177	-0.09	0.02	-0.02	(-0.09, 0.04)	
	PLACEBO	180	-0.06	0.02			
Item 17: Insight	PAROXETINE	177	-0.09	0.03	-0.03	(-0.10, 0.05)	
	PLACEBO	180	-0.06	0.03			

Includes studies 329 and placebo controlled phase of 453
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.38
Summary of Analysis for CGI Global Improvement in the Elderly (>65 Years) - Proportion of Responders
Adult Placebo Controlled Trials
On-Therapy LOCF

Paroxetine			Placebo			Treatment Comparison*			
n	N	%	n	N	%	Odds Ratio	Lower 95% CI Limit	Upper 95% CI Limit	P-value
221	372	59.4	122	268	45.5	1.75	1.28	2.41	<0.001

Note: Responders are subjects who have a score of 1 or 2
* The odds ratio represents the odds of improving with paroxetine relative to that with placebo
Note: 54 subjects had no on-therapy CGI global improvement assessment (37 paroxetine subjects and 17 placebo subjects)

EMEA LOQs Table 1.39
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Body System	Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
TOTAL	TOTAL	286	70.4	174	61.7
	Total Male Subjects *	187	100.0	107	100.0
	Total Male-Specific AEs *	24	12.8	6	5.6
	Total Female Subjects **	219	100.0	175	100.0
	Total Female-Specific AEs **	4	1.8	3	1.7
	Total Non Gender-Specific AEs	282	69.5	173	61.3
Body as a Whole	TOTAL	136	33.5	73	25.9
	ABDOMEN ENLARGED	1	0.2	0	0.0
	ABDOMINAL PAIN	16	3.9	11	3.9
	ACCIDENTAL OVERDOSE	1	0.2	0	0.0
	ALLERGIC REACTION	1	0.2	0	0.0
	ASTHENIA	48	11.8	15	5.3
	BACK PAIN	8	2.0	6	2.1
	CELLULITIS	1	0.2	0	0.0
	CHEST PAIN	3	0.7	5	1.8
	CHILLS	3	0.7	3	1.1
	FACE EDEMA	2	0.5	0	0.0
	FEVER	4	1.0	2	0.7
	FLU SYNDROME	7	1.7	2	0.7
	HEADACHE	47	11.6	30	10.6
	INFECTION	13	3.2	2	0.7
	MALAISE	3	0.7	0	0.0
	NECK PAIN	1	0.2	0	0.0
	NEOPLASM	0	0.0	2	0.7
	PAIN	6	1.5	7	2.5
	SURGICAL PROCEDURE	1	0.2	0	0.0
	TRAUMA	19	4.7	11	3.9
Cardiovascular System	TOTAL	51	12.6	21	7.4
	ANGINA PECTORIS	2	0.5	0	0.0
	ARRHYTHMIA	2	0.5	1	0.4
	AV BLOCK	0	0.0	2	0.7
	BRADYCARDIA	3	0.7	0	0.0
	BUNDLE BRANCH BLOCK	1	0.2	0	0.0
	CEREBROVASCULAR DISORDER	0	0.0	1	0.4
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	1	0.4
	EXTRASYSTOLES	1	0.2	0	0.0
	HEART FAILURE	1	0.2	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.39
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Body System	Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
Cardiovascular System	HYPERTENSION	5	1.2	4	1.4
	HYPOTENSION	17	4.2	4	1.4
	MIGRAINE	3	0.7	2	0.7
	MYOCARDIAL ISCHEMIA	1	0.2	0	0.0
	PALLOR	1	0.2	0	0.0
	PALPITATION	4	1.0	1	0.4
	PERIPHERAL VASCULAR DISORDER	2	0.5	0	0.0
	PHLEBITIS	1	0.2	0	0.0
	POSTURAL HYPOTENSION	4	1.0	1	0.4
	SYNCOPE	2	0.5	3	1.1
	TACHYCARDIA	2	0.5	2	0.7
	VASCULAR ANOMALY	1	0.2	0	0.0
	VASODILATATION	8	2.0	2	0.7
Digestive System	TOTAL	175	43.1	75	26.6
	CONSTIPATION	45	11.1	8	2.8
	DECREASED APPETITE	26	6.4	3	1.1
	DIARRHEA	47	11.6	15	5.3
	DIGESTIVE SYSTEM DISORDER	0	0.0	1	0.4
	DRY MOUTH	40	9.9	19	6.7
	DYSPEPSIA	24	5.9	11	3.9
	DYSPHAGIA	2	0.5	1	0.4
	ERUCTATION	1	0.2	0	0.0
	ESOPHAGITIS	1	0.2	0	0.0
	FLATULENCE	20	4.9	10	3.5
	GALL BLADDER DISORDER	0	0.0	1	0.4
	GASTROENTERITIS	1	0.2	2	0.7
	GASTROINTESTINAL DISORDER	3	0.7	1	0.4
	GINGIVITIS	3	0.7	2	0.7
	HEPATOSPLENOMEGALY	1	0.2	0	0.0
	INCREASED APPETITE	5	1.2	2	0.7
	INTESTINAL OBSTRUCTION	1	0.2	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	3	0.7	0	0.0
	NAUSEA	48	11.8	25	8.9
	PEPTIC ULCER	1	0.2	1	0.4
	RECTAL DISORDER	0	0.0	1	0.4
	RECTAL HEMORRHAGE	0	0.0	1	0.4
	STOMACH ULCER	1	0.2	0	0.0
	TOOTH CARIES	1	0.2	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.39
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Body System	Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
Digestive System	TOOTH DISORDER	3	0.7	1	0.4
	ULCERATIVE STOMATITIS	2	0.5	1	0.4
	VOMITING	8	2.0	5	1.8
Endocrine System	TOTAL	4	1.0	3	1.1
	DIABETES MELLITUS	2	0.5	2	0.7
	HYPOTHYROIDISM	1	0.2	1	0.4
	TESTES DISORDER *	1	0.5	0	0.0
Hemic and Lymphatic System	TOTAL	7	1.7	3	1.1
	ANEMIA	2	0.5	0	0.0
	CHRONIC LYMPHOCYTIC LEUKEMIA	1	0.2	0	0.0
	EOSINOPHILIA	1	0.2	0	0.0
	LEUKOPENIA	0	0.0	1	0.4
	LYMPHADENOPATHY	0	0.0	1	0.4
	PURPURA	4	1.0	1	0.4
Metabolic and Nutritional Disorders	TOTAL	12	3.0	11	3.9
	GENERALIZED EDEMA	1	0.2	0	0.0
	GOUT	0	0.0	1	0.4
	HYPERCHOLESTEREMIA	1	0.2	1	0.4
	HYPERGLYCEMIA	3	0.7	1	0.4
	HYPERKALEMIA	1	0.2	0	0.0
	HYPERNATREMIA	0	0.0	1	0.4
	HYPONATREMIA	1	0.2	0	0.0
	NPN INCREASED	0	0.0	1	0.4
	PERIPHERAL EDEMA	2	0.5	2	0.7
	RESPIRATORY ALKALOSIS	0	0.0	1	0.4
	SGOT INCREASED	0	0.0	1	0.4
	SGPT INCREASED	0	0.0	1	0.4
	THIRST	1	0.2	0	0.0
	WEIGHT GAIN	1	0.2	2	0.7
	WEIGHT LOSS	1	0.2	1	0.4
Musculoskeletal System	TOTAL	23	5.7	26	9.2
	ARTHRALGIA	10	2.5	5	1.8

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.39
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Body System	Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
Musculoskeletal System	ARTHRITIS	0	0.0	5	1.8
	ARTHROSIS	1	0.2	1	0.4
	BONE DISORDER	1	0.2	1	0.4
	BURSITIS	1	0.2	2	0.7
	MYALGIA	7	1.7	8	2.8
	MYASTHENIA	1	0.2	2	0.7
	MYOPATHY	0	0.0	1	0.4
	MYOSITIS	1	0.2	0	0.0
	TENDINOUS DISORDER	1	0.2	1	0.4
Nervous System	TOTAL	173	42.6	78	27.7
	ABNORMAL DREAMS	6	1.5	4	1.4
	AGITATION	9	2.2	5	1.8
	AMNESIA	0	0.0	2	0.7
	ANXIETY	11	2.7	5	1.8
	ATAXIA	3	0.7	0	0.0
	CONCENTRATION IMPAIRED	3	0.7	0	0.0
	CONFUSION	6	1.5	6	2.1
	CONVULSION	1	0.2	0	0.0
	DEPERSONALIZATION	2	0.5	1	0.4
	DEPRESSION	4	1.0	5	1.8
	DIZZINESS	35	8.6	17	6.0
	DYSARTHRIA	1	0.2	0	0.0
	EMOTIONAL LABILITY	3	0.7	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.4
	HALLUCINATIONS	2	0.5	0	0.0
	HOSTILITY	0	0.0	2	0.7
	HYPERTONIA	3	0.7	2	0.7
	HYPESTHESIA	0	0.0	2	0.7
	HYPOKINESIA	0	0.0	1	0.4
	HYPOTONIA	0	0.0	1	0.4
	INSOMNIA	39	9.6	24	8.5
	LACK OF EMOTION	3	0.7	0	0.0
	LIBIDO DECREASED	17	4.2	0	0.0
	LIBIDO INCREASED	0	0.0	1	0.4
	MYOCLONUS	6	1.5	0	0.0
	NERVOUSNESS	19	4.7	11	3.9
	NEURALGIA	1	0.2	2	0.7
	NEURONPATHY	1	0.2	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.39
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Body System	Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
Nervous System	PARALYSIS	2	0.5	0	0.0
	PARESTHESIA	6	1.5	4	1.4
	PERIPHERAL NEURITIS	1	0.2	0	0.0
	SOMNOLENCE	59	14.5	15	5.3
	TREMOR	30	7.4	2	0.7
	TRISMUS	1	0.2	0	0.0
	VERTIGO	3	0.7	2	0.7
	VESTIBULAR DISORDER	1	0.2	0	0.0
	WITHDRAWAL SYNDROME	1	0.2	0	0.0
Respiratory System	TOTAL	56	13.8	42	14.9
	ASTHMA	1	0.2	2	0.7
	BRONCHITIS	9	2.2	5	1.8
	COUGH INCREASED	4	1.0	1	0.4
	DYSPNEA	4	1.0	3	1.1
	EPISTAXIS	0	0.0	1	0.4
	HEMOPTYSIS	0	0.0	1	0.4
	HYPERVENTILATION	0	0.0	1	0.4
	LARYNX DISORDER	0	0.0	1	0.4
	PHARYNGITIS	4	1.0	1	0.4
	PNEUMONIA	4	1.0	0	0.0
	RESPIRATORY DISORDER	27	6.7	21	7.4
	RHINITIS	3	0.7	2	0.7
	SINUSITIS	6	1.5	8	2.8
	VOICE ALTERATION	1	0.2	1	0.4
Skin and Appendages	TOTAL	45	11.1	16	5.7
	ALOPECIA	1	0.2	0	0.0
	DRY SKIN	1	0.2	1	0.4
	EXFOLIATIVE DERMATITIS	1	0.2	1	0.4
	FUNGAL DERMATITIS	1	0.2	0	0.0
	HERPES SIMPLEX	1	0.2	0	0.0
	HERPES ZOSTER	0	0.0	1	0.4
	MACULOPAPULAR RASH	1	0.2	0	0.0
	PRURITUS	5	1.2	4	1.4
	PUSTULAR RASH	1	0.2	0	0.0
	RASH	8	2.0	2	0.7
	SEBORRHEA	1	0.2	0	0.0
	SKIN BENIGN NEOPLASM	0	0.0	1	0.4
	SKIN DISORDER	3	0.7	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.39
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Body System	Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
Skin and Appendages	SKIN HYPERTROPHY	0	0.0	1	0.4
	SKIN ULCER	1	0.2	0	0.0
	SWEATING	25	6.2	5	1.8
	URTICARIA	1	0.2	1	0.4
Special Senses	TOTAL	36	8.9	20	7.1
	ABNORMAL VISION	13	3.2	3	1.1
	ABNORMALITY OF ACCOMMODATION	1	0.2	0	0.0
	BLURRED VISION	0	0.0	1	0.4
	CATARACT SPECIFIED	1	0.2	2	0.7
	CONJUNCTIVITIS	3	0.7	2	0.7
	DEAFNESS	1	0.2	0	0.0
	EAR PAIN	1	0.2	1	0.4
	EYE APPENDAGE DISORDER	0	0.0	1	0.4
	EYE DISORDER	2	0.5	1	0.4
	OTITIS MEDIA	2	0.5	4	1.4
	TASTE PERVERSION	5	1.2	4	1.4
	TINNITUS	9	2.2	1	0.4
	VISUAL FIELD DEFECT	1	0.2	1	0.4
Urogenital System	TOTAL	53	13.1	27	9.6
	ABNORMAL EJACULATION *	9	4.8	2	1.9
	ALBUMINURIA	1	0.2	3	1.1
	BREAST PAIN **	0	0.0	1	0.6
	CYSTITIS	1	0.2	5	1.8
	DYSURIA	1	0.2	3	1.1
	FEMALE GENITAL DISORDERS **	3	1.4	0	0.0
	GLYCOSURIA	1	0.2	0	0.0
	HAEMATURIA	2	0.5	0	0.0
	IMPOTENCE *	15	8.0	3	2.8
	KIDNEY FUNCTION ABNORMAL	1	0.2	0	0.0
	NEPHRITIS	0	0.0	1	0.4
	NOCTURIA	1	0.2	0	0.0
	PROSTATE DISORDER *	1	0.5	3	2.8
	PYURIA	1	0.2	0	0.0
	URINARY FREQUENCY	10	2.5	0	0.0
	URINARY INCONTINENCE	0	0.0	2	0.7
	URINARY RETENTION	2	0.5	0	0.0
	URINARY TRACT INFECTION	14	3.4	7	2.5
	URINATION IMPAIRED	1	0.2	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.39

Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term in the Elderly (>65 Years)

Adult Placebo Controlled Trials

Randomised Phase

Body System	Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
Urogenital System	URINE ABNORMALITY	0	0.0	2	0.7
	VAGINA DISORDERS **	0	0.0	1	0.6
	VAGINAL MONILIASIS **	1	0.5	0	0.0
	VAGINITIS **	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.40
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

	Paroxetine (N=406)		Placebo (N=282)	
Preferred Term	n	%	n	%
TOTAL	286	70.4	174	61.7
Total Male Subjects *	187	100.0	107	100.0
Total Male-Specific AEs *	24	12.8	6	5.6
Total Female Subjects **	219	100.0	175	100.0
Total Female-Specific AEs **	4	1.8	3	1.7
Total Non Gender-Specific AEs	282	69.5	173	61.3
SOMNOLENCE	59	14.5	15	5.3
NAUSEA	48	11.8	25	8.9
ASTHENIA	48	11.8	15	5.3
HEADACHE	47	11.6	30	10.6
DIARRHEA	47	11.6	15	5.3
CONSTIPATION	45	11.1	8	2.8
DRY MOUTH	40	9.9	19	6.7
INSOMNIA	39	9.6	24	8.5
DIZZINESS	35	8.6	17	6.0
IMPOTENCE *	15	8.0	3	2.8
TREMOR	30	7.4	2	0.7
RESPIRATORY DISORDER	27	6.7	21	7.4
DECREASED APPETITE	26	6.4	3	1.1
SWEATING	25	6.2	5	1.8
DYSPEPSIA	24	5.9	11	3.9
FLATULENCE	20	4.9	10	3.5
ABNORMAL EJACULATION *	9	4.8	2	1.9
NERVOUSNESS	19	4.7	11	3.9
TRAUMA	19	4.7	11	3.9
HYPOTENSION	17	4.2	4	1.4
LIBIDO DECREASED	17	4.2	0	0.0
ABDOMINAL PAIN	16	3.9	11	3.9
URINARY TRACT INFECTION	14	3.4	7	2.5
ABNORMAL VISION	13	3.2	3	1.1
INFECTION	13	3.2	2	0.7
ANXIETY	11	2.7	5	1.8
ARTHRALGIA	10	2.5	5	1.8
URINARY FREQUENCY	10	2.5	0	0.0
AGITATION	9	2.2	5	1.8
BRONCHITIS	9	2.2	5	1.8
TINNITUS	9	2.2	1	0.4
BACK PAIN	8	2.0	6	2.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.40
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

	Paroxetine (N=406)		Placebo (N=282)	
Preferred Term	n	%	n	%
VOMITING	8	2.0	5	1.8
RASH	8	2.0	2	0.7
VASODILATATION	8	2.0	2	0.7
MYALGIA	7	1.7	8	2.8
FLU SYNDROME	7	1.7	2	0.7
SINUSITIS	6	1.5	8	2.8
PAIN	6	1.5	7	2.5
CONFUSION	6	1.5	6	2.1
ABNORMAL DREAMS	6	1.5	4	1.4
PARESTHESIA	6	1.5	4	1.4
MYOCLONUS	6	1.5	0	0.0
FEMALE GENITAL DISORDERS **	3	1.4	0	0.0
HYPERTENSION	5	1.2	4	1.4
PRURITUS	5	1.2	4	1.4
TASTE PERVERSION	5	1.2	4	1.4
INCREASED APPETITE	5	1.2	2	0.7
DEPRESSION	4	1.0	5	1.8
DYSPNEA	4	1.0	3	1.1
FEVER	4	1.0	2	0.7
COUGH INCREASED	4	1.0	1	0.4
PALPITATION	4	1.0	1	0.4
PHARYNGITIS	4	1.0	1	0.4
POSTURAL HYPOTENSION	4	1.0	1	0.4
PURPURA	4	1.0	1	0.4
PNEUMONIA	4	1.0	0	0.0
CHEST PAIN	3	0.7	5	1.8
CHILLS	3	0.7	3	1.1
CONJUNCTIVITIS	3	0.7	2	0.7
GINGIVITIS	3	0.7	2	0.7
HYPERTONIA	3	0.7	2	0.7
MIGRAINE	3	0.7	2	0.7
RHINITIS	3	0.7	2	0.7
VERTIGO	3	0.7	2	0.7
GASTROINTESTINAL DISORDER	3	0.7	1	0.4
HYPERGLYCEMIA	3	0.7	1	0.4
TOOTH DISORDER	3	0.7	1	0.4
ATAXIA	3	0.7	0	0.0
BRADYCARDIA	3	0.7	0	0.0
CONCENTRATION IMPAIRED	3	0.7	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.40
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

	Paroxetine (N=406)		Placebo (N=282)	
Preferred Term	n	%	n	%
EMOTIONAL LABILITY	3	0.7	0	0.0
LACK OF EMOTION	3	0.7	0	0.0
LIVER FUNCTION TESTS ABNORMAL	3	0.7	0	0.0
MALAISE	3	0.7	0	0.0
SKIN DISORDER	3	0.7	0	0.0
PROSTATE DISORDER *	1	0.5	3	2.8
OTITIS MEDIA	2	0.5	4	1.4
SYNCOPE	2	0.5	3	1.1
DIABETES MELLITUS	2	0.5	2	0.7
PERIPHERAL EDEMA	2	0.5	2	0.7
TACHYCARDIA	2	0.5	2	0.7
ARRHYTHMIA	2	0.5	1	0.4
DEPERSONALIZATION	2	0.5	1	0.4
DYSPHAGIA	2	0.5	1	0.4
EYE DISORDER	2	0.5	1	0.4
ULCERATIVE STOMATITIS	2	0.5	1	0.4
ANEMIA	2	0.5	0	0.0
ANGINA PECTORIS	2	0.5	0	0.0
FACE EDEMA	2	0.5	0	0.0
HAEMATURIA	2	0.5	0	0.0
HALLUCINATIONS	2	0.5	0	0.0
PARALYSIS	2	0.5	0	0.0
PERIPHERAL VASCULAR DISORDER	2	0.5	0	0.0
TESTES DISORDER *	1	0.5	0	0.0
URINARY RETENTION	2	0.5	0	0.0
VAGINAL MONILIASIS **	1	0.5	0	0.0
CYSTITIS	1	0.2	5	1.8
ALBUMINURIA	1	0.2	3	1.1
DYSURIA	1	0.2	3	1.1
ASTHMA	1	0.2	2	0.7
BURSITIS	1	0.2	2	0.7
CATARACT SPECIFIED	1	0.2	2	0.7
GASTROENTERITIS	1	0.2	2	0.7
MYASTHENIA	1	0.2	2	0.7
NEURALGIA	1	0.2	2	0.7
WEIGHT GAIN	1	0.2	2	0.7
ARTHROSIS	1	0.2	1	0.4
BONE DISORDER	1	0.2	1	0.4
DRY SKIN	1	0.2	1	0.4

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.40
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
EAR PAIN	1	0.2	1	0.4
EXFOLIATIVE DERMATITIS	1	0.2	1	0.4
HYPERCHOLESTEREMIA	1	0.2	1	0.4
HYPOTHYROIDISM	1	0.2	1	0.4
PEPTIC ULCER	1	0.2	1	0.4
TENDINOUS DISORDER	1	0.2	1	0.4
URTICARIA	1	0.2	1	0.4
VISUAL FIELD DEFECT	1	0.2	1	0.4
VOICE ALTERATION	1	0.2	1	0.4
WEIGHT LOSS	1	0.2	1	0.4
ABDOMEN ENLARGED	1	0.2	0	0.0
ABNORMALITY OF ACCOMMODATION	1	0.2	0	0.0
ACCIDENTAL OVERDOSE	1	0.2	0	0.0
ALLERGIC REACTION	1	0.2	0	0.0
ALOPECIA	1	0.2	0	0.0
BUNDLE BRANCH BLOCK	1	0.2	0	0.0
CELLULITIS	1	0.2	0	0.0
CHRONIC LYMPHOCYTIC LEUKEMIA	1	0.2	0	0.0
CONVULSION	1	0.2	0	0.0
DEAFNESS	1	0.2	0	0.0
DYSARTHRIA	1	0.2	0	0.0
EOSINOPHILIA	1	0.2	0	0.0
ERUCTATION	1	0.2	0	0.0
ESOPHAGITIS	1	0.2	0	0.0
EXTRASYSTOLES	1	0.2	0	0.0
FUNGAL DERMATITIS	1	0.2	0	0.0
GENERALIZED EDEMA	1	0.2	0	0.0
GLYCOSURIA	1	0.2	0	0.0
HEART FAILURE	1	0.2	0	0.0
HEPATOSPLENOMEGALY	1	0.2	0	0.0
HERPES SIMPLEX	1	0.2	0	0.0
HYPERKALEMIA	1	0.2	0	0.0
HYPONATREMIA	1	0.2	0	0.0
INTESTINAL OBSTRUCTION	1	0.2	0	0.0
KIDNEY FUNCTION ABNORMAL	1	0.2	0	0.0
MACULOPAPULAR RASH	1	0.2	0	0.0
MYOCARDIAL ISCHEMIA	1	0.2	0	0.0
MYOSITIS	1	0.2	0	0.0
NECK PAIN	1	0.2	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.40
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

	Paroxetine (N=406)		Placebo (N=282)	
Preferred Term	n	%	n	%
NEUROPATHY	1	0.2	0	0.0
NOCTURIA	1	0.2	0	0.0
PALLOR	1	0.2	0	0.0
PERIPHERAL NEURITIS	1	0.2	0	0.0
PHLEBITIS	1	0.2	0	0.0
PUSTULAR RASH	1	0.2	0	0.0
PYURIA	1	0.2	0	0.0
SEBORRHEA	1	0.2	0	0.0
SKIN ULCER	1	0.2	0	0.0
STOMACH ULCER	1	0.2	0	0.0
SURGICAL PROCEDURE	1	0.2	0	0.0
THIRST	1	0.2	0	0.0
TOOTH CARIES	1	0.2	0	0.0
TRISMUS	1	0.2	0	0.0
URINATION IMPAIRED	1	0.2	0	0.0
VASCULAR ANOMALY	1	0.2	0	0.0
VESTIBULAR DISORDER	1	0.2	0	0.0
WITHDRAWAL SYNDROME	1	0.2	0	0.0
ARTHRITIS	0	0.0	5	1.8
AMNESIA	0	0.0	2	0.7
AV BLOCK	0	0.0	2	0.7
HOSTILITY	0	0.0	2	0.7
HYPESTHESIA	0	0.0	2	0.7
NEOPLASM	0	0.0	2	0.7
URINARY INCONTINENCE	0	0.0	2	0.7
URINE ABNORMALITY	0	0.0	2	0.7
BREAST PAIN **	0	0.0	1	0.6
VAGINA DISORDERS **	0	0.0	1	0.6
VAGINITIS **	0	0.0	1	0.6
BLURRED VISION	0	0.0	1	0.4
CEREBROVASCULAR DISORDER	0	0.0	1	0.4
DIGESTIVE SYSTEM DISORDER	0	0.0	1	0.4
ELECTROCARDIOGRAM ABNORMAL	0	0.0	1	0.4
EPISTAXIS	0	0.0	1	0.4
EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.4
EYE APPENDAGE DISORDER	0	0.0	1	0.4
GALL BLADDER DISORDER	0	0.0	1	0.4
GOUT	0	0.0	1	0.4
HEMOPTYSIS	0	0.0	1	0.4

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.40
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency in the Elderly (>65 Years)
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=406) n	%	Placebo (N=282) n	%
HERPES ZOSTER	0	0.0	1	0.4
HYPERNATREMIA	0	0.0	1	0.4
HYPERVENTILATION	0	0.0	1	0.4
HYPOKINESIA	0	0.0	1	0.4
HYPOTONIA	0	0.0	1	0.4
LARYNX DISORDER	0	0.0	1	0.4
LEUKOPENIA	0	0.0	1	0.4
LIBIDO INCREASED	0	0.0	1	0.4
LYMPHADENOPATHY	0	0.0	1	0.4
MYOPATHY	0	0.0	1	0.4
NEPHRITIS	0	0.0	1	0.4
NPN INCREASED	0	0.0	1	0.4
RECTAL DISORDER	0	0.0	1	0.4
RECTAL HEMORRHAGE	0	0.0	1	0.4
RESPIRATORY ALKALOSIS	0	0.0	1	0.4
SGOT INCREASED	0	0.0	1	0.4
SGPT INCREASED	0	0.0	1	0.4
SKIN BENIGN NEOPLASM	0	0.0	1	0.4
SKIN HYPERTROPHY	0	0.0	1	0.4

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 10mg (N=105)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
TOTAL	TOTAL	44	41.9	27	25.7	13	12.4	9	8.6	21	20.0	73	69.5
	Total Male Subjects *	55	100.0	55	100.0	55	100.0	55	100.0	55	100.0	55	100.0
	Total Male-Specific AEs *	2	3.6	1	1.8	1	1.8	1	1.8	1	1.8	6	10.9
	Total Female Subjects **	50	100.0	50	100.0	50	100.0	50	100.0	50	100.0	50	100.0
	Total Female-Specific AEs **	2	4.0	0	0.0	0	0.0	1	2.0	0	0.0	3	6.0
	Total Non Gender-Specific AEs	43	41.0	27	25.7	13	12.4	7	6.7	21	20.0	72	68.6
Body as a Whole	TOTAL	7	6.7	7	6.7	2	1.9	1	1.0	9	8.6	25	23.8
	ABDOMINAL PAIN	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	ASTHENIA	1	1.0	2	1.9	0	0.0	0	0.0	0	0.0	3	2.9
	BACK PAIN	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0	2	1.9
	CHEST PAIN	1	1.0	0	0.0	1	1.0	0	0.0	1	1.0	3	2.9
	CHILLS	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	CHILLS AND FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FLU SYNDROME	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	HEADACHE	4	3.8	3	2.9	0	0.0	1	1.0	2	1.9	10	9.5
	HERNIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MONILIASIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	NECK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	NECK RIGIDITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SURGICAL PROCEDURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	3	2.9	3	2.9
Cardiovascular System	TOTAL	3	2.9	3	2.9	1	1.0	0	0.0	2	1.9	9	8.6
	ANGINA PECTORIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BRADYCARDIA	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	HYPERTENSION	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	MYOCARDIAL ISCHEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PALPITATION	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	2	1.9
	PERIPHERAL VASCULAR DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	POSTURAL HYPOTENSION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	SYNCOPE	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	TACHYCARDIA	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 10mg (N=105)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Cardiovascular System	VASCULAR HEADACHE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VASODILATATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	VENTRICULAR EXTRASYSTOLES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Digestive System	TOTAL	24	22.9	8	7.6	4	3.8	3	2.9	7	6.7	39	37.1
	BRUXISM	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	2	1.9
	BUCCAL CAVITY DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONSTIPATION	2	1.9	3	2.9	0	0.0	0	0.0	0	0.0	5	4.8
	DECREASED APPETITE	0	0.0	2	1.9	0	0.0	0	0.0	0	0.0	2	1.9
	DIARRHEA	7	6.7	1	1.0	1	1.0	0	0.0	1	1.0	10	9.5
	DRY MOUTH	8	7.6	0	0.0	0	0.0	0	0.0	3	2.9	11	10.5
	DYSPEPSIA	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	2	1.9
	DYSPHAGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ERUCTATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	FLATULENCE	2	1.9	0	0.0	1	1.0	1	1.0	0	0.0	4	3.8
	GASTROINTESTINAL FLU	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INCREASED APPETITE	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	2	1.9
	MELENA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MOUTH ULCERATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NAUSEA	10	9.5	1	1.0	1	1.0	1	1.0	2	1.9	15	14.3
	NAUSEA AND VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NAUSEA VOMITING AND DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	OROPHARYNX DISORDER	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	GOUT	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PERIPHERAL EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	WEIGHT LOSS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 10mg (N=105)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Musculoskeletal System	TOTAL	2	1.9	0	0.0	1	1.0	0	0.0	2	1.9	5	4.8
	ARTHRALGIA	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	2	1.9
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	MYASTHENIA	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	MYOPATHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TRAUMATIC FRACTURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	20	19.0	11	10.5	4	3.8	1	1.0	4	3.8	36	34.3
	ABNORMAL DREAMS	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	AGITATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ALCOHOL ABUSE	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ANXIETY	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	2	1.9
	CNS STIMULATION	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0	2	1.9
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	CONFUSION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	DEPERSONALIZATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DEPRESSION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	DIZZINESS	5	4.8	1	1.0	1	1.0	0	0.0	0	0.0	7	6.7
	DRUGGED FEELING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	INCOORDINATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	INSOMNIA	5	4.8	2	1.9	1	1.0	0	0.0	1	1.0	9	8.6
	LIBIDO DECREASED	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	2	1.9
	MYOCLONUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NERVOUSNESS	2	1.9	3	2.9	0	0.0	0	0.0	1	1.0	6	5.7
	PARESTHESIA	1	1.0	2	1.9	0	0.0	0	0.0	0	0.0	3	2.9
	SOMNOLENCE	10	9.5	2	1.9	0	0.0	0	0.0	1	1.0	13	12.4
	TREMOR	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VERTIGO	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
Respiratory System	TOTAL	0	0.0	4	3.8	2	1.9	2	1.9	3	2.9	11	10.5
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9	2	1.9
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PNEUMONIA	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	RESPIRATORY DISORDER	0	0.0	1	1.0	1	1.0	1	1.0	0	0.0	3	2.9
	RESPIRATORY FLU	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 10mg (N=105)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Respiratory System	RHINITIS	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	2	1.9
	YAWN	0	0.0	2	1.9	0	0.0	0	0.0	0	0.0	2	1.9
Skin and Appendages	TOTAL	2	1.9	1	1.0	0	0.0	0	0.0	1	1.0	4	3.8
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DERMATOSES, GENERAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	HAIR DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PRURITUS	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	RASH	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	SKIN DISCOLORATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	URTICARIA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
Special Senses	TOTAL	5	4.8	0	0.0	0	0.0	1	1.0	1	1.0	7	6.7
	BLURRED VISION	3	2.9	0	0.0	0	0.0	0	0.0	0	0.0	3	2.9
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	EYE DISORDER	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PUPILLARY DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TASTE PERVERSION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	TINNITUS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	VISION DISORDERS	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
Urogenital System	TOTAL	4	3.8	1	1.0	2	1.9	2	1.9	2	1.9	11	10.5
	ABNORMAL EJACULATION *	2	3.6	0	0.0	0	0.0	0	0.0	1	1.8	3	5.5
	BREAST PAIN **	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DYSMENORRHEA **	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	FEMALE GENITAL DISORDERS **	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	IMPOTENCE *	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8
	KIDNEY CALCULUS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	MALE GENITAL DISORDERS *	0	0.0	0	0.0	1	1.8	1	1.8	0	0.0	2	3.6
	MASTITIS **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NOCTURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINARY FREQUENCY	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	URINARY RETENTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 10mg (N=105)

Body System	Preferred Term	Days 1-7 n	%	Days 8-14 n	%	Days 15-21 n	%	Days 22-28 n	%	Days >28 n	%	Total n	%
Urogenital System	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 20mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
TOTAL	TOTAL	59	55.7	37	34.9	15	14.2	13	12.3	19	17.9	80	75.5
	Total Male Subjects *	48	100.0	48	100.0	48	100.0	48	100.0	48	100.0	48	100.0
	Total Male-Specific AEs *	3	6.3	3	6.3	1	2.1	0	0.0	1	2.1	8	16.7
	Total Female Subjects **	58	100.0	58	100.0	58	100.0	58	100.0	58	100.0	58	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	59	55.7	37	34.9	15	14.2	13	12.3	18	17.0	80	75.5
Body as a Whole	TOTAL	18	17.0	7	6.6	7	6.6	4	3.8	6	5.7	37	34.9
	ABDOMINAL PAIN	2	1.9	0	0.0	0	0.0	1	0.9	0	0.0	3	2.8
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ASTHENIA	7	6.6	0	0.0	1	0.9	1	0.9	1	0.9	10	9.4
	BACK PAIN	0	0.0	0	0.0	2	1.9	0	0.0	1	0.9	3	2.8
	CHEST PAIN	2	1.9	0	0.0	1	0.9	0	0.0	0	0.0	3	2.8
	CHILLS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CHILLS AND FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FEVER	0	0.0	1	0.9	2	1.9	0	0.0	0	0.0	3	2.8
	FLU SYNDROME	1	0.9	1	0.9	0	0.0	1	0.9	1	0.9	4	3.8
	HEADACHE	7	6.6	5	4.7	1	0.9	1	0.9	1	0.9	15	14.2
	HERNIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MONILIASIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK RIGIDITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PAIN	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	2	1.9
	SURGICAL PROCEDURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
Cardiovascular System	TOTAL	2	1.9	3	2.8	1	0.9	0	0.0	1	0.9	7	6.6
	ANGINA PECTORIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BRADYCARDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	HYPERTENSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MYOCARDIAL ISCHEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PALPITATION	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	2	1.9
	PERIPHERAL VASCULAR DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	POSTURAL HYPOTENSION	1	0.9	2	1.9	0	0.0	0	0.0	0	0.0	3	2.8
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TACHYCARDIA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 20mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Cardiovascular System	VASCULAR HEADACHE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VASODILATATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VENTRICULAR EXTRASYSTOLES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Digestive System	TOTAL	39	36.8	17	16.0	4	3.8	3	2.8	6	5.7	57	53.8
	BRUXISM	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	BUCCAL CAVITY DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONSTIPATION	5	4.7	2	1.9	1	0.9	0	0.0	0	0.0	8	7.5
	DECREASED APPETITE	5	4.7	1	0.9	0	0.0	0	0.0	0	0.0	6	5.7
	DIARRHEA	16	15.1	1	0.9	0	0.0	1	0.9	2	1.9	20	18.9
	DRY MOUTH	7	6.6	10	9.4	1	0.9	0	0.0	1	0.9	19	17.9
	DYSPEPSIA	2	1.9	1	0.9	0	0.0	0	0.0	0	0.0	3	2.8
	DYSPHAGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ERUCTATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FLATULENCE	2	1.9	2	1.9	0	0.0	0	0.0	0	0.0	4	3.8
	GASTROINTESTINAL FLU	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	INCREASED APPETITE	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	MELENA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MOUTH ULCERATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NAUSEA	18	17.0	4	3.8	2	1.9	3	2.8	1	0.9	28	26.4
	NAUSEA AND VOMITING	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	NAUSEA VOMITING AND DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	OROPHARYNX DISORDER	3	2.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.8
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	VOMITING	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
Hemic and Lymphatic System	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	GOUT	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PERIPHERAL EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	WEIGHT LOSS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 20mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Musculoskeletal System	TOTAL	4	3.8	1	0.9	1	0.9	0	0.0	2	1.9	8	7.5
	ARTHRALGIA	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9	2	1.9
	MYALGIA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	MYASTHENIA	3	2.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.8
	MYOPATHY	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	TRAUMATIC FRACTURE	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
Nervous System	TOTAL	29	27.4	12	11.3	6	5.7	5	4.7	2	1.9	46	43.4
	ABNORMAL DREAMS	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	2	1.9
	AGITATION	2	1.9	1	0.9	0	0.0	0	0.0	0	0.0	3	2.8
	ALCOHOL ABUSE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ANXIETY	4	3.8	1	0.9	1	0.9	0	0.0	0	0.0	6	5.7
	CNS STIMULATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONCENTRATION IMPAIRED	1	0.9	2	1.9	0	0.0	0	0.0	0	0.0	3	2.8
	CONFUSION	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	DEPERSONALIZATION	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DIZZINESS	4	3.8	3	2.8	0	0.0	0	0.0	0	0.0	7	6.6
	DRUGGED FEELING	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	EMOTIONAL LABILITY	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	INCOORDINATION	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	INSOMNIA	5	4.7	3	2.8	0	0.0	0	0.0	0	0.0	8	7.5
	LIBIDO DECREASED	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	MYOCLONUS	0	0.0	0	0.0	2	1.9	1	0.9	0	0.0	3	2.8
	NERVOUSNESS	4	3.8	1	0.9	1	0.9	0	0.0	0	0.0	6	5.7
	PARESTHESIA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	SOMNOLENCE	11	10.4	3	2.8	2	1.9	2	1.9	1	0.9	19	17.9
	TREMOR	5	4.7	1	0.9	0	0.0	1	0.9	1	0.9	8	7.5
	VERTIGO	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
Respiratory System	TOTAL	7	6.6	2	1.9	3	2.8	1	0.9	3	2.8	16	15.1
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9	2	1.9
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PHARYNGITIS	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	2	1.9
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	RESPIRATORY DISORDER	2	1.9	2	1.9	1	0.9	1	0.9	3	2.8	9	8.5
	RESPIRATORY FLU	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 20mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Respiratory System	RHINITIS	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	YAWN	5	4.7	0	0.0	0	0.0	0	0.0	0	0.0	5	4.7
Skin and Appendages	TOTAL	3	2.8	3	2.8	3	2.8	2	1.9	3	2.8	13	12.3
	ACNE	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	2	1.9
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DERMATOSES, GENERAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	HAIR DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	MACULOPAPULAR RASH	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	PRURITUS	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	RASH	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	2	1.9
	SKIN DISCOLORATION	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	SWEATING	1	0.9	2	1.9	2	1.9	0	0.0	2	1.9	7	6.6
	URTICARIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Special Senses	TOTAL	6	5.7	4	3.8	0	0.0	0	0.0	0	0.0	10	9.4
	BLURRED VISION	3	2.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.8
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	EYE DISORDER	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PUPILLARY DISORDER	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	TASTE PERVERSION	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	2	1.9
	TINNITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VISION DISORDERS	3	2.8	1	0.9	0	0.0	0	0.0	0	0.0	4	3.8
Urogenital System	TOTAL	6	5.7	4	3.8	2	1.9	0	0.0	1	0.9	13	12.3
	ABNORMAL EJACULATION *	1	2.1	2	4.2	0	0.0	0	0.0	0	0.0	3	6.3
	BREAST PAIN **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DYSMENORRHEA **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	IMPOTENCE *	0	0.0	1	2.1	0	0.0	0	0.0	1	2.1	2	4.2
	KIDNEY CALCULUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MALE GENITAL DISORDERS *	2	4.2	1	2.1	1	2.1	0	0.0	0	0.0	4	8.3
	MASTITIS **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NOCTURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINARY FREQUENCY	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	2	1.9
	URINARY RETENTION	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 20mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Urogenital System	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINATION IMPAIRED	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	2	1.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 30mg (N=104)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
TOTAL	TOTAL	70	67.3	19	18.3	20	19.2	10	9.6	23	22.1	85	81.7
	Total Male Subjects *	50	100.0	50	100.0	50	100.0	50	100.0	50	100.0	50	100.0
	Total Male-Specific AEs *	5	10.0	1	2.0	2	4.0	1	2.0	2	4.0	10	20.0
	Total Female Subjects **	54	100.0	54	100.0	54	100.0	54	100.0	54	100.0	54	100.0
	Total Female-Specific AEs **	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	2	3.7
	Total Non Gender-Specific AEs	69	66.3	18	17.3	18	17.3	8	7.7	22	21.2	85	81.7
Body as a Whole	TOTAL	20	19.2	4	3.8	4	3.8	2	1.9	7	6.7	34	32.7
	ABDOMINAL PAIN	2	1.9	0	0.0	1	1.0	0	0.0	0	0.0	3	2.9
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ASTHENIA	9	8.7	2	1.9	1	1.0	1	1.0	1	1.0	14	13.5
	BACK PAIN	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	2	1.9
	CHEST PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CHILLS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	CHILLS AND FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	FLU SYNDROME	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	2	1.9
	HEADACHE	8	7.7	3	2.9	1	1.0	1	1.0	2	1.9	15	14.4
	HERNIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INFECTION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	MONILIASIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK RIGIDITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SURGICAL PROCEDURE	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9	2	1.9
Cardiovascular System	TOTAL	7	6.7	1	1.0	0	0.0	2	1.9	2	1.9	11	10.6
	ANGINA PECTORIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BRADYCARDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	HYPERTENSION	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	MYOCARDIAL ISCHEMIA	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	2	1.9
	PALPITATION	2	1.9	1	1.0	0	0.0	1	1.0	0	0.0	4	3.8
	PERIPHERAL VASCULAR DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	POSTURAL HYPOTENSION	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	SYNCOPE	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	TACHYCARDIA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 30mg (N=104)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Cardiovascular System	VASCULAR HEADACHE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VASODILATATION	3	2.9	0	0.0	0	0.0	0	0.0	1	1.0	4	3.8
	VENTRICULAR EXTRASYSTOLES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Digestive System	TOTAL	46	44.2	7	6.7	7	6.7	1	1.0	9	8.7	56	53.8
	BRUXISM	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	2	1.9
	BUCCAL CAVITY DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONSTIPATION	5	4.8	1	1.0	2	1.9	0	0.0	2	1.9	10	9.6
	DECREASED APPETITE	4	3.8	0	0.0	0	0.0	0	0.0	0	0.0	4	3.8
	DIARRHEA	6	5.8	2	1.9	0	0.0	0	0.0	0	0.0	8	7.7
	DRY MOUTH	10	9.6	2	1.9	2	1.9	1	1.0	1	1.0	16	15.4
	DYSPEPSIA	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	DYSPHAGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ERUCTATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FLATULENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	GASTROINTESTINAL FLU	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	INCREASED APPETITE	2	1.9	0	0.0	0	0.0	0	0.0	2	1.9	4	3.8
	MELENA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MOUTH ULCERATION	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	NAUSEA	31	29.8	3	2.9	0	0.0	0	0.0	1	1.0	35	33.7
	NAUSEA AND VOMITING	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	NAUSEA VOMITING AND DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	OROPHARYNX DISORDER	2	1.9	1	1.0	0	0.0	0	0.0	0	0.0	3	2.9
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9	2	1.9
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
Hemic and Lymphatic System	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	GOUT	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PERIPHERAL EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	WEIGHT LOSS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 30mg (N=104)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Musculoskeletal System	TOTAL	2	1.9	1	1.0	0	0.0	0	0.0	0	0.0	3	2.9
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MYALGIA	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	2	1.9
	MYASTHENIA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	MYOPATHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TRAUMATIC FRACTURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	40	38.5	7	6.7	5	4.8	3	2.9	4	3.8	53	51.0
	ABNORMAL DREAMS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	AGITATION	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	2	1.9
	ALCOHOL ABUSE	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	ANXIETY	5	4.8	1	1.0	0	0.0	0	0.0	0	0.0	6	5.8
	CNS STIMULATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONCENTRATION IMPAIRED	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	CONFUSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DEPERSONALIZATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	DIZZINESS	7	6.7	0	0.0	1	1.0	0	0.0	1	1.0	9	8.7
	DRUGGED FEELING	4	3.8	0	0.0	0	0.0	0	0.0	0	0.0	4	3.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	INCOORDINATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INSOMNIA	9	8.7	0	0.0	1	1.0	1	1.0	0	0.0	11	10.6
	LIBIDO DECREASED	1	1.0	1	1.0	1	1.0	0	0.0	0	0.0	3	2.9
	MYOCLONUS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	NERVOUSNESS	4	3.8	0	0.0	0	0.0	0	0.0	0	0.0	4	3.8
	PARESTHESIA	5	4.8	0	0.0	0	0.0	0	0.0	0	0.0	5	4.8
	SOMNOLENCE	14	13.5	4	3.8	1	1.0	0	0.0	2	1.9	21	20.2
	TREMOR	5	4.8	1	1.0	2	1.9	0	0.0	0	0.0	8	7.7
	VERTIGO	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
Respiratory System	TOTAL	5	4.8	2	1.9	3	2.9	1	1.0	4	3.8	15	14.4
	BRONCHITIS	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DYSPNEA	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	RESPIRATORY DISORDER	0	0.0	2	1.9	2	1.9	0	0.0	2	1.9	6	5.8
	RESPIRATORY FLU	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 30mg (N=104)

Body System	Preferred Term	Days 1-7 n	%	Days 8-14 n	%	Days 15-21 n	%	Days 22-28 n	%	Days >28 n	%	Total n	%
Respiratory System	RHINITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	YAWN	3	2.9	0	0.0	1	1.0	0	0.0	0	0.0	4	3.8
Skin and Appendages	TOTAL	5	4.8	0	0.0	3	2.9	0	0.0	3	2.9	11	10.6
	ACNE	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	DERMATOSES, GENERAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	HAIR DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SKIN DISCOLORATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SWEATING	5	4.8	0	0.0	3	2.9	0	0.0	1	1.0	9	8.7
	URTICARIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
Special Senses	TOTAL	3	2.9	0	0.0	3	2.9	2	1.9	2	1.9	8	7.7
	BLURRED VISION	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	2	1.9
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	EYE DISORDER	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9	2	1.9
	PUPILLARY DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TASTE PERVERSION	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	TINNITUS	2	1.9	0	0.0	0	0.0	1	1.0	0	0.0	3	2.9
	VISION DISORDERS	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
Urogenital System	TOTAL	7	6.7	1	1.0	3	2.9	2	1.9	3	2.9	15	14.4
	ABNORMAL EJACULATION *	2	4.0	1	2.0	1	2.0	0	0.0	1	2.0	5	10.0
	BREAST PAIN **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CYSTITIS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	DYSMENORRHEA **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS **	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	IMPOTENCE *	2	4.0	0	0.0	1	2.0	0	0.0	0	0.0	3	6.0
	KIDNEY CALCULUS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0
	MALE GENITAL DISORDERS *	1	2.0	0	0.0	0	0.0	1	2.0	1	2.0	3	6.0
	MASTITIS **	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9
	NOCTURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	URINARY RETENTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 30mg (N=104)

Body System	Preferred Term	Days 1-7 n	%	Days 8-14 n	%	Days 15-21 n	%	Days 22-28 n	%	Days >28 n	%	Total n	%
Urogenital System	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 40mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
TOTAL	TOTAL	72	67.9	22	20.8	13	12.3	13	12.3	31	29.2	89	84.0
	Total Male Subjects *	55	100.0	55	100.0	55	100.0	55	100.0	55	100.0	55	100.0
	Total Male-Specific AEs *	6	10.9	3	5.5	0	0.0	0	0.0	1	1.8	10	18.2
	Total Female Subjects **	51	100.0	51	100.0	51	100.0	51	100.0	51	100.0	51	100.0
	Total Female-Specific AEs **	0	0.0	1	2.0	0	0.0	1	2.0	0	0.0	2	3.9
	Total Non Gender-Specific AEs	72	67.9	20	18.9	13	12.3	12	11.3	30	28.3	88	83.0
Body as a Whole	TOTAL	25	23.6	4	3.8	1	0.9	1	0.9	10	9.4	37	34.9
	ABDOMINAL PAIN	5	4.7	0	0.0	0	0.0	0	0.0	0	0.0	5	4.7
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ASTHENIA	10	9.4	2	1.9	0	0.0	0	0.0	1	0.9	13	12.3
	BACK PAIN	2	1.9	0	0.0	0	0.0	0	0.0	1	0.9	3	2.8
	CHEST PAIN	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	CHILLS	2	1.9	1	0.9	1	0.9	0	0.0	0	0.0	4	3.8
	CHILLS AND FEVER	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	FEVER	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	FLU SYNDROME	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	HEADACHE	10	9.4	1	0.9	0	0.0	1	0.9	6	5.7	18	17.0
	HERNIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	MONILIASIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK RIGIDITY	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	PAIN	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	2	1.9
	SURGICAL PROCEDURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Cardiovascular System	TOTAL	4	3.8	1	0.9	0	0.0	0	0.0	4	3.8	9	8.5
	ANGINA PECTORIS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	BRADYCARDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	HYPERTENSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MYOCARDIAL ISCHEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PALPITATION	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	PERIPHERAL VASCULAR DISORDER	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	POSTURAL HYPOTENSION	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TACHYCARDIA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 40mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Cardiovascular System	VASCULAR HEADACHE	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	VASODILATATION	2	1.9	0	0.0	0	0.0	0	0.0	1	0.9	3	2.8
	VENTRICULAR EXTRASYSTOLES	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
Digestive System	TOTAL	52	49.1	4	3.8	6	5.7	5	4.7	9	8.5	67	63.2
	BRUXISM	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BUCCAL CAVITY DISORDERS	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	2	1.9
	CONSTIPATION	4	3.8	3	2.8	4	3.8	0	0.0	2	1.9	13	12.3
	DECREASED APPETITE	4	3.8	0	0.0	0	0.0	0	0.0	1	0.9	5	4.7
	DIARRHEA	13	12.3	0	0.0	0	0.0	0	0.0	2	1.9	15	14.2
	DRY MOUTH	17	16.0	0	0.0	2	1.9	0	0.0	2	1.9	21	19.8
	DYSPEPSIA	1	0.9	2	1.9	0	0.0	3	2.8	0	0.0	6	5.7
	DYSPHAGIA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	ERUCTATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FLATULENCE	2	1.9	1	0.9	0	0.0	0	0.0	0	0.0	3	2.8
	GASTROINTESTINAL FLU	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INCREASED APPETITE	1	0.9	0	0.0	0	0.0	0	0.0	2	1.9	3	2.8
	MELENA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	MOUTH ULCERATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NAUSEA	36	34.0	0	0.0	0	0.0	1	0.9	0	0.0	37	34.9
	NAUSEA AND VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NAUSEA VOMITING AND DIARRHEA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	OROPHARYNX DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
Metabolic and Nutritional Disorders	TOTAL	1	0.9	1	0.9	2	1.9	0	0.0	3	2.8	7	6.6
	EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	GOUT	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	PERIPHERAL EDEMA	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	2	1.9
	THIRST	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	WEIGHT GAIN	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	2	1.9
	WEIGHT LOSS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 40mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Musculoskeletal System	TOTAL	3	2.8	0	0.0	1	0.9	0	0.0	0	0.0	4	3.8
	ARTHRALGIA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MYASTHENIA	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	MYOPATHY	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	2	1.9
	TRAUMATIC FRACTURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	45	42.5	11	10.4	6	5.7	4	3.8	8	7.5	57	53.8
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	AGITATION	3	2.8	1	0.9	0	0.0	0	0.0	0	0.0	4	3.8
	ALCOHOL ABUSE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ANXIETY	5	4.7	1	0.9	0	0.0	0	0.0	0	0.0	6	5.7
	CNS STIMULATION	3	2.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.8
	CONCENTRATION IMPAIRED	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	CONFUSION	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	DEPERSONALIZATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DIZZINESS	8	7.5	0	0.0	2	1.9	0	0.0	3	2.8	13	12.3
	DRUGGED FEELING	5	4.7	1	0.9	0	0.0	0	0.0	0	0.0	6	5.7
	EMOTIONAL LABILITY	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	INCOORDINATION	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	INSOMNIA	7	6.6	3	2.8	2	1.9	0	0.0	0	0.0	12	11.3
	LIBIDO DECREASED	3	2.8	1	0.9	1	0.9	0	0.0	0	0.0	5	4.7
	MYOCLONUS	2	1.9	0	0.0	0	0.0	2	1.9	1	0.9	5	4.7
	NERVOUSNESS	2	1.9	1	0.9	0	0.0	0	0.0	0	0.0	3	2.8
	PARESTHESIA	6	5.7	0	0.0	0	0.0	0	0.0	0	0.0	6	5.7
	SOMNOLENCE	17	16.0	3	2.8	0	0.0	1	0.9	1	0.9	22	20.8
	TREMOR	10	9.4	1	0.9	1	0.9	2	1.9	1	0.9	15	14.2
	VERTIGO	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
Respiratory System	TOTAL	5	4.7	3	2.8	1	0.9	2	1.9	6	5.7	16	15.1
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	COUGH INCREASED	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PHARYNGITIS	0	0.0	0	0.0	1	0.9	0	0.0	2	1.9	3	2.8
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	RESPIRATORY DISORDER	1	0.9	2	1.9	0	0.0	2	1.9	4	3.8	9	8.5
	RESPIRATORY FLU	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 40mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Respiratory System	RHINITIS	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	2	1.9
	YAWN	4	3.8	1	0.9	0	0.0	0	0.0	0	0.0	5	4.7
Skin and Appendages	TOTAL	8	7.5	2	1.9	1	0.9	0	0.0	2	1.9	12	11.3
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DERMATOSES, GENERAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	HAIR DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9
	SKIN DISCOLORATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SWEATING	8	7.5	2	1.9	1	0.9	0	0.0	1	0.9	12	11.3
	URTICARIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Special Senses	TOTAL	8	7.5	1	0.9	0	0.0	0	0.0	1	0.9	10	9.4
	BLURRED VISION	6	5.7	1	0.9	0	0.0	0	0.0	1	0.9	8	7.5
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	EYE DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PUPILLARY DISORDER	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	TASTE PERVERSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TINNITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VISION DISORDERS	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
Urogenital System	TOTAL	8	7.5	5	4.7	0	0.0	1	0.9	3	2.8	17	16.0
	ABNORMAL EJACULATION *	4	7.3	3	5.5	0	0.0	0	0.0	0	0.0	7	12.7
	BREAST PAIN **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DYSMENORRHEA **	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	FEMALE GENITAL DISORDERS **	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	IMPOTENCE *	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	KIDNEY CALCULUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MALE GENITAL DISORDERS *	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8	2	3.6
	MASTITIS **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NOCTURIA	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	URINARY FREQUENCY	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	2	1.9
	URINARY RETENTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Paroxetine 40mg (N=106)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Urogenital System	URINARY TRACT INFECTION	1	0.9	0	0.0	0	0.0	0	0.0	2	1.9	3	2.8
	URINATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Placebo (N=53)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
TOTAL	TOTAL	13	24.5	10	18.9	8	15.1	5	9.4	11	20.8	31	58.5
	Total Male Subjects *	24	100.0	24	100.0	24	100.0	24	100.0	24	100.0	24	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	29	100.0	29	100.0	29	100.0	29	100.0	29	100.0	29	100.0
	Total Female-Specific AEs **	1	3.4	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4
	Total Non Gender-Specific AEs	12	22.6	10	18.9	8	15.1	5	9.4	11	20.8	31	58.5
Body as a Whole	TOTAL	4	7.5	1	1.9	2	3.8	1	1.9	3	5.7	10	18.9
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ASTHENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BACK PAIN	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	CHEST PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9
	CHILLS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9
	CHILLS AND FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FLU SYNDROME	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	HEADACHE	3	5.7	0	0.0	2	3.8	0	0.0	0	0.0	5	9.4
	HERNIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9
	MONILIASIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NECK RIGIDITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SURGICAL PROCEDURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TRAUMA	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9	2	3.8
Cardiovascular System	TOTAL	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	2	3.8
	ANGINA PECTORIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BRADYCARDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	HYPERTENSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MYOCARDIAL ISCHEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PALPITATION	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	2	3.8
	PERIPHERAL VASCULAR DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	POSTURAL HYPOTENSION	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TACHYCARDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Placebo (N=53)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Cardiovascular System	VASCULAR HEADACHE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VASODILATATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VENTRICULAR EXTRASYSTOLES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Digestive System	TOTAL	9	17.0	3	5.7	1	1.9	3	5.7	2	3.8	16	30.2
	BRUXISM	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BUCCAL CAVITY DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONSTIPATION	3	5.7	0	0.0	0	0.0	0	0.0	0	0.0	3	5.7
	DECREASED APPETITE	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	DIARRHEA	1	1.9	2	3.8	0	0.0	0	0.0	1	1.9	4	7.5
	DRY MOUTH	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	DYSPEPSIA	2	3.8	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	DYSPHAGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ERUCTATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	FLATULENCE	2	3.8	0	0.0	0	0.0	1	1.9	0	0.0	3	5.7
	GASTROINTESTINAL FLU	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INCREASED APPETITE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MELENA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MOUTH ULCERATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NAUSEA	2	3.8	1	1.9	0	0.0	2	3.8	2	3.8	7	13.2
	NAUSEA AND VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NAUSEA VOMITING AND DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	OROPHARYNX DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8
	EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	GOUT	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PERIPHERAL EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	THIRST	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	WEIGHT LOSS	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Placebo (N=53)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Musculoskeletal System	TOTAL	0	0.0	0	0.0	0	0.0	1	1.9	2	3.8	3	5.7
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9
	MYALGIA	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	2	3.8
	MYASTHENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MYOPATHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TRAUMATIC FRACTURE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	3.8	5	9.4	4	7.5	0	0.0	1	1.9	11	20.8
	ABNORMAL DREAMS	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ALCOHOL ABUSE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CNS STIMULATION	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DEPERSONALIZATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DIZZINESS	2	3.8	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	DRUGGED FEELING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INCOORDINATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	INSOMNIA	0	0.0	3	5.7	1	1.9	0	0.0	1	1.9	5	9.4
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MYOCLONUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PARESTHESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	SOMNOLENCE	0	0.0	2	3.8	2	3.8	0	0.0	0	0.0	4	7.5
	TREMOR	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VERTIGO	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Respiratory System	TOTAL	1	1.9	1	1.9	0	0.0	1	1.9	5	9.4	7	13.2
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	COUGH INCREASED	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	1	1.9	3	5.7	4	7.5
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	RESPIRATORY DISORDER	1	1.9	1	1.9	0	0.0	1	1.9	2	3.8	5	9.4
	RESPIRATORY FLU	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Placebo (N=53)

Body System	Preferred Term	Days 1-7 n	%	Days 8-14 n	%	Days 15-21 n	%	Days 22-28 n	%	Days >28 n	%	Total n	%
Respiratory System	RHINITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	YAWN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	1	1.9	2	3.8	0	0.0	1	1.9	4	7.5
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	DERMATOSES, GENERAL	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	HAIR DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9
	SKIN DISCOLORATION	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	SWEATING	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9
	URTICARIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Special Senses	TOTAL	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9
	BLURRED VISION	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	EYE DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	PUPILLARY DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TASTE PERVERSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	TINNITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VISION DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Urogenital System	TOTAL	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8
	ABNORMAL EJACULATION *	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	BREAST PAIN **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	CYSTITIS	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	DYSMENORRHEA **	1	3.4	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4
	FEMALE GENITAL DISORDERS **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	IMPOTENCE *	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	KIDNEY CALCULUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MALE GENITAL DISORDERS *	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	MASTITIS **	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	NOCTURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINARY FREQUENCY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINARY RETENTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.41
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term
and by time of first occurrence from first dose of Medication
Study 009
Randomised Phase

Treatment Group : Placebo (N=53)

Body System	Preferred Term	Days 1-7 n	Days 1-7 %	Days 8-14 n	Days 8-14 %	Days 15-21 n	Days 15-21 %	Days 22-28 n	Days 22-28 %	Days >28 n	Days >28 %	Total n	Total %
Urogenital System	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	URINATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 5 mg

Body System	Preferred Term	Paroxetine (N=11) n	%	Placebo (N=9) n	%
TOTAL	TOTAL	5	45.5	2	22.2
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	11	100.0	9	100.0
	Total Female-Specific AEs **	1	9.1	0	0.0
	Total Non Gender-Specific AEs	4	36.4	2	22.2
Body as a Whole	TOTAL	3	27.3	1	11.1
	ALLERGIC REACTION	1	9.1	0	0.0
	HEADACHE	1	9.1	1	11.1
	INFECTION	1	9.1	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	11.1
	MIGRAINE	0	0.0	1	11.1
Respiratory System	TOTAL	2	18.2	1	11.1
	BRONCHITIS	0	0.0	1	11.1
	COUGH INCREASED	1	9.1	0	0.0
	RESPIRATORY DISORDER	1	9.1	0	0.0
Urogenital System	TOTAL	1	9.1	0	0.0
	METRORRHAGIA **	1	9.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
TOTAL	TOTAL	586	75.6	528	71.6
	Total Male Subjects *	183	100.0	149	100.0
	Total Male-Specific AEs *	17	9.3	4	2.7
	Total Female Subjects **	592	100.0	588	100.0
	Total Female-Specific AEs **	92	15.5	64	10.9
	Total Non Gender-Specific AEs	575	74.2	519	70.4
Body as a Whole	TOTAL	329	42.5	283	38.4
	ABDOMINAL PAIN	31	4.0	28	3.8
	ABNORMAL LABORATORY VALUE	4	0.5	4	0.5
	ALLERGIC REACTION	9	1.2	9	1.2
	ASTHENIA	85	11.0	39	5.3
	BACK PAIN	33	4.3	28	3.8
	CELLULITIS	0	0.0	2	0.3
	CHEST PAIN	9	1.2	10	1.4
	CHILLS	3	0.4	2	0.3
	FACE EDEMA	2	0.3	0	0.0
	FEVER	4	0.5	6	0.8
	FLU SYNDROME	4	0.5	4	0.5
	HEADACHE	168	21.7	175	23.7
	INFECTION	55	7.1	51	6.9
	MALAISE	2	0.3	0	0.0
	MONILIASIS	3	0.4	1	0.1
	NECK PAIN	1	0.1	0	0.0
	NEOPLASM	1	0.1	0	0.0
	PAIN	6	0.8	16	2.2
	TRAUMA	37	4.8	26	3.5
Cardiovascular System	TOTAL	59	7.6	46	6.2
	ANGINA PECTORIS	2	0.3	1	0.1
	BRADYCARDIA	1	0.1	0	0.0
	CARDIOVASCULAR DISORDER	0	0.0	1	0.1
	CEREBROVASCULAR DISORDER	0	0.0	2	0.3
	ELECTROCARDIOGRAM ABNORMAL	1	0.1	3	0.4
	HAEMATOMA	3	0.4	0	0.0
	HYPERTENSION	8	1.0	5	0.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
Cardiovascular System	HYPOTENSION	1	0.1	2	0.3
	MIGRAINE	14	1.8	8	1.1
	MYOCARDIAL INFARCT	0	0.0	1	0.1
	PALPITATION	9	1.2	15	2.0
	PERIPHERAL VASCULAR DISORDER	1	0.1	0	0.0
	POSTURAL HYPOTENSION	2	0.3	3	0.4
	SYNCOPE	3	0.4	1	0.1
	TACHYCARDIA	7	0.9	1	0.1
	VASCULAR ANOMALY	0	0.0	1	0.1
	VASODILATATION	10	1.3	6	0.8
Digestive System	TOTAL	279	36.0	216	29.3
	BRUXISM	7	0.9	0	0.0
	COLITIS	1	0.1	0	0.0
	CONSTIPATION	38	4.9	24	3.3
	DECREASED APPETITE	20	2.6	7	0.9
	DIARRHEA	76	9.8	37	5.0
	DRY MOUTH	57	7.4	41	5.6
	DYSPEPSIA	32	4.1	34	4.6
	DYSPHAGIA	1	0.1	1	0.1
	ERUCTATION	5	0.6	1	0.1
	ESOPHAGITIS	1	0.1	1	0.1
	FECAL INCONTINENCE	0	0.0	1	0.1
	FLATULENCE	18	2.3	18	2.4
	GASTRITIS	2	0.3	4	0.5
	GASTROENTERITIS	5	0.6	5	0.7
	GASTROINTESTINAL DISORDER	1	0.1	4	0.5
	GASTROINTESTINAL HEMORRHAGE	1	0.1	0	0.0
	GINGIVITIS	5	0.6	6	0.8
	HEMATEMESIS	0	0.0	1	0.1
	INCREASED APPETITE	12	1.5	9	1.2
	LIVER FUNCTION TESTS ABNORMAL	1	0.1	1	0.1
	MELENA	0	0.0	3	0.4
	NAUSEA	107	13.8	74	10.0
	OROPHARYNX DISORDER	2	0.3	0	0.0
	PEPTIC ULCER	0	0.0	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
Digestive System	RECTAL DISORDER	1	0.1	0	0.0
	RECTAL HEMORRHAGE	1	0.1	0	0.0
	STOMATITIS	1	0.1	0	0.0
	TONGUE DISCOLORATION	1	0.1	0	0.0
	TOOTH CARIES	1	0.1	1	0.1
	TOOTH DISORDER	8	1.0	12	1.6
	ULCERATIVE STOMATITIS	2	0.3	0	0.0
	VOMITING	7	0.9	15	2.0
Endocrine System	TOTAL	3	0.4	3	0.4
	DIABETES MELLITUS	1	0.1	1	0.1
	FERTILITY DECREASED FEMALE **	1	0.2	0	0.0
	GOITER	0	0.0	1	0.1
	THYROID DISORDER	1	0.1	1	0.1
Hemic and Lymphatic System	TOTAL	14	1.8	13	1.8
	ANEMIA	5	0.6	7	0.9
	HYPOCHROMIC ANEMIA	1	0.1	1	0.1
	LEUKOCYTOSIS	2	0.3	0	0.0
	LEUKOPENIA	0	0.0	2	0.3
	LYMPHADENOPATHY	1	0.1	0	0.0
	PURPURA	6	0.8	3	0.4
	THROMBOCYTOPENIA	0	0.0	1	0.1
Metabolic and Nutritional Disorders	TOTAL	28	3.6	32	4.3
	EDEMA	1	0.1	0	0.0
	GENERALIZED EDEMA	1	0.1	1	0.1
	PERIPHERAL EDEMA	6	0.8	5	0.7
	THIRST	2	0.3	4	0.5
	WEIGHT GAIN	17	2.2	17	2.3
	WEIGHT LOSS	2	0.3	6	0.8
Musculoskeletal System	TOTAL	43	5.5	41	5.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
Musculoskeletal System	ARTHRALGIA	17	2.2	17	2.3
	ARTHRITIS	3	0.4	2	0.3
	ARTHROSIS	3	0.4	1	0.1
	BONE DISORDER	1	0.1	0	0.0
	BURSITIS	1	0.1	0	0.0
	MYALGIA	20	2.6	22	3.0
	MYASTHENIA	3	0.4	0	0.0
	MYOSITIS	0	0.0	2	0.3
	TENDINOUS DISORDER	0	0.0	2	0.3
Nervous System	TOTAL	287	37.0	192	26.1
	ABNORMAL DREAMS	12	1.5	10	1.4
	AGITATION	6	0.8	14	1.9
	ALCOHOL ABUSE	1	0.1	0	0.0
	AMNESIA	0	0.0	2	0.3
	ANXIETY	13	1.7	10	1.4
	ATAXIA	0	0.0	3	0.4
	CNS STIMULATION	2	0.3	1	0.1
	CONCENTRATION IMPAIRED	10	1.3	7	0.9
	CONFUSION	3	0.4	0	0.0
	CONVULSION	1	0.1	0	0.0
	DEPERSONALIZATION	4	0.5	4	0.5
	DEPRESSION	5	0.6	13	1.8
	DIPLOPIA	0	0.0	1	0.1
	DIZZINESS	50	6.5	40	5.4
	DYSTONIA	2	0.3	1	0.1
	EMOTIONAL LABILITY	5	0.6	4	0.5
	HALLUCINATIONS	1	0.1	0	0.0
	HYPERKINESIA	3	0.4	4	0.5
	HYPERTONIA	5	0.6	9	1.2
	HYPESTHESIA	2	0.3	5	0.7
	HYPOKINESIA	1	0.1	0	0.0
	INCOORDINATION	1	0.1	0	0.0
	INSOMNIA	83	10.7	48	6.5
	LACK OF EMOTION	8	1.0	6	0.8
	LIBIDO DECREASED	59	7.6	29	3.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
Nervous System	LIBIDO INCREASED	4	0.5	1	0.1
	MANIC REACTION	1	0.1	1	0.1
	MYOCLONUS	1	0.1	2	0.3
	NERVOUSNESS	29	3.7	32	4.3
	NEUROPATHY	0	0.0	2	0.3
	NEUROSIS	0	0.0	1	0.1
	NEUROVASCULAR COMPRESSION	1	0.1	1	0.1
	NYSTAGMUS	0	0.0	1	0.1
	PARALYSIS	0	0.0	1	0.1
	PARESTHESIA	11	1.4	7	0.9
	SOMNOLENCE	74	9.5	43	5.8
	SPEECH DISORDER	0	0.0	1	0.1
	THINKING ABNORMAL	2	0.3	2	0.3
	TREMOR	12	1.5	4	0.5
	VERTIGO	3	0.4	4	0.5
Respiratory System	TOTAL	173	22.3	168	22.8
	ASTHMA	1	0.1	0	0.0
	BRONCHITIS	9	1.2	12	1.6
	COUGH INCREASED	15	1.9	13	1.8
	DYSPNEA	9	1.2	8	1.1
	EPISTAXIS	0	0.0	3	0.4
	HEMOPTYSIS	1	0.1	1	0.1
	HICCUP	1	0.1	0	0.0
	HYPERVENTILATION	1	0.1	0	0.0
	LARYNX DISORDER	2	0.3	1	0.1
	PHARYNGITIS	20	2.6	26	3.5
	PLEURA DISORDER	0	0.0	1	0.1
	PNEUMONIA	4	0.5	3	0.4
	RESPIRATORY DISORDER	82	10.6	78	10.6
	RESPIRATORY FLU	1	0.1	0	0.0
	RHINITIS	18	2.3	16	2.2
	SINUSITIS	45	5.8	42	5.7
	VOICE ALTERATION	1	0.1	0	0.0
	YAWN	9	1.2	3	0.4
Skin and Appendages	TOTAL	62	8.0	53	7.2

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
Skin and Appendages	ACNE	4	0.5	4	0.5
	ALOPECIA	1	0.1	2	0.3
	CONTACT DERMATITIS	0	0.0	2	0.3
	DERMATOSES, GENERAL	0	0.0	1	0.1
	DRY SKIN	2	0.3	4	0.5
	ECZEMA	1	0.1	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	0.1
	HAIR DISORDERS	0	0.0	1	0.1
	HERPES SIMPLEX	0	0.0	4	0.5
	MACULOPAPULAR RASH	0	0.0	2	0.3
	MELANOSIS	0	0.0	1	0.1
	NAIL DISORDER	0	0.0	1	0.1
	PHOTOSENSITIVITY	0	0.0	1	0.1
	PRURITUS	12	1.5	8	1.1
	PUSTULAR RASH	1	0.1	0	0.0
	RASH	7	0.9	10	1.4
	SEBORRHEA	0	0.0	1	0.1
	SKIN BENIGN NEOPLASM	1	0.1	1	0.1
	SKIN DISCOLORATION	0	0.0	1	0.1
	SKIN DISORDER	0	0.0	1	0.1
	SKIN HYPERTROPHY	2	0.3	2	0.3
	SKIN ULCER	0	0.0	1	0.1
	SWEAT GLAND DISORDER	1	0.1	0	0.0
	SWEATING	35	4.5	9	1.2
	URTICARIA	4	0.5	1	0.1
Special Senses	TOTAL	35	4.5	21	2.8
	ABNORMAL VISION	9	1.2	6	0.8
	BLINDNESS	0	0.0	1	0.1
	BLURRED VISION	3	0.4	1	0.1
	CONJUNCTIVITIS	2	0.3	3	0.4
	EAR DISORDER	1	0.1	0	0.0
	EAR PAIN	0	0.0	2	0.3
	EYE APPENDAGE DISORDER	1	0.1	0	0.0
	EYE DISORDER	2	0.3	1	0.1
	EYE HEMORRHAGE	0	0.0	1	0.1
	EYE PAIN	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
Special Senses	KERATOCONJUNCTIVITIS	1	0.1	1	0.1
	OTITIS MEDIA	11	1.4	0	0.0
	PHOTOPHOBIA	1	0.1	1	0.1
	TASTE PERVERSION	1	0.1	2	0.3
	TINNITUS	3	0.4	4	0.5
	VISION DISORDERS	1	0.1	0	0.0
	VISUAL FIELD DEFECT	0	0.0	1	0.1
Urogenital System	TOTAL	128	16.5	93	12.6
	ABNORMAL EJACULATION *	13	7.1	3	2.0
	ABORTION **	0	0.0	1	0.2
	AMENORRHEA **	0	0.0	1	0.2
	BREAST ENLARGEMENT **	2	0.3	0	0.0
	BREAST NEOPLASM **	2	0.3	0	0.0
	BREAST PAIN **	4	0.7	1	0.2
	CYSTITIS	6	0.8	7	0.9
	DYSMENORRHEA **	34	5.7	36	6.1
	DYSURIA	0	0.0	1	0.1
	ENDOMETRIAL DISORDER **	1	0.2	1	0.2
	FEMALE GENITAL DISORDERS **	28	4.7	6	1.0
	FEMALE LACTATION **	1	0.2	0	0.0
	GLYCOSURIA	1	0.1	0	0.0
	HAEMATURIA	3	0.4	2	0.3
	IMPOTENCE *	3	1.6	0	0.0
	KIDNEY CALCULUS	1	0.1	3	0.4
	MALE GENITAL DISORDERS *	2	1.1	0	0.0
	MASTITIS **	0	0.0	1	0.2
	MENORRHAGIA **	6	1.0	4	0.7
	MENSTRUAL DISORDER **	10	1.7	7	1.2
	NEPHRITIS	1	0.1	1	0.1
	PAPANICOLAU SMEAR SUSPICIOUS **	0	0.0	2	0.3
	PENIS DISORDER *	0	0.0	1	0.7
	POLYURIA	1	0.1	0	0.0
	PROSTATE DISORDER *	1	0.5	0	0.0
	UNINTENDED PREGNANCY **	2	0.3	1	0.2
	URINARY FREQUENCY	8	1.0	6	0.8
	URINARY RETENTION	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Body System	Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
Urogenital System	URINARY TRACT INFECTION	9	1.2	15	2.0
	URINATION IMPAIRED	2	0.3	0	0.0
	VAGINAL MONILIASIS **	7	1.2	10	1.7
	VAGINITIS **	4	0.7	2	0.3

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
TOTAL	TOTAL	1174	83.6	987	74.5
	Total Male Subjects *	439	100.0	411	100.0
	Total Male-Specific AEs *	94	21.4	13	3.2
	Total Female Subjects **	966	100.0	913	100.0
	Total Female-Specific AEs **	136	14.1	96	10.5
	Total Non Gender-Specific AEs	1163	82.8	975	73.6
Body as a Whole	TOTAL	662	47.1	541	40.9
	ABDOMINAL PAIN	71	5.1	48	3.6
	ABNORMAL LABORATORY VALUE	4	0.3	4	0.3
	ABSCESS	2	0.1	0	0.0
	ALLERGIC REACTION	14	1.0	22	1.7
	ANAPHYLACTOID REACTION	1	0.1	0	0.0
	ASTHENIA	210	14.9	71	5.4
	BACK PAIN	50	3.6	59	4.5
	CELLULITIS	0	0.0	3	0.2
	CHEST PAIN	19	1.4	17	1.3
	CHILLS	5	0.4	3	0.2
	FEVER	16	1.1	12	0.9
	FLU SYNDROME	13	0.9	7	0.5
	HEADACHE	322	22.9	330	24.9
	HYPOTHERMIA	1	0.1	0	0.0
	INFECTION	85	6.0	77	5.8
	INTENTIONAL OVERDOSE	4	0.3	2	0.2
	MALAISE	5	0.4	1	0.1
	MONILIASIS	2	0.1	1	0.1
	NECK RIGIDITY	0	0.0	1	0.1
	NEOPLASM	2	0.1	1	0.1
	PAIN	26	1.9	35	2.6
	SURGICAL PROCEDURE	3	0.2	0	0.0
	TRAUMA	68	4.8	57	4.3
Cardiovascular System	TOTAL	102	7.3	81	6.1
	ANGINA PECTORIS	0	0.0	1	0.1
	ARRHYTHMIA	2	0.1	1	0.1
	AV BLOCK	1	0.1	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Cardiovascular System	BRADYCARDIA	1	0.1	0	0.0
	CARDIOVASCULAR DISORDER	1	0.1	2	0.2
	CEREBROVASCULAR DISORDER	0	0.0	2	0.2
	ELECTROCARDIOGRAM ABNORMAL	2	0.1	3	0.2
	EXTRASYSTOLES	3	0.2	0	0.0
	HYPERTENSION	9	0.6	9	0.7
	HYPOTENSION	4	0.3	3	0.2
	MIGRAINE	19	1.4	20	1.5
	MYOCARDIAL INFARCT	0	0.0	1	0.1
	PALPITATION	22	1.6	23	1.7
	PHLEBITIS	2	0.1	0	0.0
	POSTURAL HYPOTENSION	7	0.5	3	0.2
	SUPRAVENTRICULAR TACHYCARDIA	2	0.1	0	0.0
	SYNCOPE	6	0.4	2	0.2
	TACHYCARDIA	13	0.9	4	0.3
	THROMBOPHLEBITIS	1	0.1	0	0.0
	VASCULAR ANOMALY	0	0.0	1	0.1
	VASODILATATION	22	1.6	10	0.8
Digestive System	TOTAL	689	49.0	416	31.4
	BRUXISM	16	1.1	0	0.0
	CARDIOSPASM	1	0.1	0	0.0
	CHOLECYSTITIS	1	0.1	0	0.0
	COLITIS	0	0.0	2	0.2
	CONSTIPATION	99	7.0	53	4.0
	DECREASED APPETITE	70	5.0	15	1.1
	DIARRHEA	161	11.5	88	6.6
	DIGESTIVE SYSTEM DISORDER	1	0.1	1	0.1
	DRY MOUTH	172	12.2	77	5.8
	DUODENITIS	1	0.1	0	0.0
	DYSPEPSIA	70	5.0	61	4.6
	DYSPHAGIA	11	0.8	1	0.1
	ERUCTATION	2	0.1	2	0.2
	ESOPHAGITIS	0	0.0	2	0.2
	FECAL INCONTINENCE	0	0.0	1	0.1
	FLATULENCE	31	2.2	31	2.3

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Digestive System	GALL BLADDER DISORDER	0	0.0	1	0.1
	GASTRITIS	1	0.1	5	0.4
	GASTROENTERITIS	8	0.6	7	0.5
	GASTROINTESTINAL DISORDER	10	0.7	10	0.8
	GASTROINTESTINAL FLU	1	0.1	0	0.0
	GINGIVITIS	10	0.7	13	1.0
	GLOSSITIS	1	0.1	0	0.0
	HEMATEMESIS	0	0.0	1	0.1
	INCREASED APPETITE	32	2.3	18	1.4
	INCREASED SALIVATION	1	0.1	1	0.1
	LIVER FUNCTION TESTS ABNORMAL	3	0.2	4	0.3
	MELENA	1	0.1	3	0.2
	NAUSEA	295	21.0	117	8.8
	NAUSEA AND VOMITING	1	0.1	1	0.1
	OROPHARYNX DISORDER	4	0.3	0	0.0
	PEPTIC ULCER	0	0.0	1	0.1
	PERIODONTAL ABSCESS	0	0.0	1	0.1
	RECTAL DISORDER	8	0.6	1	0.1
	RECTAL HEMORRHAGE	2	0.1	1	0.1
	STOMACH ULCER	1	0.1	0	0.0
	STOMATITIS	1	0.1	1	0.1
	TOOTH CARIES	1	0.1	3	0.2
	TOOTH DISORDER	17	1.2	24	1.8
	ULCERATIVE STOMATITIS	5	0.4	2	0.2
	VOMITING	32	2.3	30	2.3
Endocrine System	TOTAL	8	0.6	5	0.4
	DIABETES MELLITUS	1	0.1	1	0.1
	FERTILITY DECREASED FEMALE **	1	0.1	0	0.0
	GOITER	0	0.0	1	0.1
	HYPERTHYROIDISM	1	0.1	1	0.1
	HYPOTHYROIDISM	1	0.1	0	0.0
	OVARY DISORDER **	2	0.2	1	0.1
	THYROID DISORDER	2	0.1	1	0.1
Hemic and Lymphatic System	TOTAL	23	1.6	18	1.4

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Hemic and Lymphatic System	ANEMIA	6	0.4	7	0.5
	BLEEDING TIME INCREASED	1	0.1	0	0.0
	EOSINOPHILIA	1	0.1	1	0.1
	HYPOCHROMIC ANEMIA	3	0.2	1	0.1
	LEUKOCYTOSIS	2	0.1	1	0.1
	LEUKOPENIA	3	0.2	3	0.2
	LYMPHADENOPATHY	1	0.1	0	0.0
	LYMPHOMA LIKE REACTION	1	0.1	0	0.0
	MONOCYTOSIS	0	0.0	1	0.1
	PURPURA	6	0.4	5	0.4
	THROMBOCYTHEMIA	0	0.0	1	0.1
	THROMBOCYTOPENIA	0	0.0	1	0.1
Metabolic and Nutritional Disorders	TOTAL	65	4.6	50	3.8
	BILIRUBINEMIA	2	0.1	0	0.0
	EDEMA	2	0.1	1	0.1
	GENERALIZED EDEMA	1	0.1	1	0.1
	HYPERCHOLESTEREMIA	1	0.1	2	0.2
	HYPERGLYCEMIA	2	0.1	1	0.1
	HYPERLIPEMIA	0	0.0	2	0.2
	HYPOGLYCEMIA	1	0.1	0	0.0
	NPN INCREASED	1	0.1	0	0.0
	OBESITY	1	0.1	0	0.0
	PERIPHERAL EDEMA	6	0.4	10	0.8
	SGOT INCREASED	0	0.0	1	0.1
	SGPT INCREASED	2	0.1	2	0.2
	THIRST	7	0.5	5	0.4
	WEIGHT GAIN	32	2.3	22	1.7
	WEIGHT LOSS	10	0.7	6	0.5
Musculoskeletal System	TOTAL	85	6.0	94	7.1
	ARTHRALGIA	31	2.2	34	2.6
	ARTHRITIS	8	0.6	4	0.3

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Musculoskeletal System	ARTHROSIS	5	0.4	6	0.5
	BONE DISORDER	2	0.1	2	0.2
	BONE PAIN	1	0.1	0	0.0
	BURSITIS	1	0.1	2	0.2
	MYALGIA	31	2.2	46	3.5
	MYASTHENIA	6	0.4	1	0.1
	MYOPATHY	2	0.1	0	0.0
	MYOSITIS	0	0.0	2	0.2
	TENDINOUS DISORDER	2	0.1	5	0.4
	TRAUMATIC FRACTURE	1	0.1	0	0.0
Nervous System	TOTAL	712	50.7	398	30.1
	ABNORMAL DREAMS	43	3.1	18	1.4
	ABNORMAL GAIT	2	0.1	0	0.0
	AGITATION	31	2.2	27	2.0
	ALCOHOL ABUSE	2	0.1	2	0.2
	AMNESIA	10	0.7	7	0.5
	ANXIETY	60	4.3	29	2.2
	APHASIA	1	0.1	0	0.0
	ATAXIA	5	0.4	3	0.2
	CNS STIMULATION	0	0.0	1	0.1
	CONCENTRATION IMPAIRED	41	2.9	12	0.9
	CONFUSION	13	0.9	4	0.3
	CONVULSION	1	0.1	0	0.0
	DEPERSONALIZATION	11	0.8	6	0.5
	DEPRESSION	23	1.6	34	2.6
	DIPLOPIA	0	0.0	1	0.1
	DIZZINESS	160	11.4	75	5.7
	DRUG DEPENDENCE	1	0.1	0	0.0
	DRUGGED FEELING	2	0.1	0	0.0
	DYSKINESIA	0	0.0	1	0.1
	DYSTONIA	5	0.4	3	0.2
	EMOTIONAL LABILITY	12	0.9	17	1.3
	EUPHORIA	1	0.1	0	0.0
	HALLUCINATIONS	1	0.1	1	0.1
	HOSTILITY	3	0.2	3	0.2

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** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Nervous System	HYPERKINESIA	15	1.1	5	0.4
	HYPERTONIA	17	1.2	14	1.1
	HYPESTHESIA	9	0.6	5	0.4
	HYPOKINESIA	3	0.2	0	0.0
	INCOORDINATION	3	0.2	0	0.0
	INSOMNIA	179	12.7	108	8.2
	INTRACRANIAL HYPERTENSION	0	0.0	1	0.1
	LACK OF EMOTION	13	0.9	8	0.6
	LIBIDO DECREASED	134	9.5	41	3.1
	LIBIDO INCREASED	3	0.2	1	0.1
	MANIC DEPRESSIVE REACTION	1	0.1	0	0.0
	MANIC REACTION	2	0.1	2	0.2
	MYOCLONUS	19	1.4	7	0.5
	NERVOUSNESS	77	5.5	61	4.6
	NEURALGIA	3	0.2	0	0.0
	NEUROPATHY	1	0.1	2	0.2
	NEUROSIS	2	0.1	2	0.2
	NEUROVASCULAR COMPRESSION	0	0.0	1	0.1
	NYSTAGMUS	2	0.1	1	0.1
	PARALYSIS	2	0.1	2	0.2
	PARANOID REACTION	2	0.1	0	0.0
	PARESTHESIA	23	1.6	18	1.4
	REFLEXES INCREASED	1	0.1	0	0.0
	SOMNOLENCE	224	15.9	84	6.3
	SPEECH DISORDER	0	0.0	2	0.2
	STUPOR	1	0.1	0	0.0
	THINKING ABNORMAL	8	0.6	5	0.4
	TORTICOLLIS	2	0.1	0	0.0
	TREMOR	76	5.4	8	0.6
	VERTIGO	10	0.7	6	0.5
	VESTIBULAR DISORDER	2	0.1	1	0.1
	WITHDRAWAL SYNDROME	1	0.1	0	0.0
Respiratory System	TOTAL	318	22.6	278	21.0
	ASTHMA	4	0.3	2	0.2
	BRONCHITIS	17	1.2	18	1.4
	COUGH INCREASED	18	1.3	21	1.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Respiratory System	DYSPNEA	8	0.6	10	0.8
	EMPHYSEMA	1	0.1	0	0.0
	EPISTAXIS	5	0.4	8	0.6
	HEMOPTYSIS	0	0.0	2	0.2
	HYPERVENTILATION	2	0.1	0	0.0
	LARYNX DISORDER	2	0.1	2	0.2
	PHARYNGITIS	44	3.1	46	3.5
	PLEURA DISORDER	4	0.3	2	0.2
	PNEUMONIA	8	0.6	3	0.2
	PNEUMOTHORAX	0	0.0	1	0.1
	RESPIRATORY DISORDER	132	9.4	126	9.5
	RHINITIS	25	1.8	29	2.2
	SINUSITIS	63	4.5	69	5.2
	YAWN	48	3.4	3	0.2
Skin and Appendages	TOTAL	162	11.5	88	6.6
	ACNE	9	0.6	7	0.5
	ALOPECIA	0	0.0	3	0.2
	CONTACT DERMATITIS	3	0.2	3	0.2
	DERMATOSES, GENERAL	0	0.0	1	0.1
	DRY SKIN	2	0.1	4	0.3
	ECZEMA	7	0.5	0	0.0
	EXFOLIATIVE DERMATITIS	1	0.1	0	0.0
	FUNGAL DERMATITIS	2	0.1	1	0.1
	FURUNCULOSIS	2	0.1	0	0.0
	HAIR DISORDERS	1	0.1	2	0.2
	HERPES SIMPLEX	7	0.5	11	0.8
	HERPES ZOSTER	2	0.1	0	0.0
	HIRSUTISM	0	0.0	1	0.1
	MACULOPAPULAR RASH	1	0.1	2	0.2
	MELANOSIS	0	0.0	1	0.1
	NAIL DISORDER	1	0.1	2	0.2
	PHOTOSENSITIVITY	2	0.1	1	0.1
	PRURITUS	9	0.6	11	0.8
	RASH	14	1.0	23	1.7
	SEBORRHEA	0	0.0	1	0.1
	SKIN BENIGN NEOPLASM	2	0.1	1	0.1

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** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Skin and Appendages	SKIN CARCINOMA	1	0.1	0	0.0
	SKIN DISCOLORATION	1	0.1	1	0.1
	SKIN DISORDER	4	0.3	1	0.1
	SKIN HYPERTROPHY	1	0.1	4	0.3
	SKIN ULCER	0	0.0	1	0.1
	SWEATING	100	7.1	14	1.1
	SWEATING DECREASED	0	0.0	1	0.1
	URTICARIA	4	0.3	2	0.2
	VESICULOBULLOUS RASH	2	0.1	0	0.0
Special Searches	TOTAL	1	0.1	0	0.0
	PUNCTURE SITE REACTION	1	0.1	0	0.0
Special Senses	TOTAL	104	7.4	44	3.3
	ABNORMAL VISION	30	2.1	8	0.6
	ANISOCORIA	1	0.1	0	0.0
	BLEPHARITIS	2	0.1	0	0.0
	BLINDNESS	0	0.0	1	0.1
	BLURRED VISION	3	0.2	2	0.2
	CONJUNCTIVITIS	9	0.6	9	0.7
	DEAFNESS	1	0.1	0	0.0
	EAR DISORDER	4	0.3	1	0.1
	EAR PAIN	10	0.7	2	0.2
	EYE DISORDER	4	0.3	1	0.1
	EYE HEMORRHAGE	0	0.0	2	0.2
	EYE PAIN	3	0.2	1	0.1
	KERATOCONJUNCTIVITIS	7	0.5	1	0.1
	MYDRIASIS	1	0.1	0	0.0
	OTITIS EXTERNA	2	0.1	0	0.0
	OTITIS MEDIA	9	0.6	4	0.3
	PAROSMIA	1	0.1	0	0.0
	PHOTOPHOBIA	0	0.0	1	0.1
	PUPILLARY DISORDER	1	0.1	0	0.0
	TASTE PERVERSION	12	0.9	5	0.4
	TINNITUS	11	0.8	10	0.8
	VISION DISORDERS	4	0.3	0	0.0
	VISUAL FIELD DEFECT	0	0.0	1	0.1

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** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Urogenital System	TOTAL	287	20.4	158	11.9
	ABNORMAL EJACULATION *	69	15.7	8	1.9
	ABORTION **	0	0.0	1	0.1
	ALBUMINURIA	0	0.0	2	0.2
	AMENORRHEA **	2	0.2	2	0.2
	BREAST CARCINOMA **	0	0.0	1	0.1
	BREAST ENLARGEMENT **	0	0.0	1	0.1
	BREAST PAIN **	3	0.3	3	0.3
	CERVICITIS **	1	0.1	0	0.0
	CYSTITIS	2	0.1	9	0.7
	DYSMENORRHEA **	29	3.0	44	4.8
	DYSPARUNIA **	1	0.1	0	0.0
	DYSURIA	7	0.5	4	0.3
	ENDOMETRIAL DISORDER **	2	0.2	1	0.1
	FEMALE GENITAL DISORDERS **	68	7.0	8	0.9
	FIBROCYSTIC BREAST **	1	0.1	0	0.0
	GLYCOSURIA	1	0.1	1	0.1
	HAEMATURIA	1	0.1	7	0.5
	IMPOTENCE *	24	5.5	5	1.2
	KIDNEY CALCULUS	2	0.1	5	0.4
	LEUKORRHEA	1	0.1	0	0.0
	MALE GENITAL DISORDERS *	4	0.9	0	0.0
	MASTITIS **	0	0.0	1	0.1
	MENORRHAGIA **	4	0.4	11	1.2
	MENSTRUAL DISORDER **	16	1.7	14	1.5
	METRORRHAGIA **	4	0.4	3	0.3
	NEPHRITIS	1	0.1	1	0.1
	NOCTURIA	2	0.1	0	0.0
	PAPANICOLAU SMEAR SUSPICIOUS **	0	0.0	3	0.3
	PENIS DISORDER *	0	0.0	1	0.2
	POLYURIA	1	0.1	0	0.0
	PROSTATE DISORDER *	2	0.5	1	0.2
	PYURIA	1	0.1	0	0.0
	SALPINGITIS	1	0.1	0	0.0
	UNINTENDED PREGNANCY **	2	0.2	1	0.1
	URINARY CASTS	1	0.1	0	0.0
	URINARY FREQUENCY	28	2.0	13	1.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Body System	Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
Urogenital System	URINARY RETENTION	2	0.1	1	0.1
	URINARY TRACT DISORDER	1	0.1	0	0.0
	URINARY TRACT INFECTION	22	1.6	21	1.6
	URINATION IMPAIRED	10	0.7	1	0.1
	URINE ABNORMALITY	2	0.1	1	0.1
	UTERINE FIBROIDS ENLARGED **	1	0.1	1	0.1
	UTERINE NEOPLASM	1	0.1	0	0.0
	UTERUS DISORDERS **	1	0.1	0	0.0
	VAGINAL HEMORRHAGE **	4	0.4	1	0.1
	VAGINAL MONILIASIS **	7	0.7	11	1.2
	VAGINITIS **	12	1.2	3	0.3

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 30 mg

Body System	Preferred Term	Paroxetine (N=150) n	%	Placebo (N=101) n	%
TOTAL	TOTAL	124	82.7	59	58.4
	Total Male Subjects *	65	100.0	42	100.0
	Total Male-Specific AEs *	12	18.5	0	0.0
	Total Female Subjects **	85	100.0	59	100.0
	Total Female-Specific AEs **	2	2.4	1	1.7
	Total Non Gender-Specific AEs	124	82.7	59	58.4
Body as a Whole	TOTAL	51	34.0	21	20.8
	ABDOMINAL PAIN	7	4.7	2	2.0
	ASTHENIA	17	11.3	4	4.0
	BACK PAIN	2	1.3	1	1.0
	CHEST PAIN	0	0.0	3	3.0
	CHILLS	4	2.7	1	1.0
	FEVER	1	0.7	0	0.0
	FLU SYNDROME	2	1.3	0	0.0
	HEADACHE	22	14.7	9	8.9
	INFECTION	1	0.7	1	1.0
	MALAISE	2	1.3	0	0.0
	NECK PAIN	1	0.7	0	0.0
	OVERDOSE	0	0.0	1	1.0
	PAIN	0	0.0	1	1.0
	SURGICAL PROCEDURE	1	0.7	0	0.0
	TRAUMA	2	1.3	2	2.0
Cardiovascular System	TOTAL	16	10.7	4	4.0
	HYPERTENSION	1	0.7	0	0.0
	MYOCARDIAL ISCHEMIA	2	1.3	0	0.0
	PALPITATION	5	3.3	3	3.0
	POSTURAL HYPOTENSION	2	1.3	1	1.0
	SYNCOPE	3	2.0	0	0.0
	TACHYCARDIA	3	2.0	0	0.0
	VASODILATATION	5	3.3	1	1.0
Digestive System	TOTAL	81	54.0	31	30.7
	BRUXISM	2	1.3	0	0.0
	CONSTIPATION	15	10.0	3	3.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 30 mg

Body System	Preferred Term	Paroxetine (N=150) n	%	Placebo (N=101) n	%
Digestive System	DECREASED APPETITE	6	4.0	3	3.0
	DIARRHEA	11	7.3	6	5.9
	DRY MOUTH	22	14.7	3	3.0
	DYSPEPSIA	9	6.0	7	6.9
	FLATULENCE	2	1.3	3	3.0
	GASTROINTESTINAL FLU	1	0.7	0	0.0
	GLOSSITIS	1	0.7	0	0.0
	INCREASED APPETITE	4	2.7	0	0.0
	INCREASED SALIVATION	1	0.7	0	0.0
	MOUTH ULCERATION	1	0.7	0	0.0
	NAUSEA	50	33.3	14	13.9
	NAUSEA AND VOMITING	1	0.7	0	0.0
	OROPHARYNX DISORDER	3	2.0	0	0.0
	TOOTH DISORDER	2	1.3	0	0.0
	VOMITING	7	4.7	1	1.0
Metabolic and Nutritional Disorders	TOTAL	2	1.3	2	2.0
	PERIPHERAL EDEMA	1	0.7	0	0.0
	THIRST	0	0.0	1	1.0
	WEIGHT GAIN	1	0.7	0	0.0
	WEIGHT LOSS	1	0.7	1	1.0
Musculoskeletal System	TOTAL	3	2.0	4	4.0
	ARTHRALGIA	0	0.0	1	1.0
	MYALGIA	2	1.3	3	3.0
	MYASTHENIA	1	0.7	0	0.0
Nervous System	TOTAL	79	52.7	26	25.7
	ABNORMAL DREAMS	2	1.3	3	3.0
	AGITATION	3	2.0	0	0.0
	ALCOHOL ABUSE	2	1.3	0	0.0
	AMNESIA	0	0.0	1	1.0
	ANXIETY	7	4.7	0	0.0
	CNS STIMULATION	0	0.0	2	2.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 30 mg

Body System	Preferred Term	Paroxetine (N=150) n	%	Placebo (N=101) n	%
Nervous System	CONCENTRATION IMPAIRED	1	0.7	0	0.0
	CONFUSION	0	0.0	2	2.0
	DEPERSONALIZATION	1	0.7	1	1.0
	DEPRESSION	2	1.3	0	0.0
	DIZZINESS	15	10.0	6	5.9
	DRUGGED FEELING	5	3.3	0	0.0
	DYSARTHRIA	0	0.0	1	1.0
	EMOTIONAL LABILITY	1	0.7	0	0.0
	INSOMNIA	15	10.0	9	8.9
	LIBIDO DECREASED	5	3.3	0	0.0
	MANIC REACTION	0	0.0	1	1.0
	MYOCLONUS	1	0.7	0	0.0
	NERVOUSNESS	5	3.3	1	1.0
	PARESTHESIA	5	3.3	2	2.0
	SOMNOLENCE	32	21.3	6	5.9
	TREMOR	15	10.0	0	0.0
	VERTIGO	1	0.7	0	0.0
Respiratory System	TOTAL	18	12.0	7	6.9
	BRONCHITIS	2	1.3	0	0.0
	COUGH INCREASED	0	0.0	1	1.0
	DYSPNEA	2	1.3	1	1.0
	EPISTAXIS	1	0.7	0	0.0
	HYPERVENTILATION	1	0.7	0	0.0
	PHARYNGITIS	1	0.7	4	4.0
	RESPIRATORY DISORDER	6	4.0	5	5.0
	RHINITIS	1	0.7	0	0.0
	YAWN	4	2.7	0	0.0
Skin and Appendages	TOTAL	15	10.0	7	6.9
	ACNE	1	0.7	0	0.0
	CONTACT DERMATITIS	1	0.7	0	0.0
	DERMATOSES, GENERAL	0	0.0	1	1.0
	PRURITUS	1	0.7	1	1.0
	RASH	1	0.7	2	2.0
	SKIN DISCOLORATION	0	0.0	1	1.0
	SWEATING	13	8.7	2	2.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 30 mg

Body System	Preferred Term	Paroxetine (N=150) n	%	Placebo (N=101) n	%
Skin and Appendages	URTICARIA	1	0.7	0	0.0
Special Senses	TOTAL	14	9.3	5	5.0
	BLURRED VISION	3	2.0	3	3.0
	EYE DISORDER	1	0.7	0	0.0
	EYE PAIN	1	0.7	0	0.0
	OTITIS MEDIA	2	1.3	0	0.0
	TASTE PERVERSION	5	3.3	2	2.0
	TINNITUS	3	2.0	0	0.0
	VISION DISORDERS	1	0.7	0	0.0
Urogenital System	TOTAL	18	12.0	3	3.0
	ABNORMAL EJACULATION *	6	9.2	0	0.0
	CYSTITIS	1	0.7	1	1.0
	DYSMENORRHEA **	0	0.0	1	1.7
	FEMALE GENITAL DISORDERS **	1	1.2	0	0.0
	IMPOTENCE *	5	7.7	0	0.0
	KIDNEY CALCULUS	1	0.7	0	0.0
	MALE GENITAL DISORDERS *	3	4.6	0	0.0
	MASTITIS **	1	1.2	0	0.0
	URINARY FREQUENCY	2	1.3	1	1.0
	URINATION IMPAIRED	2	1.3	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
TOTAL	TOTAL	739	84.6	611	75.4
	Total Male Subjects *	391	100.0	350	100.0
	Total Male-Specific AEs *	131	33.5	9	2.6
	Total Female Subjects **	483	100.0	460	100.0
	Total Female-Specific AEs **	44	9.1	44	9.6
	Total Non Gender-Specific AEs	735	84.1	609	75.2
Body as a Whole	TOTAL	401	45.9	347	42.8
	ABDOMINAL PAIN	32	3.7	34	4.2
	ACCIDENTAL OVERDOSE	1	0.1	0	0.0
	ALLERGIC REACTION	13	1.5	15	1.9
	ASTHENIA	145	16.6	37	4.6
	BACK PAIN	24	2.7	40	4.9
	CELLULITIS	1	0.1	1	0.1
	CHEST PAIN	10	1.1	15	1.9
	CHILLS	9	1.0	3	0.4
	CHILLS AND FEVER	1	0.1	0	0.0
	FACE EDEMA	3	0.3	0	0.0
	FEVER	12	1.4	10	1.2
	FLU SYNDROME	25	2.9	10	1.2
	HEADACHE	205	23.5	202	24.9
	HERNIA	2	0.2	0	0.0
	INFECTION	37	4.2	39	4.8
	INTENTIONAL OVERDOSE	9	1.0	13	1.6
	MALAISE	5	0.6	3	0.4
	NECK PAIN	2	0.2	0	0.0
	NECK RIGIDITY	1	0.1	0	0.0
	NEOPLASM	1	0.1	1	0.1
	PAIN	12	1.4	26	3.2
	SURGICAL PROCEDURE	0	0.0	2	0.2
	TRAUMA	35	4.0	40	4.9
Cardiovascular System	TOTAL	87	10.0	63	7.8
	ANGINA PECTORIS	3	0.3	2	0.2
	ARRHYTHMIA	0	0.0	1	0.1
	ATRIAL FIBRILLATION	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Cardiovascular System	AV BLOCK	0	0.0	1	0.1
	CARDIAC DISORDERS	1	0.1	0	0.0
	CARDIOVASCULAR DISORDER	0	0.0	2	0.2
	CEREBROVASCULAR DISORDER	0	0.0	1	0.1
	ELECTROCARDIOGRAM ABNORMAL	1	0.1	0	0.0
	HAEMATOMA	6	0.7	1	0.1
	HYPERTENSION	9	1.0	6	0.7
	HYPOTENSION	1	0.1	3	0.4
	MIGRAINE	13	1.5	15	1.9
	PALPITATION	14	1.6	17	2.1
	PERIPHERAL VASCULAR DISORDER	2	0.2	0	0.0
	POSTURAL HYPOTENSION	3	0.3	2	0.2
	SYNCOPE	11	1.3	7	0.9
	TACHYCARDIA	4	0.5	5	0.6
	VASCULAR HEADACHE	1	0.1	0	0.0
	VASODILATATION	29	3.3	6	0.7
	VASOSPASM	0	0.0	1	0.1
	VENTRICULAR EXTRASYSTOLES	1	0.1	0	0.0
Digestive System	TOTAL	457	52.3	266	32.8
	BLOODY DIARRHEA	1	0.1	0	0.0
	BRUXISM	6	0.7	0	0.0
	BUCCAL CAVITY DISORDERS	2	0.2	0	0.0
	BULIMIA	1	0.1	1	0.1
	COLITIS	3	0.3	2	0.2
	CONSTIPATION	97	11.1	41	5.1
	DECREASED APPETITE	51	5.8	11	1.4
	DIARRHEA	101	11.6	59	7.3
	DIGESTIVE SYSTEM DISORDER	0	0.0	1	0.1
	DRY MOUTH	127	14.5	44	5.4
	DYSPEPSIA	34	3.9	43	5.3
	DYSPHAGIA	6	0.7	0	0.0
	ERUCTATION	2	0.2	3	0.4
	ESOPHAGITIS	1	0.1	1	0.1
	FECAL INCONTINENCE	1	0.1	0	0.0
	FLATULENCE	17	1.9	19	2.3

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Digestive System	GALL BLADDER DISORDER	0	0.0	1	0.1
	GASTRITIS	0	0.0	2	0.2
	GASTROENTERITIS	1	0.1	4	0.5
	GASTROINTESTINAL DISORDER	5	0.6	7	0.9
	GASTROINTESTINAL FLU	1	0.1	0	0.0
	GINGIVITIS	7	0.8	7	0.9
	GLOSSITIS	1	0.1	0	0.0
	HEMATEMESIS	1	0.1	0	0.0
	ILEITIS	1	0.1	0	0.0
	INCREASED APPETITE	14	1.6	11	1.4
	INCREASED SALIVATION	0	0.0	1	0.1
	LIVER FUNCTION TESTS ABNORMAL	4	0.5	3	0.4
	MELENA	3	0.3	1	0.1
	NAUSEA	211	24.1	82	10.1
	NAUSEA AND VOMITING	4	0.5	4	0.5
	NAUSEA VOMITING AND DIARRHEA	1	0.1	0	0.0
	OROPHARYNX DISORDER	1	0.1	0	0.0
	PANCREATITIS	0	0.0	1	0.1
	PEPTIC ULCER	1	0.1	0	0.0
	RECTAL DISORDER	0	0.0	1	0.1
	RECTAL HEMORRHAGE	2	0.2	1	0.1
	SALIVARY GLAND ENLARGEMENT	1	0.1	0	0.0
	SIALADENITIS	1	0.1	0	0.0
	STOMACH ULCER	0	0.0	1	0.1
	STOMATITIS	1	0.1	1	0.1
	TOOTH CARIES	2	0.2	2	0.2
	TOOTH DISORDER	7	0.8	12	1.5
	TOOTH MALFORMATION	1	0.1	0	0.0
	ULCERATIVE STOMATITIS	0	0.0	2	0.2
	VOMITING	21	2.4	17	2.1
Endocrine System	TOTAL	5	0.6	3	0.4
	DIABETES MELLITUS	1	0.1	0	0.0
	HYPERTHYROIDISM	0	0.0	1	0.1
	HYPOTHYROIDISM	1	0.1	0	0.0
	OVARY DISORDER **	1	0.2	2	0.4
	TESTES DISORDER *	1	0.3	0	0.0

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** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Endocrine System	THYROID DISORDER	1	0.1	0	0.0
Hemic and Lymphatic System	TOTAL	14	1.6	6	0.7
	ANEMIA	4	0.5	0	0.0
	EOSINOPHILIA	0	0.0	1	0.1
	HYPOCHROMIC ANEMIA	2	0.2	0	0.0
	LEUKOCYTOSIS	1	0.1	1	0.1
	LEUKOPENIA	2	0.2	1	0.1
	LYMPHADENOPATHY	1	0.1	0	0.0
	MONOCYTOSIS	0	0.0	1	0.1
	PURPURA	4	0.5	2	0.2
	THROMBOCYTHEMIA	0	0.0	1	0.1
	THROMBOCYTOPENIA	0	0.0	1	0.1
Metabolic and Nutritional Disorders	TOTAL	43	4.9	26	3.2
	ALKALINE PHOSPHATASE INCREASED	2	0.2	0	0.0
	BILIRUBINEMIA	2	0.2	0	0.0
	EDEMA	2	0.2	1	0.1
	GOUT	1	0.1	0	0.0
	HYPERCHOLESTEREMIA	0	0.0	2	0.2
	HYPERGLYCEMIA	1	0.1	1	0.1
	HYPERLIPEMIA	0	0.0	2	0.2
	HYPERPHOSPHATEMIA	1	0.1	0	0.0
	HYPOGLYCEMIA	1	0.1	1	0.1
	IRON DISORDERS	1	0.1	0	0.0
	PERIPHERAL EDEMA	4	0.5	4	0.5
	SGOT INCREASED	2	0.2	1	0.1
	SGPT INCREASED	1	0.1	2	0.2
	THIRST	6	0.7	2	0.2
	WEIGHT GAIN	18	2.1	9	1.1
	WEIGHT LOSS	5	0.6	3	0.4
Musculoskeletal System	TOTAL	51	5.8	68	8.4

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** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Musculoskeletal System	ARTHRALGIA	9	1.0	21	2.6
	ARTHRITIS	3	0.3	2	0.2
	ARTHROSIS	1	0.1	6	0.7
	BONE DISORDER	1	0.1	2	0.2
	BURSITIS	1	0.1	2	0.2
	GENERALIZED SPASM	1	0.1	0	0.0
	MYALGIA	27	3.1	32	4.0
	MYASTHENIA	4	0.5	1	0.1
	MYOPATHY	2	0.2	0	0.0
	TENDINOUS DISORDER	2	0.2	3	0.4
	TETANY	1	0.1	0	0.0
	TRAUMATIC FRACTURE	1	0.1	2	0.2
Nervous System	TOTAL	502	57.4	311	38.4
	ABNORMAL DREAMS	21	2.4	14	1.7
	AGITATION	24	2.7	20	2.5
	ALCOHOL ABUSE	5	0.6	9	1.1
	AMNESIA	11	1.3	7	0.9
	ANTISOCIAL REACTION	2	0.2	0	0.0
	ANXIETY	61	7.0	35	4.3
	ATAXIA	4	0.5	0	0.0
	CNS STIMULATION	7	0.8	8	1.0
	CONCENTRATION IMPAIRED	24	2.7	8	1.0
	CONFUSION	13	1.5	4	0.5
	DELIRIUM	1	0.1	0	0.0
	DEPERSONALIZATION	8	0.9	4	0.5
	DEPRESSION	21	2.4	30	3.7
	DIZZINESS	97	11.1	61	7.5
	DRUGGED FEELING	6	0.7	1	0.1
	DYSKINESIA	2	0.2	1	0.1
	DYSTONIA	2	0.2	3	0.4
	EMOTIONAL LABILITY	31	3.5	29	3.6
	EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.1
	HALLUCINATIONS	3	0.3	2	0.2
	HOSTILITY	1	0.1	3	0.4
	HYPERKINESIA	8	0.9	4	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Nervous System	HYPERTONIA	10	1.1	6	0.7
	HYPESTHESIA	6	0.7	3	0.4
	HYPOKINESIA	5	0.6	0	0.0
	HYSTERIA	2	0.2	1	0.1
	INCOORDINATION	2	0.2	2	0.2
	INSOMNIA	146	16.7	95	11.7
	INTRACRANIAL HYPERTENSION	0	0.0	1	0.1
	LACK OF EMOTION	11	1.3	4	0.5
	LIBIDO DECREASED	65	7.4	13	1.6
	LIBIDO INCREASED	3	0.3	0	0.0
	MANIC REACTION	2	0.2	1	0.1
	MENINGITIS	0	0.0	1	0.1
	MYOCLONUS	22	2.5	7	0.9
	NERVOUS SYSTEM DISORDER	1	0.1	0	0.0
	NERVOUSNESS	48	5.5	40	4.9
	NEURALGIA	0	0.0	1	0.1
	NEUROSIS	0	0.0	1	0.1
	NEUROVASCULAR COMPRESSION	0	0.0	1	0.1
	NYSTAGMUS	1	0.1	1	0.1
	PARALYSIS	3	0.3	2	0.2
	PARANOID REACTION	1	0.1	1	0.1
	PARESTHESIA	29	3.3	16	2.0
	PERSONALITY DISORDER	0	0.0	1	0.1
	PSYCHOSIS	1	0.1	0	0.0
	SOMNOLENCE	173	19.8	59	7.3
	SPEECH DISORDER	1	0.1	3	0.4
	THINKING ABNORMAL	5	0.6	4	0.5
	TORTICOLLIS	1	0.1	0	0.0
	TREMOR	81	9.3	8	1.0
	TRISMUS	1	0.1	0	0.0
	VERTIGO	7	0.8	5	0.6
	VESTIBULAR DISORDER	2	0.2	1	0.1
Respiratory System	TOTAL	158	18.1	156	19.3
	ASPIRATION PNEUMONIA	1	0.1	0	0.0
	ASTHMA	3	0.3	3	0.4
	BRONCHITIS	10	1.1	13	1.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Respiratory System	CARCINOMA OF LARYNX	1	0.1	0	0.0
	COUGH INCREASED	8	0.9	13	1.6
	DYSPNEA	7	0.8	6	0.7
	EPISTAXIS	4	0.5	5	0.6
	HEMOPTYSIS	0	0.0	2	0.2
	HYPERVENTILATION	1	0.1	2	0.2
	LARYNX DISORDER	0	0.0	1	0.1
	PHARYNGITIS	23	2.6	29	3.6
	PLEURA DISORDER	0	0.0	1	0.1
	PNEUMONIA	2	0.2	2	0.2
	RESPIRATORY DISORDER	65	7.4	70	8.6
	RESPIRATORY FLU	0	0.0	1	0.1
	RHINITIS	18	2.1	20	2.5
	SINUSITIS	26	3.0	32	4.0
	SPUTUM INCREASED	0	0.0	1	0.1
	TRACHEA DISORDER	0	0.0	1	0.1
	VOICE ALTERATION	1	0.1	0	0.0
	YAWN	26	3.0	0	0.0
Skin and Appendages	TOTAL	111	12.7	55	6.8
	ACNE	3	0.3	4	0.5
	ALOPECIA	0	0.0	2	0.2
	CONTACT DERMATITIS	0	0.0	1	0.1
	DERMATOSES, GENERAL	0	0.0	1	0.1
	DRY SKIN	1	0.1	1	0.1
	ECCHYMOSIS	1	0.1	0	0.0
	FUNGAL DERMATITIS	1	0.1	1	0.1
	FURUNCULOSIS	1	0.1	1	0.1
	HAIR DISORDERS	0	0.0	1	0.1
	HERPES SIMPLEX	2	0.2	7	0.9
	HIRSUTISM	0	0.0	1	0.1
	MACULOPAPULAR RASH	1	0.1	1	0.1
	NAIL DISORDER	1	0.1	1	0.1
	PHOTOSENSITIVITY	4	0.5	0	0.0
	PRURITUS	9	1.0	6	0.7
	RASH	25	2.9	15	1.9
	SEBORRHEA	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Skin and Appendages	SKIN BENIGN NEOPLASM	1	0.1	0	0.0
	SKIN DISCOLORATION	1	0.1	1	0.1
	SKIN HYPERTROPHY	1	0.1	2	0.2
	SWEATING	69	7.9	12	1.5
	SWEATING DECREASED	0	0.0	1	0.1
	URTICARIA	3	0.3	1	0.1
Special Senses	TOTAL	69	7.9	34	4.2
	ABNORMAL VISION	25	2.9	6	0.7
	ABNORMALITY OF ACCOMMODATION	3	0.3	0	0.0
	BLINDNESS	0	0.0	1	0.1
	BLURRED VISION	9	1.0	1	0.1
	CONJUNCTIVITIS	4	0.5	6	0.7
	DEAFNESS	1	0.1	0	0.0
	EAR DISORDER	1	0.1	1	0.1
	EAR PAIN	2	0.2	0	0.0
	EYE DISORDER	2	0.2	0	0.0
	EYE HEMORRHAGE	1	0.1	1	0.1
	EYE PAIN	0	0.0	1	0.1
	KERATOCONJUNCTIVITIS	1	0.1	1	0.1
	MYDRIASIS	1	0.1	0	0.0
	OTITIS MEDIA	1	0.1	4	0.5
	PHOTOPHOBIA	1	0.1	1	0.1
	PUPILLARY DISORDER	1	0.1	0	0.0
	RETINAL DISORDER	1	0.1	0	0.0
	TASTE PERVERSION	6	0.7	5	0.6
	TINNITUS	10	1.1	10	1.2
	VISION DISORDERS	2	0.2	2	0.2
Urogenital System	TOTAL	207	23.7	84	10.4
	ABNORMAL EJACULATION *	105	26.9	5	1.4
	ABORTION **	0	0.0	1	0.2
	ALBUMINURIA	1	0.1	2	0.2
	AMENORRHEA **	3	0.6	1	0.2
	BREAST CARCINOMA **	0	0.0	1	0.2
	BREAST ENLARGEMENT **	0	0.0	1	0.2
	BREAST PAIN **	0	0.0	1	0.2

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Body System	Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
Urogenital System	CYSTITIS	6	0.7	7	0.9
	DYSMENORRHEA **	13	2.7	16	3.5
	DYSURIA	5	0.6	4	0.5
	EPIDIDYMITIS	1	0.1	0	0.0
	FEMALE BREAST DISORDERS **	1	0.2	0	0.0
	FEMALE GENITAL DISORDERS **	24	5.0	3	0.7
	GLYCOSURIA	0	0.0	1	0.1
	HAEMATURIA	1	0.1	6	0.7
	IMPOTENCE *	32	8.2	5	1.4
	KIDNEY CALCULUS	1	0.1	2	0.2
	LEUKORRHEA	1	0.1	0	0.0
	MALE GENITAL DISORDERS *	3	0.8	0	0.0
	MASTITIS **	1	0.2	0	0.0
	MENORRHAGIA **	0	0.0	8	1.7
	MENSTRUAL DISORDER **	3	0.6	6	1.3
	METRORRHAGIA **	0	0.0	3	0.7
	NEPHRITIS	1	0.1	0	0.0
	NOCTURIA	2	0.2	0	0.0
	PAPANICOLAU SMEAR SUSPICIOUS **	0	0.0	2	0.4
	PROSTATE DISORDER *	1	0.3	1	0.3
	PYURIA	2	0.2	0	0.0
	UNINTENDED PREGNANCY **	1	0.2	1	0.2
	URINARY FREQUENCY	13	1.5	8	1.0
	URINARY INCONTINENCE	1	0.1	0	0.0
	URINARY RETENTION	2	0.2	1	0.1
	URINARY TRACT INFECTION	8	0.9	10	1.2
	URINATION IMPAIRED	12	1.4	1	0.1
	URINE ABNORMALITY	1	0.1	1	0.1
	UTERINE FIBROIDS ENLARGED **	0	0.0	1	0.2
	VAGINAL HEMORRHAGE **	0	0.0	1	0.2
	VAGINAL MONILIASIS **	1	0.2	1	0.2
	VAGINITIS **	3	0.6	1	0.2

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 50 mg

Body System	Preferred Term	Paroxetine (N=57) n	%	Placebo (N=60) n	%
TOTAL	TOTAL	46	80.7	46	76.7
	Total Male Subjects *	37	100.0	42	100.0
	Total Male-Specific AEs *	3	8.1	2	4.8
	Total Female Subjects **	20	100.0	18	100.0
	Total Female-Specific AEs **	1	5.0	1	5.6
	Total Non Gender-Specific AEs	45	78.9	46	76.7
Body as a Whole	TOTAL	24	42.1	24	40.0
	ABDOMEN ENLARGED	1	1.8	0	0.0
	ABDOMINAL PAIN	3	5.3	0	0.0
	ALLERGIC REACTION	1	1.8	0	0.0
	ASTHENIA	6	10.5	7	11.7
	BACK PAIN	1	1.8	2	3.3
	CHEST PAIN	0	0.0	1	1.7
	FACE EDEMA	1	1.8	0	0.0
	FLU SYNDROME	0	0.0	3	5.0
	HEADACHE	15	26.3	11	18.3
	MALAISE	3	5.3	1	1.7
	NECK PAIN	1	1.8	0	0.0
	TRAUMA	0	0.0	2	3.3
Cardiovascular System	TOTAL	13	22.8	12	20.0
	ANGINA PECTORIS	0	0.0	1	1.7
	HYPERTENSION	3	5.3	1	1.7
	HYPOTENSION	7	12.3	3	5.0
	MIGRAINE	0	0.0	1	1.7
	PALPITATION	0	0.0	2	3.3
	POSTURAL HYPOTENSION	1	1.8	1	1.7
	SYNCOPE	1	1.8	1	1.7
	TACHYCARDIA	4	7.0	4	6.7
	VASODILATATION	1	1.8	2	3.3
Digestive System	TOTAL	27	47.4	16	26.7
	CONSTIPATION	4	7.0	2	3.3
	DECREASED APPETITE	4	7.0	2	3.3
	DIARRHEA	9	15.8	4	6.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 50 mg

Body System	Preferred Term	Paroxetine (N=57) n	%	Placebo (N=60) n	%
Digestive System	DRY MOUTH	3	5.3	3	5.0
	DYSPEPSIA	0	0.0	2	3.3
	FLATULENCE	1	1.8	0	0.0
	GASTROENTERITIS	1	1.8	1	1.7
	INCREASED APPETITE	2	3.5	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	1	1.7
	NAUSEA	11	19.3	3	5.0
	PERIODONTAL ABSCESS	0	0.0	1	1.7
	TOOTH DISORDER	0	0.0	1	1.7
	VOMITING	2	3.5	1	1.7
Hemic and Lymphatic System	TOTAL	1	1.8	1	1.7
	LEUKOCYTOSIS	1	1.8	1	1.7
	THROMBOCYTHEMIA	1	1.8	0	0.0
Metabolic and Nutritional Disorders	TOTAL	8	14.0	3	5.0
	ALKALINE PHOSPHATASE INCREASED	1	1.8	0	0.0
	SGPT INCREASED	1	1.8	0	0.0
	WEIGHT GAIN	5	8.8	1	1.7
	WEIGHT LOSS	1	1.8	2	3.3
Musculoskeletal System	TOTAL	4	7.0	5	8.3
	MYALGIA	1	1.8	2	3.3
	MYASTHENIA	2	3.5	2	3.3
	MYOPATHY	1	1.8	1	1.7
Nervous System	TOTAL	30	52.6	17	28.3
	AMNESIA	0	0.0	1	1.7
	ANXIETY	6	10.5	4	6.7
	CNS STIMULATION	1	1.8	0	0.0
	DEPRESSION	2	3.5	0	0.0
	DIZZINESS	2	3.5	1	1.7
	DRUG DEPENDENCE	0	0.0	1	1.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 50 mg

Body System	Preferred Term	Paroxetine (N=57) n	%	Placebo (N=60) n	%
Nervous System	DYSARTHRIA	0	0.0	1	1.7
	DYSKINESIA	1	1.8	0	0.0
	INSOMNIA	5	8.8	5	8.3
	LACK OF EMOTION	0	0.0	1	1.7
	LIBIDO DECREASED	6	10.5	3	5.0
	NERVOUSNESS	2	3.5	0	0.0
	NEUROPATHY	0	0.0	2	3.3
	PARESTHESIA	1	1.8	4	6.7
	REFLEXES DECREASED	1	1.8	0	0.0
	SOMNOLENCE	4	7.0	2	3.3
	SPEECH DISORDER	0	0.0	1	1.7
	TREMOR	5	8.8	2	3.3
	VERTIGO	3	5.3	0	0.0
	WITHDRAWAL SYNDROME	1	1.8	0	0.0
Respiratory System	TOTAL	4	7.0	7	11.7
	ASTHMA	1	1.8	1	1.7
	BRONCHITIS	0	0.0	2	3.3
	COUGH INCREASED	1	1.8	0	0.0
	PHARYNGITIS	0	0.0	1	1.7
	RESPIRATORY DISORDER	1	1.8	2	3.3
	RHINITIS	0	0.0	1	1.7
	SINUSITIS	1	1.8	1	1.7
Skin and Appendages	TOTAL	11	19.3	5	8.3
	ACNE	0	0.0	1	1.7
	ECZEMA	0	0.0	1	1.7
	PRURITUS	4	7.0	0	0.0
	RASH	2	3.5	0	0.0
	SWEATING	6	10.5	3	5.0
Special Senses	TOTAL	7	12.3	6	10.0
	ABNORMAL VISION	1	1.8	0	0.0
	ABNORMALITY OF ACCOMMODATION	0	0.0	1	1.7
	BLURRED VISION	1	1.8	0	0.0
	MYDRIASIS	1	1.8	0	0.0
	PHOTOPHOBIA	0	0.0	1	1.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 50 mg

Body System	Preferred Term	Paroxetine (N=57) n	%	Placebo (N=60) n	%
Special Senses	TASTE PERVERSION	2	3.5	2	3.3
	TINNITUS	1	1.8	0	0.0
	VISION DISORDERS	1	1.8	3	5.0
	VISUAL FIELD DEFECT	1	1.8	0	0.0
Urogenital System	TOTAL	6	10.5	7	11.7
	ABNORMAL EJACULATION *	1	2.7	0	0.0
	AMENORRHEA **	1	5.0	0	0.0
	CYSTITIS	0	0.0	1	1.7
	DYSURIA	1	1.8	1	1.7
	HAEMATURIA	0	0.0	1	1.7
	IMPOTENCE *	1	2.7	1	2.4
	MALE GENITAL DISORDERS *	1	2.7	0	0.0
	NOCTURIA	1	1.8	0	0.0
	PROSTATE DISORDER *	0	0.0	1	2.4
	PYURIA	0	0.0	1	1.7
	URINARY FREQUENCY	0	0.0	1	1.7
	URINARY RETENTION	0	0.0	1	1.7
	URINARY TRACT INFECTION	1	1.8	1	1.7
	UTERINE HEMORRHAGE **	0	0.0	1	5.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

Body System	Preferred Term	Paroxetine (N=182) n	%	Placebo (N=184) n	%
TOTAL	TOTAL	164	90.1	154	83.7
	Total Male Subjects *	126	100.0	115	100.0
	Total Male-Specific AEs *	58	46.0	4	3.5
	Total Female Subjects **	56	100.0	69	100.0
	Total Female-Specific AEs **	5	8.9	7	10.1
	Total Non Gender-Specific AEs	160	87.9	154	83.7
Body as a Whole	TOTAL	90	49.5	94	51.1
	ABDOMINAL PAIN	7	3.8	7	3.8
	ALLERGIC REACTION	0	0.0	3	1.6
	ASTHENIA	40	22.0	17	9.2
	BACK PAIN	3	1.6	9	4.9
	CHEST PAIN	1	0.5	2	1.1
	CHILLS	3	1.6	0	0.0
	FEVER	6	3.3	1	0.5
	HEADACHE	41	22.5	59	32.1
	INFECTION	12	6.6	8	4.3
	MALAISE	2	1.1	0	0.0
	NEOPLASM	1	0.5	1	0.5
	PAIN	4	2.2	6	3.3
	TRAUMA	6	3.3	3	1.6
Cardiovascular System	TOTAL	17	9.3	8	4.3
	ARRHYTHMIA	1	0.5	0	0.0
	CARDIOVASCULAR DISORDER	0	0.0	1	0.5
	HYPERTENSION	2	1.1	1	0.5
	HYPOTENSION	0	0.0	1	0.5
	MIGRAINE	0	0.0	1	0.5
	PALPITATION	4	2.2	2	1.1
	SYNCOPE	2	1.1	0	0.0
	TACHYCARDIA	1	0.5	2	1.1
	VASODILATATION	7	3.8	0	0.0
Digestive System	TOTAL	101	55.5	68	37.0
	BRUXISM	2	1.1	0	0.0
	COLITIS	0	0.0	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

Body System	Preferred Term	Paroxetine (N=182) n	%	Placebo (N=184) n	%
Digestive System	CONSTIPATION	23	12.6	11	6.0
	DECREASED APPETITE	19	10.4	2	1.1
	DIARRHEA	24	13.2	21	11.4
	DIGESTIVE SYSTEM DISORDER	0	0.0	1	0.5
	DRY MOUTH	23	12.6	11	6.0
	DYSPEPSIA	8	4.4	7	3.8
	DYSPHAGIA	2	1.1	0	0.0
	FLATULENCE	8	4.4	7	3.8
	GASTRITIS	0	0.0	1	0.5
	GASTROENTERITIS	0	0.0	1	0.5
	GASTROINTESTINAL DISORDER	1	0.5	0	0.0
	GINGIVITIS	1	0.5	1	0.5
	INCREASED APPETITE	13	7.1	5	2.7
	INCREASED SALIVATION	0	0.0	1	0.5
	LIVER FUNCTION TESTS ABNORMAL	3	1.6	3	1.6
	NAUSEA	39	21.4	13	7.1
	STOMATITIS	1	0.5	0	0.0
	TOOTH CARIES	0	0.0	1	0.5
	TOOTH DISORDER	1	0.5	3	1.6
	ULCERATIVE STOMATITIS	1	0.5	2	1.1
	VOMITING	9	4.9	4	2.2
Endocrine System	TOTAL	0	0.0	2	1.1
	HYPERTHYROIDISM	0	0.0	1	0.5
	OVARY DISORDER **	0	0.0	1	1.4
Hemic and Lymphatic System	TOTAL	3	1.6	1	0.5
	ANEMIA	1	0.5	0	0.0
	EOSINOPHILIA	0	0.0	1	0.5
	LYMPHADENOPATHY	1	0.5	0	0.0
	PURPURA	1	0.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	5	2.7	6	3.3
	EDEMA	0	0.0	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

Body System	Preferred Term	Paroxetine (N=182) n	%	Placebo (N=184) n	%
Metabolic and Nutritional Disorders	HYPERCHOLESTEREMIA	2	1.1	0	0.0
	HYPERLIPEMIA	0	0.0	2	1.1
	PERIPHERAL EDEMA	0	0.0	1	0.5
	SGPT INCREASED	1	0.5	1	0.5
	WEIGHT GAIN	2	1.1	2	1.1
	WEIGHT LOSS	1	0.5	0	0.0
Musculoskeletal System	TOTAL	16	8.8	14	7.6
	ARTHRALGIA	4	2.2	6	3.3
	BONE DISORDER	1	0.5	0	0.0
	MYALGIA	10	5.5	7	3.8
	MYASTHENIA	4	2.2	0	0.0
	TENDINOUS DISORDER	0	0.0	1	0.5
Nervous System	TOTAL	131	72.0	71	38.6
	ABNORMAL DREAMS	5	2.7	2	1.1
	AGITATION	3	1.6	3	1.6
	ALCOHOL ABUSE	0	0.0	1	0.5
	AMNESIA	3	1.6	0	0.0
	ANXIETY	7	3.8	5	2.7
	ATAXIA	1	0.5	0	0.0
	BRAIN EDEMA	1	0.5	0	0.0
	CONCENTRATION IMPAIRED	7	3.8	1	0.5
	CONFUSION	1	0.5	1	0.5
	DEPERSONALIZATION	4	2.2	2	1.1
	DEPRESSION	3	1.6	8	4.3
	DIZZINESS	25	13.7	13	7.1
	DYSKINESIA	0	0.0	1	0.5
	DYSTONIA	4	2.2	2	1.1
	EMOTIONAL LABILITY	0	0.0	3	1.6
	EUPHORIA	1	0.5	0	0.0
	HOSTILITY	1	0.5	1	0.5
	HYPERKINESIA	4	2.2	1	0.5
	HYPERTONIA	5	2.7	2	1.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

Body System	Preferred Term	Paroxetine (N=182) n	%	Placebo (N=184) n	%
Nervous System	HYPESTHESIA	3	1.6	0	0.0
	INSOMNIA	57	31.3	24	13.0
	LIBIDO DECREASED	18	9.9	5	2.7
	MYOCLONUS	10	5.5	2	1.1
	NERVOUSNESS	23	12.6	13	7.1
	NEUROSIS	1	0.5	1	0.5
	PARALYSIS	1	0.5	1	0.5
	PARESTHESIA	5	2.7	5	2.7
	SOMNOLENCE	58	31.9	14	7.6
	THINKING ABNORMAL	0	0.0	1	0.5
	TREMOR	22	12.1	1	0.5
	VERTIGO	1	0.5	2	1.1
Respiratory System	TOTAL	45	24.7	41	22.3
	BRONCHITIS	1	0.5	2	1.1
	COUGH INCREASED	4	2.2	3	1.6
	DYSPNEA	1	0.5	2	1.1
	HEMOPTYSIS	0	0.0	1	0.5
	HICCUP	1	0.5	0	0.0
	LARYNX DISORDER	1	0.5	1	0.5
	PHARYNGITIS	4	2.2	7	3.8
	PLEURA DISORDER	0	0.0	1	0.5
	RESPIRATORY DISORDER	10	5.5	22	12.0
	RHINITIS	5	2.7	5	2.7
	SINUSITIS	8	4.4	9	4.9
	YAWN	15	8.2	0	0.0
Skin and Appendages	TOTAL	33	18.1	9	4.9
	ACNE	1	0.5	1	0.5
	CONTACT DERMATITIS	3	1.6	0	0.0
	HERPES SIMPLEX	1	0.5	2	1.1
	HERPES ZOSTER	1	0.5	0	0.0
	HIRSUTISM	0	0.0	1	0.5
	MACULOPAPULAR RASH	1	0.5	0	0.0
	PRURITUS	3	1.6	2	1.1
	PUSTULAR RASH	1	0.5	0	0.0
	RASH	5	2.7	3	1.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

Body System	Preferred Term	Paroxetine (N=182) n	%	Placebo (N=184) n	%
Skin and Appendages	SKIN DISORDER	1	0.5	0	0.0
	SKIN HYPERTROPHY	0	0.0	1	0.5
	SWEAT GLAND DISORDER	1	0.5	0	0.0
	SWEATING	18	9.9	2	1.1
	SWEATING DECREASED	0	0.0	1	0.5
	URTICARIA	2	1.1	0	0.0
Special Senses	TOTAL	23	12.6	8	4.3
	ABNORMAL VISION	5	2.7	1	0.5
	BLEPHARITIS	1	0.5	0	0.0
	CONJUNCTIVITIS	1	0.5	2	1.1
	EAR DISORDER	2	1.1	1	0.5
	EYE DISORDER	1	0.5	0	0.0
	EYE PAIN	0	0.0	1	0.5
	KERATOCONJUNCTIVITIS	1	0.5	0	0.0
	MYDRIASIS	2	1.1	0	0.0
	OTITIS MEDIA	1	0.5	1	0.5
	PHOTOPHOBIA	1	0.5	0	0.0
	TASTE PERVERSION	7	3.8	1	0.5
	TINNITUS	2	1.1	1	0.5
Urogenital System	TOTAL	76	41.8	20	10.9
	ABNORMAL EJACULATION *	52	41.3	2	1.7
	ALBUMINURIA	0	0.0	1	0.5
	BREAST CARCINOMA **	0	0.0	1	1.4
	CYSTITIS	1	0.5	1	0.5
	DYSMENORRHEA **	1	1.8	4	5.8
	DYSURIA	3	1.6	1	0.5
	FEMALE GENITAL DISORDERS **	4	7.1	0	0.0
	HAEMATURIA	0	0.0	2	1.1
	IMPOTENCE *	10	7.9	2	1.7
	KIDNEY CALCULUS	1	0.5	0	0.0
	MENORRHAGIA **	0	0.0	1	1.4
	NOCTURIA	1	0.5	0	0.0
	PROSTATE DISORDER *	1	0.8	0	0.0
	URINARY FREQUENCY	6	3.3	6	3.3
	URINARY RETENTION	3	1.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.42
Number (%) of Patients with Adverse Events On Therapy by Body System and Preferred Term by Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

Body System	Preferred Term	Paroxetine (N=182) n	%	Placebo (N=184) n	%
Urogenital System	URINARY TRACT INFECTION	2	1.1	1	0.5
	URINATION IMPAIRED	6	3.3	0	0.0
	URINE ABNORMALITY	0	0.0	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 5 mg

	Paroxetine (N=11)		Placebo (N=9)	
Preferred Term	n	%	n	%
TOTAL	5	45.5	2	22.2
Total Male-Specific AEs *	0	0.0	0	0.0
Total Female Subjects **	11	100.0	9	100.0
Total Female-Specific AEs **	1	9.1	0	0.0
Total Non Gender-Specific AEs	4	36.4	2	22.2
HEADACHE	1	9.1	1	11.1
ALLERGIC REACTION	1	9.1	0	0.0
COUGH INCREASED	1	9.1	0	0.0
INFECTION	1	9.1	0	0.0
METRORRHAGIA **	1	9.1	0	0.0
RESPIRATORY DISORDER	1	9.1	0	0.0
BRONCHITIS	0	0.0	1	11.1
MIGRAINE	0	0.0	1	11.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

	Paroxetine (N=775)		Placebo (N=737)	
Preferred Term	n	%	n	%
TOTAL	586	75.6	528	71.6
Total Male Subjects *	183	100.0	149	100.0
Total Male-Specific AEs *	17	9.3	4	2.7
Total Female Subjects **	592	100.0	588	100.0
Total Female-Specific AEs **	92	15.5	64	10.9
Total Non Gender-Specific AEs	575	74.2	519	70.4
HEADACHE	168	21.7	175	23.7
NAUSEA	107	13.8	74	10.0
ASTHENIA	85	11.0	39	5.3
INSOMNIA	83	10.7	48	6.5
RESPIRATORY DISORDER	82	10.6	78	10.6
DIARRHEA	76	9.8	37	5.0
SOMNOLENCE	74	9.5	43	5.8
LIBIDO DECREASED	59	7.6	29	3.9
DRY MOUTH	57	7.4	41	5.6
INFECTION	55	7.1	51	6.9
ABNORMAL EJACULATION *	13	7.1	3	2.0
DIZZINESS	50	6.5	40	5.4
SINUSITIS	45	5.8	42	5.7
DYSMENORRHEA **	34	5.7	36	6.1
CONSTIPATION	38	4.9	24	3.3
TRAUMA	37	4.8	26	3.5
FEMALE GENITAL DISORDERS **	28	4.7	6	1.0
SWEATING	35	4.5	9	1.2
BACK PAIN	33	4.3	28	3.8
DYSPEPSIA	32	4.1	34	4.6
ABDOMINAL PAIN	31	4.0	28	3.8
NERVOUSNESS	29	3.7	32	4.3
PHARYNGITIS	20	2.6	26	3.5
MYALGIA	20	2.6	22	3.0
DECREASED APPETITE	20	2.6	7	0.9
FLATULENCE	18	2.3	18	2.4
RHINITIS	18	2.3	16	2.2
ARTHRALGIA	17	2.2	17	2.3
WEIGHT GAIN	17	2.2	17	2.3
COUGH INCREASED	15	1.9	13	1.8

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

	Paroxetine (N=775)		Placebo (N=737)	
Preferred Term	n	%	n	%
MIGRAINE	14	1.8	8	1.1
ANXIETY	13	1.7	10	1.4
MENSTRUAL DISORDER **	10	1.7	7	1.2
IMPOTENCE *	3	1.6	0	0.0
ABNORMAL DREAMS	12	1.5	10	1.4
INCREASED APPETITE	12	1.5	9	1.2
PRURITUS	12	1.5	8	1.1
TREMOR	12	1.5	4	0.5
PARESTHESIA	11	1.4	7	0.9
OTITIS MEDIA	11	1.4	0	0.0
CONCENTRATION IMPAIRED	10	1.3	7	0.9
VASODILATATION	10	1.3	6	0.8
PALPITATION	9	1.2	15	2.0
URINARY TRACT INFECTION	9	1.2	15	2.0
BRONCHITIS	9	1.2	12	1.6
CHEST PAIN	9	1.2	10	1.4
ALLERGIC REACTION	9	1.2	9	1.2
DYSPNEA	9	1.2	8	1.1
ABNORMAL VISION	9	1.2	6	0.8
YAWN	9	1.2	3	0.4
VAGINAL MONILIASIS **	7	1.2	10	1.7
MALE GENITAL DISORDERS *	2	1.1	0	0.0
TOOTH DISORDER	8	1.0	12	1.6
LACK OF EMOTION	8	1.0	6	0.8
URINARY FREQUENCY	8	1.0	6	0.8
HYPERTENSION	8	1.0	5	0.7
MENORRHAGIA **	6	1.0	4	0.7
VOMITING	7	0.9	15	2.0
RASH	7	0.9	10	1.4
TACHYCARDIA	7	0.9	1	0.1
BRUXISM	7	0.9	0	0.0
PAIN	6	0.8	16	2.2
AGITATION	6	0.8	14	1.9
CYSTITIS	6	0.8	7	0.9
PERIPHERAL EDEMA	6	0.8	5	0.7
PURPURA	6	0.8	3	0.4
VAGINITIS **	4	0.7	2	0.3

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

	Paroxetine (N=775)		Placebo (N=737)	
Preferred Term	n	%	n	%
BREAST PAIN **	4	0.7	1	0.2
DEPRESSION	5	0.6	13	1.8
HYPERTONIA	5	0.6	9	1.2
ANEMIA	5	0.6	7	0.9
GINGIVITIS	5	0.6	6	0.8
GASTROENTERITIS	5	0.6	5	0.7
EMOTIONAL LABILITY	5	0.6	4	0.5
ERUCTATION	5	0.6	1	0.1
FEVER	4	0.5	6	0.8
ABNORMAL LABORATORY VALUE	4	0.5	4	0.5
ACNE	4	0.5	4	0.5
DEPERSONALIZATION	4	0.5	4	0.5
FLU SYNDROME	4	0.5	4	0.5
PNEUMONIA	4	0.5	3	0.4
LIBIDO INCREASED	4	0.5	1	0.1
URTICARIA	4	0.5	1	0.1
PROSTATE DISORDER *	1	0.5	0	0.0
HYPERKINESIA	3	0.4	4	0.5
TINNITUS	3	0.4	4	0.5
VERTIGO	3	0.4	4	0.5
ARTHRITIS	3	0.4	2	0.3
CHILLS	3	0.4	2	0.3
HAEMATURIA	3	0.4	2	0.3
ARTHROSIS	3	0.4	1	0.1
BLURRED VISION	3	0.4	1	0.1
MONILIASIS	3	0.4	1	0.1
SYNCOPE	3	0.4	1	0.1
CONFUSION	3	0.4	0	0.0
HAEMATOMA	3	0.4	0	0.0
MYASTHENIA	3	0.4	0	0.0
WEIGHT LOSS	2	0.3	6	0.8
HYPESTHESIA	2	0.3	5	0.7
DRY SKIN	2	0.3	4	0.5
GASTRITIS	2	0.3	4	0.5
THIRST	2	0.3	4	0.5
CONJUNCTIVITIS	2	0.3	3	0.4
POSTURAL HYPOTENSION	2	0.3	3	0.4

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

	Paroxetine (N=775)		Placebo (N=737)	
Preferred Term	n	%	n	%
SKIN HYPERTROPHY	2	0.3	2	0.3
THINKING ABNORMAL	2	0.3	2	0.3
UNINTENDED PREGNANCY **	2	0.3	1	0.2
ANGINA PECTORIS	2	0.3	1	0.1
CNS STIMULATION	2	0.3	1	0.1
DYSTONIA	2	0.3	1	0.1
EYE DISORDER	2	0.3	1	0.1
LARYNX DISORDER	2	0.3	1	0.1
BREAST ENLARGEMENT **	2	0.3	0	0.0
BREAST NEOPLASM **	2	0.3	0	0.0
FACE EDEMA	2	0.3	0	0.0
LEUKOCYTOSIS	2	0.3	0	0.0
MALAISE	2	0.3	0	0.0
OROPHARYNX DISORDER	2	0.3	0	0.0
ULCERATIVE STOMATITIS	2	0.3	0	0.0
URINATION IMPAIRED	2	0.3	0	0.0
ENDOMETRIAL DISORDER **	1	0.2	1	0.2
FEMALE LACTATION **	1	0.2	0	0.0
FERTILITY DECREASED FEMALE **	1	0.2	0	0.0
GASTROINTESTINAL DISORDER	1	0.1	4	0.5
ELECTROCARDIOGRAM ABNORMAL	1	0.1	3	0.4
KIDNEY CALCULUS	1	0.1	3	0.4
ALOPECIA	1	0.1	2	0.3
HYPOTENSION	1	0.1	2	0.3
MYOCLONUS	1	0.1	2	0.3
TASTE PERVERSION	1	0.1	2	0.3
DIABETES MELLITUS	1	0.1	1	0.1
DYSPHAGIA	1	0.1	1	0.1
ESOPHAGITIS	1	0.1	1	0.1
GENERALIZED EDEMA	1	0.1	1	0.1
HEMOPTYSIS	1	0.1	1	0.1
HYPOCHROMIC ANEMIA	1	0.1	1	0.1
KERATOCONJUNCTIVITIS	1	0.1	1	0.1
LIVER FUNCTION TESTS ABNORMAL	1	0.1	1	0.1
MANIC REACTION	1	0.1	1	0.1
NEPHRITIS	1	0.1	1	0.1
NEUROVASCULAR COMPRESSION	1	0.1	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

	Paroxetine (N=775)		Placebo (N=737)	
Preferred Term	n	%	n	%
PHOTOPHOBIA	1	0.1	1	0.1
SKIN BENIGN NEOPLASM	1	0.1	1	0.1
THYROID DISORDER	1	0.1	1	0.1
TOOTH CARIES	1	0.1	1	0.1
ALCOHOL ABUSE	1	0.1	0	0.0
ASTHMA	1	0.1	0	0.0
BONE DISORDER	1	0.1	0	0.0
BRADYCARDIA	1	0.1	0	0.0
BURSITIS	1	0.1	0	0.0
COLITIS	1	0.1	0	0.0
CONVULSION	1	0.1	0	0.0
EAR DISORDER	1	0.1	0	0.0
ECZEMA	1	0.1	0	0.0
EDEMA	1	0.1	0	0.0
EYE APPENDAGE DISORDER	1	0.1	0	0.0
EYE PAIN	1	0.1	0	0.0
GASTROINTESTINAL HEMORRHAGE	1	0.1	0	0.0
GLYCOSURIA	1	0.1	0	0.0
HALLUCINATIONS	1	0.1	0	0.0
HICCUP	1	0.1	0	0.0
HYPERVENTILATION	1	0.1	0	0.0
HYPOKINESIA	1	0.1	0	0.0
INCOORDINATION	1	0.1	0	0.0
LYMPHADENOPATHY	1	0.1	0	0.0
NECK PAIN	1	0.1	0	0.0
NEOPLASM	1	0.1	0	0.0
PERIPHERAL VASCULAR DISORDER	1	0.1	0	0.0
POLYURIA	1	0.1	0	0.0
PUSTULAR RASH	1	0.1	0	0.0
RECTAL DISORDER	1	0.1	0	0.0
RECTAL HEMORRHAGE	1	0.1	0	0.0
RESPIRATORY FLU	1	0.1	0	0.0
STOMATITIS	1	0.1	0	0.0
SWEAT GLAND DISORDER	1	0.1	0	0.0
TONGUE DISCOLORATION	1	0.1	0	0.0
URINARY RETENTION	1	0.1	0	0.0
VISION DISORDERS	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

	Paroxetine (N=775)		Placebo (N=737)	
Preferred Term	n	%	n	%
VOICE ALTERATION	1	0.1	0	0.0
PENIS DISORDER *	0	0.0	1	0.7
HERPES SIMPLEX	0	0.0	4	0.5
ATAXIA	0	0.0	3	0.4
EPISTAXIS	0	0.0	3	0.4
MELENA	0	0.0	3	0.4
AMNESIA	0	0.0	2	0.3
CELLULITIS	0	0.0	2	0.3
CEREBROVASCULAR DISORDER	0	0.0	2	0.3
CONTACT DERMATITIS	0	0.0	2	0.3
EAR PAIN	0	0.0	2	0.3
LEUKOPENIA	0	0.0	2	0.3
MACULOPAPULAR RASH	0	0.0	2	0.3
MYOSITIS	0	0.0	2	0.3
NEUROPATHY	0	0.0	2	0.3
PAPANICOLAU SMEAR SUSPICIOUS **	0	0.0	2	0.3
TENDINOUS DISORDER	0	0.0	2	0.3
ABORTION **	0	0.0	1	0.2
AMENORRHEA **	0	0.0	1	0.2
MASTITIS **	0	0.0	1	0.2
BLINDNESS	0	0.0	1	0.1
CARDIOVASCULAR DISORDER	0	0.0	1	0.1
DERMATOSES, GENERAL	0	0.0	1	0.1
DIPLOPIA	0	0.0	1	0.1
DYSURIA	0	0.0	1	0.1
EYE HEMORRHAGE	0	0.0	1	0.1
FECAL INCONTINENCE	0	0.0	1	0.1
FUNGAL DERMATITIS	0	0.0	1	0.1
GOITER	0	0.0	1	0.1
HAIR DISORDERS	0	0.0	1	0.1
HEMATEMESIS	0	0.0	1	0.1
MELANOSIS	0	0.0	1	0.1
MYOCARDIAL INFARCT	0	0.0	1	0.1
NAIL DISORDER	0	0.0	1	0.1
NEUROSIS	0	0.0	1	0.1
NYSTAGMUS	0	0.0	1	0.1
PARALYSIS	0	0.0	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 10 mg

Preferred Term	Paroxetine (N=775) n	%	Placebo (N=737) n	%
PEPTIC ULCER	0	0.0	1	0.1
PHOTOSENSITIVITY	0	0.0	1	0.1
PLEURA DISORDER	0	0.0	1	0.1
SEBORRHEA	0	0.0	1	0.1
SKIN DISCOLORATION	0	0.0	1	0.1
SKIN DISORDER	0	0.0	1	0.1
SKIN ULCER	0	0.0	1	0.1
SPEECH DISORDER	0	0.0	1	0.1
THROMBOCYTOPENIA	0	0.0	1	0.1
VASCULAR ANOMALY	0	0.0	1	0.1
VISUAL FIELD DEFECT	0	0.0	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

Preferred Term	Paroxetine (N=1405) n	%	Placebo (N=1324) n	%
TOTAL	1174	83.6	987	74.5
Total Male Subjects *	439	100.0	411	100.0
Total Male-Specific AEs *	94	21.4	13	3.2
Total Female Subjects **	966	100.0	913	100.0
Total Female-Specific AEs **	136	14.1	96	10.5
Total Non Gender-Specific AEs	1163	82.8	975	73.6
HEADACHE	322	22.9	330	24.9
NAUSEA	295	21.0	117	8.8
SOMNOLENCE	224	15.9	84	6.3
ABNORMAL EJACULATION *	69	15.7	8	1.9
ASTHENIA	210	14.9	71	5.4
INSOMNIA	179	12.7	108	8.2
DRY MOUTH	172	12.2	77	5.8
DIARRHEA	161	11.5	88	6.6
DIZZINESS	160	11.4	75	5.7
LIBIDO DECREASED	134	9.5	41	3.1
RESPIRATORY DISORDER	132	9.4	126	9.5
SWEATING	100	7.1	14	1.1
CONSTIPATION	99	7.0	53	4.0
FEMALE GENITAL DISORDERS **	68	7.0	8	0.9
INFECTION	85	6.0	77	5.8
NERVOUSNESS	77	5.5	61	4.6
IMPOTENCE *	24	5.5	5	1.2
TREMOR	76	5.4	8	0.6
ABDOMINAL PAIN	71	5.1	48	3.6
DYSPEPSIA	70	5.0	61	4.6
DECREASED APPETITE	70	5.0	15	1.1
TRAUMA	68	4.8	57	4.3
SINUSITIS	63	4.5	69	5.2
ANXIETY	60	4.3	29	2.2
BACK PAIN	50	3.6	59	4.5
YAWN	48	3.4	3	0.2
PHARYNGITIS	44	3.1	46	3.5
ABNORMAL DREAMS	43	3.1	18	1.4
DYSMENORRHEA **	29	3.0	44	4.8
CONCENTRATION IMPAIRED	41	2.9	12	0.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
VOMITING	32	2.3	30	2.3
WEIGHT GAIN	32	2.3	22	1.7
INCREASED APPETITE	32	2.3	18	1.4
MYALGIA	31	2.2	46	3.5
ARTHRALGIA	31	2.2	34	2.6
FLATULENCE	31	2.2	31	2.3
AGITATION	31	2.2	27	2.0
ABNORMAL VISION	30	2.1	8	0.6
URINARY FREQUENCY	28	2.0	13	1.0
PAIN	26	1.9	35	2.6
RHINITIS	25	1.8	29	2.2
MENSTRUAL DISORDER **	16	1.7	14	1.5
DEPRESSION	23	1.6	34	2.6
PARESTHESIA	23	1.6	18	1.4
PALPITATION	22	1.6	23	1.7
URINARY TRACT INFECTION	22	1.6	21	1.6
VASODILATATION	22	1.6	10	0.8
MIGRAINE	19	1.4	20	1.5
CHEST PAIN	19	1.4	17	1.3
MYOCLONUS	19	1.4	7	0.5
COUGH INCREASED	18	1.3	21	1.6
TOOTH DISORDER	17	1.2	24	1.8
BRONCHITIS	17	1.2	18	1.4
HYPERTONIA	17	1.2	14	1.1
VAGINITIS **	12	1.2	3	0.3
FEVER	16	1.1	12	0.9
BRUXISM	16	1.1	0	0.0
HYPERKINESIA	15	1.1	5	0.4
RASH	14	1.0	23	1.7
ALLERGIC REACTION	14	1.0	22	1.7
LACK OF EMOTION	13	0.9	8	0.6
FLU SYNDROME	13	0.9	7	0.5
CONFUSION	13	0.9	4	0.3
TACHYCARDIA	13	0.9	4	0.3
EMOTIONAL LABILITY	12	0.9	17	1.3
TASTE PERVERSION	12	0.9	5	0.4
MALE GENITAL DISORDERS *	4	0.9	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
TINNITUS	11	0.8	10	0.8
DEPERSONALIZATION	11	0.8	6	0.5
DYSPHAGIA	11	0.8	1	0.1
GINGIVITIS	10	0.7	13	1.0
GASTROINTESTINAL DISORDER	10	0.7	10	0.8
AMNESIA	10	0.7	7	0.5
VERTIGO	10	0.7	6	0.5
WEIGHT LOSS	10	0.7	6	0.5
EAR PAIN	10	0.7	2	0.2
URINATION IMPAIRED	10	0.7	1	0.1
VAGINAL MONILIASIS **	7	0.7	11	1.2
PRURITUS	9	0.6	11	0.8
CONJUNCTIVITIS	9	0.6	9	0.7
HYPERTENSION	9	0.6	9	0.7
ACNE	9	0.6	7	0.5
HYPESTHESIA	9	0.6	5	0.4
OTITIS MEDIA	9	0.6	4	0.3
DYSPNEA	8	0.6	10	0.8
GASTROENTERITIS	8	0.6	7	0.5
THINKING ABNORMAL	8	0.6	5	0.4
ARTHRITIS	8	0.6	4	0.3
PNEUMONIA	8	0.6	3	0.2
RECTAL DISORDER	8	0.6	1	0.1
HERPES SIMPLEX	7	0.5	11	0.8
THIRST	7	0.5	5	0.4
DYSURIA	7	0.5	4	0.3
POSTURAL HYPOTENSION	7	0.5	3	0.2
KERATOCONJUNCTIVITIS	7	0.5	1	0.1
ECZEMA	7	0.5	0	0.0
PROSTATE DISORDER *	2	0.5	1	0.2
PERIPHERAL EDEMA	6	0.4	10	0.8
ANEMIA	6	0.4	7	0.5
PURPURA	6	0.4	5	0.4
SYNCOPE	6	0.4	2	0.2
MYASTHENIA	6	0.4	1	0.1
EPISTAXIS	5	0.4	8	0.6
ARTHROSIS	5	0.4	6	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
ATAXIA	5	0.4	3	0.2
CHILLS	5	0.4	3	0.2
DYSTONIA	5	0.4	3	0.2
ULCERATIVE STOMATITIS	5	0.4	2	0.2
MALAISE	5	0.4	1	0.1
MENORRHAGIA **	4	0.4	11	1.2
METRORRHAGIA **	4	0.4	3	0.3
VAGINAL HEMORRHAGE **	4	0.4	1	0.1
ABNORMAL LABORATORY VALUE	4	0.3	4	0.3
HYPOTENSION	4	0.3	3	0.2
ASTHMA	4	0.3	2	0.2
INTENTIONAL OVERDOSE	4	0.3	2	0.2
PLEURA DISORDER	4	0.3	2	0.2
URTICARIA	4	0.3	2	0.2
EAR DISORDER	4	0.3	1	0.1
EYE DISORDER	4	0.3	1	0.1
SKIN DISORDER	4	0.3	1	0.1
OROPHARYNX DISORDER	4	0.3	0	0.0
VISION DISORDERS	4	0.3	0	0.0
BREAST PAIN **	3	0.3	3	0.3
LIVER FUNCTION TESTS ABNORMAL	3	0.2	4	0.3
CONTACT DERMATITIS	3	0.2	3	0.2
HOSTILITY	3	0.2	3	0.2
LEUKOPENIA	3	0.2	3	0.2
BLURRED VISION	3	0.2	2	0.2
EYE PAIN	3	0.2	1	0.1
HYPOCHROMIC ANEMIA	3	0.2	1	0.1
LIBIDO INCREASED	3	0.2	1	0.1
EXTRASYSTOLES	3	0.2	0	0.0
HYPOKINESIA	3	0.2	0	0.0
INCOORDINATION	3	0.2	0	0.0
NEURALGIA	3	0.2	0	0.0
SURGICAL PROCEDURE	3	0.2	0	0.0
AMENORRHEA **	2	0.2	2	0.2
ENDOMETRIAL DISORDER **	2	0.2	1	0.1
OVARY DISORDER **	2	0.2	1	0.1
UNINTENDED PREGNANCY **	2	0.2	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
CYSTITIS	2	0.1	9	0.7
KIDNEY CALCULUS	2	0.1	5	0.4
TENDINOUS DISORDER	2	0.1	5	0.4
DRY SKIN	2	0.1	4	0.3
ELECTROCARDIOGRAM ABNORMAL	2	0.1	3	0.2
ALCOHOL ABUSE	2	0.1	2	0.2
BONE DISORDER	2	0.1	2	0.2
ERUCTATION	2	0.1	2	0.2
LARYNX DISORDER	2	0.1	2	0.2
MANIC REACTION	2	0.1	2	0.2
NEUROSIS	2	0.1	2	0.2
PARALYSIS	2	0.1	2	0.2
SGPT INCREASED	2	0.1	2	0.2
ARRHYTHMIA	2	0.1	1	0.1
EDEMA	2	0.1	1	0.1
FUNGAL DERMATITIS	2	0.1	1	0.1
HYPERGLYCEMIA	2	0.1	1	0.1
LEUKOCYTOSIS	2	0.1	1	0.1
MONILIASIS	2	0.1	1	0.1
NEOPLASM	2	0.1	1	0.1
NYSTAGMUS	2	0.1	1	0.1
PHOTOSENSITIVITY	2	0.1	1	0.1
RECTAL HEMORRHAGE	2	0.1	1	0.1
SKIN BENIGN NEOPLASM	2	0.1	1	0.1
THYROID DISORDER	2	0.1	1	0.1
URINARY RETENTION	2	0.1	1	0.1
URINE ABNORMALITY	2	0.1	1	0.1
VESTIBULAR DISORDER	2	0.1	1	0.1
ABNORMAL GAIT	2	0.1	0	0.0
ABSCESS	2	0.1	0	0.0
BILIRUBINEMIA	2	0.1	0	0.0
BLEPHARITIS	2	0.1	0	0.0
DRUGGED FEELING	2	0.1	0	0.0
FURUNCULOSIS	2	0.1	0	0.0
HERPES ZOSTER	2	0.1	0	0.0
HYPERVENTILATION	2	0.1	0	0.0
MYOPATHY	2	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
NOCTURIA	2	0.1	0	0.0
OTITIS EXTERNA	2	0.1	0	0.0
PARANOID REACTION	2	0.1	0	0.0
PHLEBITIS	2	0.1	0	0.0
SUPRAVENTRICULAR TACHYCARDIA	2	0.1	0	0.0
TORTICOLLIS	2	0.1	0	0.0
VESICULOBULLOUS RASH	2	0.1	0	0.0
HAEMATURIA	1	0.1	7	0.5
GASTRITIS	1	0.1	5	0.4
SKIN HYPERTROPHY	1	0.1	4	0.3
MELENA	1	0.1	3	0.2
TOOTH CARIES	1	0.1	3	0.2
BURSITIS	1	0.1	2	0.2
CARDIOVASCULAR DISORDER	1	0.1	2	0.2
HAIR DISORDERS	1	0.1	2	0.2
HYPERCHOLESTEREMIA	1	0.1	2	0.2
MACULOPAPULAR RASH	1	0.1	2	0.2
NAIL DISORDER	1	0.1	2	0.2
NEUROPATHY	1	0.1	2	0.2
AV BLOCK	1	0.1	1	0.1
DIABETES MELLITUS	1	0.1	1	0.1
DIGESTIVE SYSTEM DISORDER	1	0.1	1	0.1
EOSINOPHILIA	1	0.1	1	0.1
GENERALIZED EDEMA	1	0.1	1	0.1
GLYCOSURIA	1	0.1	1	0.1
HALLUCINATIONS	1	0.1	1	0.1
HYPERTHYROIDISM	1	0.1	1	0.1
INCREASED SALIVATION	1	0.1	1	0.1
NAUSEA AND VOMITING	1	0.1	1	0.1
NEPHRITIS	1	0.1	1	0.1
SKIN DISCOLORATION	1	0.1	1	0.1
STOMATITIS	1	0.1	1	0.1
UTERINE FIBROIDS ENLARGED **	1	0.1	1	0.1
ANAPHYLACTOID REACTION	1	0.1	0	0.0
ANISOCORIA	1	0.1	0	0.0
APHASIA	1	0.1	0	0.0
BLEEDING TIME INCREASED	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
BONE PAIN	1	0.1	0	0.0
BRADYCARDIA	1	0.1	0	0.0
CARDIOSPASM	1	0.1	0	0.0
CERVICITIS **	1	0.1	0	0.0
CHOLECYSTITIS	1	0.1	0	0.0
CONVULSION	1	0.1	0	0.0
DEAFNESS	1	0.1	0	0.0
DRUG DEPENDENCE	1	0.1	0	0.0
DUODENITIS	1	0.1	0	0.0
DYSPARUNIA **	1	0.1	0	0.0
EMPHYSEMA	1	0.1	0	0.0
EUPHORIA	1	0.1	0	0.0
EXFOLIATIVE DERMATITIS	1	0.1	0	0.0
FERTILITY DECREASED FEMALE **	1	0.1	0	0.0
FIBROCYSTIC BREAST **	1	0.1	0	0.0
GASTROINTESTINAL FLU	1	0.1	0	0.0
GLOSSITIS	1	0.1	0	0.0
HYPOGLYCEMIA	1	0.1	0	0.0
HYPOTHERMIA	1	0.1	0	0.0
HYPOTHYROIDISM	1	0.1	0	0.0
LEUKORRHEA	1	0.1	0	0.0
LYMPHADENOPATHY	1	0.1	0	0.0
LYMPHOMA LIKE REACTION	1	0.1	0	0.0
MANIC DEPRESSIVE REACTION	1	0.1	0	0.0
MYDRIASIS	1	0.1	0	0.0
NPN INCREASED	1	0.1	0	0.0
OBESITY	1	0.1	0	0.0
PAROSMIA	1	0.1	0	0.0
POLYURIA	1	0.1	0	0.0
PUNCTURE SITE REACTION	1	0.1	0	0.0
PUPILLARY DISORDER	1	0.1	0	0.0
PYURIA	1	0.1	0	0.0
REFLEXES INCREASED	1	0.1	0	0.0
SALPINGITIS	1	0.1	0	0.0
SKIN CARCINOMA	1	0.1	0	0.0
STOMACH ULCER	1	0.1	0	0.0
STUPOR	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
THROMBOPHLEBITIS	1	0.1	0	0.0
TRAUMATIC FRACTURE	1	0.1	0	0.0
URINARY CASTS	1	0.1	0	0.0
URINARY TRACT DISORDER	1	0.1	0	0.0
UTERINE NEOPLASM	1	0.1	0	0.0
UTERUS DISORDERS **	1	0.1	0	0.0
WITHDRAWAL SYNDROME	1	0.1	0	0.0
PAPANICOLAU SMEAR SUSPICIOUS **	0	0.0	3	0.3
ALOPECIA	0	0.0	3	0.2
CELLULITIS	0	0.0	3	0.2
ALBUMINURIA	0	0.0	2	0.2
CEREBROVASCULAR DISORDER	0	0.0	2	0.2
COLITIS	0	0.0	2	0.2
ESOPHAGITIS	0	0.0	2	0.2
EYE HEMORRHAGE	0	0.0	2	0.2
HEMOPTYSIS	0	0.0	2	0.2
HYPERLIPEMIA	0	0.0	2	0.2
MYOSITIS	0	0.0	2	0.2
SPEECH DISORDER	0	0.0	2	0.2
PENIS DISORDER *	0	0.0	1	0.2
ABORTION **	0	0.0	1	0.1
ANGINA PECTORIS	0	0.0	1	0.1
BLINDNESS	0	0.0	1	0.1
BREAST CARCINOMA **	0	0.0	1	0.1
BREAST ENLARGEMENT **	0	0.0	1	0.1
CNS STIMULATION	0	0.0	1	0.1
DERMATOSES, GENERAL	0	0.0	1	0.1
DIPLOPIA	0	0.0	1	0.1
DYSKINESIA	0	0.0	1	0.1
FECAL INCONTINENCE	0	0.0	1	0.1
GALL BLADDER DISORDER	0	0.0	1	0.1
GOITER	0	0.0	1	0.1
HEMATEMESIS	0	0.0	1	0.1
HIRSUTISM	0	0.0	1	0.1
INTRACRANIAL HYPERTENSION	0	0.0	1	0.1
MASTITIS **	0	0.0	1	0.1
MELANOSIS	0	0.0	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 20 mg

	Paroxetine (N=1405)		Placebo (N=1324)	
Preferred Term	n	%	n	%
MONOCYTOSIS	0	0.0	1	0.1
MYOCARDIAL INFARCT	0	0.0	1	0.1
NECK RIGIDITY	0	0.0	1	0.1
NEUROVASCULAR COMPRESSION	0	0.0	1	0.1
PEPTIC ULCER	0	0.0	1	0.1
PERIODONTAL ABSCESS	0	0.0	1	0.1
PHOTOPHOBIA	0	0.0	1	0.1
PNEUMOTHORAX	0	0.0	1	0.1
SEBORRHEA	0	0.0	1	0.1
SGOT INCREASED	0	0.0	1	0.1
SKIN ULCER	0	0.0	1	0.1
SWEATING DECREASED	0	0.0	1	0.1
THROMBOCYTHEMIA	0	0.0	1	0.1
THROMBOCYTOPENIA	0	0.0	1	0.1
VASCULAR ANOMALY	0	0.0	1	0.1
VISUAL FIELD DEFECT	0	0.0	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 30 mg

	Paroxetine (N=150)		Placebo (N=101)	
Preferred Term	n	%	n	%
TOTAL	124	82.7	59	58.4
Total Male Subjects *	65	100.0	42	100.0
Total Male-Specific AEs *	12	18.5	0	0.0
Total Female Subjects **	85	100.0	59	100.0
Total Female-Specific AEs **	2	2.4	1	1.7
Total Non Gender-Specific AEs	124	82.7	59	58.4
NAUSEA	50	33.3	14	13.9
SOMNOLENCE	32	21.3	6	5.9
HEADACHE	22	14.7	9	8.9
DRY MOUTH	22	14.7	3	3.0
ASTHENIA	17	11.3	4	4.0
INSOMNIA	15	10.0	9	8.9
DIZZINESS	15	10.0	6	5.9
CONSTIPATION	15	10.0	3	3.0
TREMOR	15	10.0	0	0.0
ABNORMAL EJACULATION *	6	9.2	0	0.0
SWEATING	13	8.7	2	2.0
IMPOTENCE *	5	7.7	0	0.0
DIARRHEA	11	7.3	6	5.9
DYSPEPSIA	9	6.0	7	6.9
ABDOMINAL PAIN	7	4.7	2	2.0
VOMITING	7	4.7	1	1.0
ANXIETY	7	4.7	0	0.0
MALE GENITAL DISORDERS *	3	4.6	0	0.0
RESPIRATORY DISORDER	6	4.0	5	5.0
DECREASED APPETITE	6	4.0	3	3.0
PALPITATION	5	3.3	3	3.0
PARESTHESIA	5	3.3	2	2.0
TASTE PERVERSION	5	3.3	2	2.0
NERVOUSNESS	5	3.3	1	1.0
VASODILATATION	5	3.3	1	1.0
DRUGGED FEELING	5	3.3	0	0.0
LIBIDO DECREASED	5	3.3	0	0.0
CHILLS	4	2.7	1	1.0
INCREASED APPETITE	4	2.7	0	0.0
YAWN	4	2.7	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 30 mg

	Paroxetine (N=150)		Placebo (N=101)	
Preferred Term	n	%	n	%
BLURRED VISION	3	2.0	3	3.0
AGITATION	3	2.0	0	0.0
OROPHARYNX DISORDER	3	2.0	0	0.0
SYNCOPE	3	2.0	0	0.0
TACHYCARDIA	3	2.0	0	0.0
TINNITUS	3	2.0	0	0.0
ABNORMAL DREAMS	2	1.3	3	3.0
FLATULENCE	2	1.3	3	3.0
MYALGIA	2	1.3	3	3.0
TRAUMA	2	1.3	2	2.0
BACK PAIN	2	1.3	1	1.0
DYSPNEA	2	1.3	1	1.0
POSTURAL HYPOTENSION	2	1.3	1	1.0
URINARY FREQUENCY	2	1.3	1	1.0
ALCOHOL ABUSE	2	1.3	0	0.0
BRONCHITIS	2	1.3	0	0.0
BRUXISM	2	1.3	0	0.0
DEPRESSION	2	1.3	0	0.0
FLU SYNDROME	2	1.3	0	0.0
MALAISE	2	1.3	0	0.0
MYOCARDIAL ISCHEMIA	2	1.3	0	0.0
OTITIS MEDIA	2	1.3	0	0.0
TOOTH DISORDER	2	1.3	0	0.0
URINATION IMPAIRED	2	1.3	0	0.0
FEMALE GENITAL DISORDERS **	1	1.2	0	0.0
MASTITIS **	1	1.2	0	0.0
PHARYNGITIS	1	0.7	4	4.0
RASH	1	0.7	2	2.0
CYSTITIS	1	0.7	1	1.0
DEPERSONALIZATION	1	0.7	1	1.0
INFECTION	1	0.7	1	1.0
PRURITUS	1	0.7	1	1.0
WEIGHT LOSS	1	0.7	1	1.0
ACNE	1	0.7	0	0.0
CONCENTRATION IMPAIRED	1	0.7	0	0.0
CONTACT DERMATITIS	1	0.7	0	0.0
EMOTIONAL LABILITY	1	0.7	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 30 mg

Preferred Term	Paroxetine (N=150) n	%	Placebo (N=101) n	%
EPISTAXIS	1	0.7	0	0.0
EYE DISORDER	1	0.7	0	0.0
EYE PAIN	1	0.7	0	0.0
FEVER	1	0.7	0	0.0
GASTROINTESTINAL FLU	1	0.7	0	0.0
GLOSSITIS	1	0.7	0	0.0
HYPERTENSION	1	0.7	0	0.0
HYPERVENTILATION	1	0.7	0	0.0
INCREASED SALIVATION	1	0.7	0	0.0
KIDNEY CALCULUS	1	0.7	0	0.0
MOUTH ULCERATION	1	0.7	0	0.0
MYASTHENIA	1	0.7	0	0.0
MYOCLONUS	1	0.7	0	0.0
NAUSEA AND VOMITING	1	0.7	0	0.0
NECK PAIN	1	0.7	0	0.0
PERIPHERAL EDEMA	1	0.7	0	0.0
RHINITIS	1	0.7	0	0.0
SURGICAL PROCEDURE	1	0.7	0	0.0
URTICARIA	1	0.7	0	0.0
VERTIGO	1	0.7	0	0.0
VISION DISORDERS	1	0.7	0	0.0
WEIGHT GAIN	1	0.7	0	0.0
CHEST PAIN	0	0.0	3	3.0
CNS STIMULATION	0	0.0	2	2.0
CONFUSION	0	0.0	2	2.0
DYSMENORRHEA **	0	0.0	1	1.7
AMNESIA	0	0.0	1	1.0
ARTHRALGIA	0	0.0	1	1.0
COUGH INCREASED	0	0.0	1	1.0
DERMATOSES, GENERAL	0	0.0	1	1.0
DYSARTHRIA	0	0.0	1	1.0
MANIC REACTION	0	0.0	1	1.0
OVERDOSE	0	0.0	1	1.0
PAIN	0	0.0	1	1.0
SKIN DISCOLORATION	0	0.0	1	1.0
THIRST	0	0.0	1	1.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
TOTAL	739	84.6	611	75.4
Total Male Subjects *	391	100.0	350	100.0
Total Male-Specific AEs *	131	33.5	9	2.6
Total Female Subjects **	483	100.0	460	100.0
Total Female-Specific AEs **	44	9.1	44	9.6
Total Non Gender-Specific AEs	735	84.1	609	75.2
ABNORMAL EJACULATION *	105	26.9	5	1.4
NAUSEA	211	24.1	82	10.1
HEADACHE	205	23.5	202	24.9
SOMNOLENCE	173	19.8	59	7.3
INSOMNIA	146	16.7	95	11.7
ASTHENIA	145	16.6	37	4.6
DRY MOUTH	127	14.5	44	5.4
DIARRHEA	101	11.6	59	7.3
DIZZINESS	97	11.1	61	7.5
CONSTIPATION	97	11.1	41	5.1
TREMOR	81	9.3	8	1.0
IMPOTENCE *	32	8.2	5	1.4
SWEATING	69	7.9	12	1.5
RESPIRATORY DISORDER	65	7.4	70	8.6
LIBIDO DECREASED	65	7.4	13	1.6
ANXIETY	61	7.0	35	4.3
DECREASED APPETITE	51	5.8	11	1.4
NERVOUSNESS	48	5.5	40	4.9
FEMALE GENITAL DISORDERS **	24	5.0	3	0.7
INFECTION	37	4.2	39	4.8
TRAUMA	35	4.0	40	4.9
DYSPEPSIA	34	3.9	43	5.3
ABDOMINAL PAIN	32	3.7	34	4.2
EMOTIONAL LABILITY	31	3.5	29	3.6
PARESTHESIA	29	3.3	16	2.0
VASODILATATION	29	3.3	6	0.7
MYALGIA	27	3.1	32	4.0
SINUSITIS	26	3.0	32	4.0
YAWN	26	3.0	0	0.0
RASH	25	2.9	15	1.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
FLU SYNDROME	25	2.9	10	1.2
ABNORMAL VISION	25	2.9	6	0.7
BACK PAIN	24	2.7	40	4.9
AGITATION	24	2.7	20	2.5
CONCENTRATION IMPAIRED	24	2.7	8	1.0
DYSMENORRHEA **	13	2.7	16	3.5
PHARYNGITIS	23	2.6	29	3.6
MYOCLONUS	22	2.5	7	0.9
DEPRESSION	21	2.4	30	3.7
VOMITING	21	2.4	17	2.1
ABNORMAL DREAMS	21	2.4	14	1.7
RHINITIS	18	2.1	20	2.5
WEIGHT GAIN	18	2.1	9	1.1
FLATULENCE	17	1.9	19	2.3
PALPITATION	14	1.6	17	2.1
INCREASED APPETITE	14	1.6	11	1.4
ALLERGIC REACTION	13	1.5	15	1.9
MIGRAINE	13	1.5	15	1.9
URINARY FREQUENCY	13	1.5	8	1.0
CONFUSION	13	1.5	4	0.5
PAIN	12	1.4	26	3.2
FEVER	12	1.4	10	1.2
URINATION IMPAIRED	12	1.4	1	0.1
AMNESIA	11	1.3	7	0.9
SYNCOPE	11	1.3	7	0.9
LACK OF EMOTION	11	1.3	4	0.5
CHEST PAIN	10	1.1	15	1.9
BRONCHITIS	10	1.1	13	1.6
TINNITUS	10	1.1	10	1.2
HYPERTONIA	10	1.1	6	0.7
ARTHRALGIA	9	1.0	21	2.6
INTENTIONAL OVERDOSE	9	1.0	13	1.6
HYPERTENSION	9	1.0	6	0.7
PRURITUS	9	1.0	6	0.7
CHILLS	9	1.0	3	0.4
BLURRED VISION	9	1.0	1	0.1
COUGH INCREASED	8	0.9	13	1.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
URINARY TRACT INFECTION	8	0.9	10	1.2
DEPERSONALIZATION	8	0.9	4	0.5
HYPERKINESIA	8	0.9	4	0.5
TOOTH DISORDER	7	0.8	12	1.5
CNS STIMULATION	7	0.8	8	1.0
GINGIVITIS	7	0.8	7	0.9
DYSPNEA	7	0.8	6	0.7
VERTIGO	7	0.8	5	0.6
MALE GENITAL DISORDERS *	3	0.8	0	0.0
CYSTITIS	6	0.7	7	0.9
TASTE PERVERSION	6	0.7	5	0.6
HYPESTHESIA	6	0.7	3	0.4
THIRST	6	0.7	2	0.2
DRUGGED FEELING	6	0.7	1	0.1
HAEMATOMA	6	0.7	1	0.1
BRUXISM	6	0.7	0	0.0
DYSPHAGIA	6	0.7	0	0.0
ALCOHOL ABUSE	5	0.6	9	1.1
GASTROINTESTINAL DISORDER	5	0.6	7	0.9
DYSURIA	5	0.6	4	0.5
THINKING ABNORMAL	5	0.6	4	0.5
MALAISE	5	0.6	3	0.4
WEIGHT LOSS	5	0.6	3	0.4
HYPOKINESIA	5	0.6	0	0.0
MENSTRUAL DISORDER **	3	0.6	6	1.3
AMENORRHEA **	3	0.6	1	0.2
VAGINITIS **	3	0.6	1	0.2
CONJUNCTIVITIS	4	0.5	6	0.7
EPISTAXIS	4	0.5	5	0.6
TACHYCARDIA	4	0.5	5	0.6
NAUSEA AND VOMITING	4	0.5	4	0.5
PERIPHERAL EDEMA	4	0.5	4	0.5
LIVER FUNCTION TESTS ABNORMAL	4	0.5	3	0.4
PURPURA	4	0.5	2	0.2
MYASTHENIA	4	0.5	1	0.1
ANEMIA	4	0.5	0	0.0
ATAXIA	4	0.5	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
PHOTOSENSITIVITY	4	0.5	0	0.0
ACNE	3	0.3	4	0.5
ASTHMA	3	0.3	3	0.4
ANGINA PECTORIS	3	0.3	2	0.2
ARTHRITIS	3	0.3	2	0.2
COLITIS	3	0.3	2	0.2
HALLUCINATIONS	3	0.3	2	0.2
PARALYSIS	3	0.3	2	0.2
POSTURAL HYPOTENSION	3	0.3	2	0.2
MELENA	3	0.3	1	0.1
URTICARIA	3	0.3	1	0.1
ABNORMALITY OF ACCOMMODATION	3	0.3	0	0.0
FACE EDEMA	3	0.3	0	0.0
LIBIDO INCREASED	3	0.3	0	0.0
PROSTATE DISORDER *	1	0.3	1	0.3
TESTES DISORDER *	1	0.3	0	0.0
HERPES SIMPLEX	2	0.2	7	0.9
DYSTONIA	2	0.2	3	0.4
ERUCTATION	2	0.2	3	0.4
TENDINOUS DISORDER	2	0.2	3	0.4
INCOORDINATION	2	0.2	2	0.2
PNEUMONIA	2	0.2	2	0.2
TOOTH CARIES	2	0.2	2	0.2
VISION DISORDERS	2	0.2	2	0.2
DYSKINESIA	2	0.2	1	0.1
EDEMA	2	0.2	1	0.1
HYSTERIA	2	0.2	1	0.1
LEUKOPENIA	2	0.2	1	0.1
MANIC REACTION	2	0.2	1	0.1
RECTAL HEMORRHAGE	2	0.2	1	0.1
SGOT INCREASED	2	0.2	1	0.1
URINARY RETENTION	2	0.2	1	0.1
VESTIBULAR DISORDER	2	0.2	1	0.1
ALKALINE PHOSPHATASE INCREASED	2	0.2	0	0.0
ANTISOCIAL REACTION	2	0.2	0	0.0
BILIRUBINEMIA	2	0.2	0	0.0
BUCCAL CAVITY DISORDERS	2	0.2	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
EAR PAIN	2	0.2	0	0.0
EYE DISORDER	2	0.2	0	0.0
HERNIA	2	0.2	0	0.0
HYPOCHROMIC ANEMIA	2	0.2	0	0.0
MYOPATHY	2	0.2	0	0.0
NECK PAIN	2	0.2	0	0.0
NOCTURIA	2	0.2	0	0.0
PERIPHERAL VASCULAR DISORDER	2	0.2	0	0.0
PYURIA	2	0.2	0	0.0
OVARY DISORDER **	1	0.2	2	0.4
UNINTENDED PREGNANCY **	1	0.2	1	0.2
VAGINAL MONILIASIS **	1	0.2	1	0.2
FEMALE BREAST DISORDERS **	1	0.2	0	0.0
MASTITIS **	1	0.2	0	0.0
ARTHROSIS	1	0.1	6	0.7
HAEMATURIA	1	0.1	6	0.7
GASTROENTERITIS	1	0.1	4	0.5
OTITIS MEDIA	1	0.1	4	0.5
HOSTILITY	1	0.1	3	0.4
HYPOTENSION	1	0.1	3	0.4
SPEECH DISORDER	1	0.1	3	0.4
ALBUMINURIA	1	0.1	2	0.2
BONE DISORDER	1	0.1	2	0.2
BURSITIS	1	0.1	2	0.2
HYPERVENTILATION	1	0.1	2	0.2
KIDNEY CALCULUS	1	0.1	2	0.2
SGPT INCREASED	1	0.1	2	0.2
SKIN HYPERTROPHY	1	0.1	2	0.2
TRAUMATIC FRACTURE	1	0.1	2	0.2
BULIMIA	1	0.1	1	0.1
CELLULITIS	1	0.1	1	0.1
DRY SKIN	1	0.1	1	0.1
EAR DISORDER	1	0.1	1	0.1
ESOPHAGITIS	1	0.1	1	0.1
EYE HEMORRHAGE	1	0.1	1	0.1
FUNGAL DERMATITIS	1	0.1	1	0.1
FURUNCULOSIS	1	0.1	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
HYPERGLYCEMIA	1	0.1	1	0.1
HYPOGLYCEMIA	1	0.1	1	0.1
KERATOCONJUNCTIVITIS	1	0.1	1	0.1
LEUKOCYTOSIS	1	0.1	1	0.1
MACULOPAPULAR RASH	1	0.1	1	0.1
NAIL DISORDER	1	0.1	1	0.1
NEOPLASM	1	0.1	1	0.1
NYSTAGMUS	1	0.1	1	0.1
PARANOID REACTION	1	0.1	1	0.1
PHOTOPHOBIA	1	0.1	1	0.1
SKIN DISCOLORATION	1	0.1	1	0.1
STOMATITIS	1	0.1	1	0.1
URINE ABNORMALITY	1	0.1	1	0.1
ACCIDENTAL OVERDOSE	1	0.1	0	0.0
ASPIRATION PNEUMONIA	1	0.1	0	0.0
ATRIAL FIBRILLATION	1	0.1	0	0.0
BLOODY DIARRHEA	1	0.1	0	0.0
CARCINOMA OF LARYNX	1	0.1	0	0.0
CARDIAC DISORDERS	1	0.1	0	0.0
CHILLS AND FEVER	1	0.1	0	0.0
DEAFNESS	1	0.1	0	0.0
DELIRIUM	1	0.1	0	0.0
DIABETES MELLITUS	1	0.1	0	0.0
ECCHYMOSIS	1	0.1	0	0.0
ELECTROCARDIOGRAM ABNORMAL	1	0.1	0	0.0
EPIDIDYMITIS	1	0.1	0	0.0
FECAL INCONTINENCE	1	0.1	0	0.0
GASTROINTESTINAL FLU	1	0.1	0	0.0
GENERALIZED SPASM	1	0.1	0	0.0
GLOSSITIS	1	0.1	0	0.0
GOUT	1	0.1	0	0.0
HEMATEMESIS	1	0.1	0	0.0
HYPERPHOSPHATEMIA	1	0.1	0	0.0
HYPOTHYROIDISM	1	0.1	0	0.0
ILEITIS	1	0.1	0	0.0
IRON DISORDERS	1	0.1	0	0.0
LEUKORRHEA	1	0.1	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
LYMPHADENOPATHY	1	0.1	0	0.0
MYDRIASIS	1	0.1	0	0.0
NAUSEA VOMITING AND DIARRHEA	1	0.1	0	0.0
NECK RIGIDITY	1	0.1	0	0.0
NEPHRITIS	1	0.1	0	0.0
NERVOUS SYSTEM DISORDER	1	0.1	0	0.0
OROPHARYNX DISORDER	1	0.1	0	0.0
PEPTIC ULCER	1	0.1	0	0.0
PSYCHOSIS	1	0.1	0	0.0
PUPILLARY DISORDER	1	0.1	0	0.0
RETINAL DISORDER	1	0.1	0	0.0
SALIVARY GLAND ENLARGEMENT	1	0.1	0	0.0
SEBORRHEA	1	0.1	0	0.0
SIALADENITIS	1	0.1	0	0.0
SKIN BENIGN NEOPLASM	1	0.1	0	0.0
TETANY	1	0.1	0	0.0
THYROID DISORDER	1	0.1	0	0.0
TOOTH MALFORMATION	1	0.1	0	0.0
TORTICOLLIS	1	0.1	0	0.0
TRISMUS	1	0.1	0	0.0
URINARY INCONTINENCE	1	0.1	0	0.0
VASCULAR HEADACHE	1	0.1	0	0.0
VENTRICULAR EXTRASYSTOLES	1	0.1	0	0.0
VOICE ALTERATION	1	0.1	0	0.0
MENORRHAGIA **	0	0.0	8	1.7
METRORRHAGIA **	0	0.0	3	0.7
PAPANICOLAU SMEAR SUSPICIOUS **	0	0.0	2	0.4
ALOPECIA	0	0.0	2	0.2
CARDIOVASCULAR DISORDER	0	0.0	2	0.2
GASTRITIS	0	0.0	2	0.2
HEMOPTYSIS	0	0.0	2	0.2
HYPERCHOLESTEREMIA	0	0.0	2	0.2
HYPERLIPEMIA	0	0.0	2	0.2
SURGICAL PROCEDURE	0	0.0	2	0.2
ULCERATIVE STOMATITIS	0	0.0	2	0.2
ABORTION **	0	0.0	1	0.2
BREAST CARCINOMA **	0	0.0	1	0.2

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

	Paroxetine (N=874)		Placebo (N=810)	
Preferred Term	n	%	n	%
BREAST ENLARGEMENT **	0	0.0	1	0.2
BREAST PAIN **	0	0.0	1	0.2
UTERINE FIBROIDS ENLARGED **	0	0.0	1	0.2
VAGINAL HEMORRHAGE **	0	0.0	1	0.2
ARRHYTHMIA	0	0.0	1	0.1
AV BLOCK	0	0.0	1	0.1
BLINDNESS	0	0.0	1	0.1
CEREBROVASCULAR DISORDER	0	0.0	1	0.1
CONTACT DERMATITIS	0	0.0	1	0.1
DERMATOSES, GENERAL	0	0.0	1	0.1
DIGESTIVE SYSTEM DISORDER	0	0.0	1	0.1
EOSINOPHILIA	0	0.0	1	0.1
EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.1
EYE PAIN	0	0.0	1	0.1
GALL BLADDER DISORDER	0	0.0	1	0.1
GLYCOSURIA	0	0.0	1	0.1
HAIR DISORDERS	0	0.0	1	0.1
HIRSUTISM	0	0.0	1	0.1
HYPERTHYROIDISM	0	0.0	1	0.1
INCREASED SALIVATION	0	0.0	1	0.1
INTRACRANIAL HYPERTENSION	0	0.0	1	0.1
LARYNX DISORDER	0	0.0	1	0.1
MENINGITIS	0	0.0	1	0.1
MONOCYTOSIS	0	0.0	1	0.1
NEURALGIA	0	0.0	1	0.1
NEUROSIS	0	0.0	1	0.1
NEUROVASCULAR COMPRESSION	0	0.0	1	0.1
PANCREATITIS	0	0.0	1	0.1
PERSONALITY DISORDER	0	0.0	1	0.1
PLEURA DISORDER	0	0.0	1	0.1
RECTAL DISORDER	0	0.0	1	0.1
RESPIRATORY FLU	0	0.0	1	0.1
SPUTUM INCREASED	0	0.0	1	0.1
STOMACH ULCER	0	0.0	1	0.1
SWEATING DECREASED	0	0.0	1	0.1
THROMBOCYTHEMIA	0	0.0	1	0.1
THROMBOCYTOPENIA	0	0.0	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.43

Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 40 mg

Preferred Term	Paroxetine (N=874) n	%	Placebo (N=810) n	%
TRACHEA DISORDER	0	0.0	1	0.1
VASOSPASM	0	0.0	1	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 50 mg

	Paroxetine (N=57)		Placebo (N=60)	
Preferred Term	n	%	n	%
TOTAL	46	80.7	46	76.7
Total Male Subjects *	37	100.0	42	100.0
Total Male-Specific AEs *	3	8.1	2	4.8
Total Female Subjects **	20	100.0	18	100.0
Total Female-Specific AEs **	1	5.0	1	5.6
Total Non Gender-Specific AEs	45	78.9	46	76.7
HEADACHE	15	26.3	11	18.3
NAUSEA	11	19.3	3	5.0
DIARRHEA	9	15.8	4	6.7
HYPOTENSION	7	12.3	3	5.0
ASTHENIA	6	10.5	7	11.7
ANXIETY	6	10.5	4	6.7
LIBIDO DECREASED	6	10.5	3	5.0
SWEATING	6	10.5	3	5.0
INSOMNIA	5	8.8	5	8.3
TREMOR	5	8.8	2	3.3
WEIGHT GAIN	5	8.8	1	1.7
TACHYCARDIA	4	7.0	4	6.7
CONSTIPATION	4	7.0	2	3.3
DECREASED APPETITE	4	7.0	2	3.3
SOMNOLENCE	4	7.0	2	3.3
PRURITUS	4	7.0	0	0.0
DRY MOUTH	3	5.3	3	5.0
HYPERTENSION	3	5.3	1	1.7
MALAISE	3	5.3	1	1.7
ABDOMINAL PAIN	3	5.3	0	0.0
VERTIGO	3	5.3	0	0.0
AMENORRHEA **	1	5.0	0	0.0
MYASTHENIA	2	3.5	2	3.3
TASTE PERVERSION	2	3.5	2	3.3
DIZZINESS	2	3.5	1	1.7
VOMITING	2	3.5	1	1.7
DEPRESSION	2	3.5	0	0.0
INCREASED APPETITE	2	3.5	0	0.0
NERVOUSNESS	2	3.5	0	0.0
RASH	2	3.5	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 50 mg

	Paroxetine (N=57)		Placebo (N=60)	
Preferred Term	n	%	n	%
IMPOTENCE *	1	2.7	1	2.4
ABNORMAL EJACULATION *	1	2.7	0	0.0
MALE GENITAL DISORDERS *	1	2.7	0	0.0
PARESTHESIA	1	1.8	4	6.7
VISION DISORDERS	1	1.8	3	5.0
BACK PAIN	1	1.8	2	3.3
MYALGIA	1	1.8	2	3.3
RESPIRATORY DISORDER	1	1.8	2	3.3
VASODILATATION	1	1.8	2	3.3
WEIGHT LOSS	1	1.8	2	3.3
ASTHMA	1	1.8	1	1.7
DYSURIA	1	1.8	1	1.7
GASTROENTERITIS	1	1.8	1	1.7
LEUKOCYTOSIS	1	1.8	1	1.7
MYOPATHY	1	1.8	1	1.7
POSTURAL HYPOTENSION	1	1.8	1	1.7
SINUSITIS	1	1.8	1	1.7
SYNCOPE	1	1.8	1	1.7
URINARY TRACT INFECTION	1	1.8	1	1.7
ABDOMEN ENLARGED	1	1.8	0	0.0
ABNORMAL VISION	1	1.8	0	0.0
ALKALINE PHOSPHATASE INCREASED	1	1.8	0	0.0
ALLERGIC REACTION	1	1.8	0	0.0
BLURRED VISION	1	1.8	0	0.0
CNS STIMULATION	1	1.8	0	0.0
COUGH INCREASED	1	1.8	0	0.0
DYSKINESIA	1	1.8	0	0.0
FACE EDEMA	1	1.8	0	0.0
FLATULENCE	1	1.8	0	0.0
MYDRIASIS	1	1.8	0	0.0
NECK PAIN	1	1.8	0	0.0
NOCTURIA	1	1.8	0	0.0
REFLEXES DECREASED	1	1.8	0	0.0
SGPT INCREASED	1	1.8	0	0.0
THROMBOCYTHEMIA	1	1.8	0	0.0
TINNITUS	1	1.8	0	0.0
VISUAL FIELD DEFECT	1	1.8	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 50 mg

	Paroxetine (N=57)		Placebo (N=60)	
Preferred Term	n	%	n	%
WITHDRAWAL SYNDROME	1	1.8	0	0.0
UTERINE HEMORRHAGE **	0	0.0	1	5.6
FLU SYNDROME	0	0.0	3	5.0
BRONCHITIS	0	0.0	2	3.3
DYSPEPSIA	0	0.0	2	3.3
NEUROPATHY	0	0.0	2	3.3
PALPITATION	0	0.0	2	3.3
TRAUMA	0	0.0	2	3.3
PROSTATE DISORDER *	0	0.0	1	2.4
ABNORMALITY OF ACCOMMODATION	0	0.0	1	1.7
ACNE	0	0.0	1	1.7
AMNESIA	0	0.0	1	1.7
ANGINA PECTORIS	0	0.0	1	1.7
CHEST PAIN	0	0.0	1	1.7
CYSTITIS	0	0.0	1	1.7
DRUG DEPENDENCE	0	0.0	1	1.7
DYSARTHRIA	0	0.0	1	1.7
ECZEMA	0	0.0	1	1.7
HAEMATURIA	0	0.0	1	1.7
LACK OF EMOTION	0	0.0	1	1.7
LIVER FUNCTION TESTS ABNORMAL	0	0.0	1	1.7
MIGRAINE	0	0.0	1	1.7
PERIODONTAL ABSCESS	0	0.0	1	1.7
PHARYNGITIS	0	0.0	1	1.7
PHOTOPHOBIA	0	0.0	1	1.7
PYURIA	0	0.0	1	1.7
RHINITIS	0	0.0	1	1.7
SPEECH DISORDER	0	0.0	1	1.7
TOOTH DISORDER	0	0.0	1	1.7
URINARY FREQUENCY	0	0.0	1	1.7
URINARY RETENTION	0	0.0	1	1.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

	Paroxetine (N=182)		Placebo (N=184)	
Preferred Term	n	%	n	%
TOTAL	164	90.1	154	83.7
Total Male Subjects *	126	100.0	115	100.0
Total Male-Specific AEs *	58	46.0	4	3.5
Total Female Subjects **	56	100.0	69	100.0
Total Female-Specific AEs **	5	8.9	7	10.1
Total Non Gender-Specific AEs	160	87.9	154	83.7
ABNORMAL EJACULATION *	52	41.3	2	1.7
SOMNOLENCE	58	31.9	14	7.6
INSOMNIA	57	31.3	24	13.0
HEADACHE	41	22.5	59	32.1
ASTHENIA	40	22.0	17	9.2
NAUSEA	39	21.4	13	7.1
DIZZINESS	25	13.7	13	7.1
DIARRHEA	24	13.2	21	11.4
NERVOUSNESS	23	12.6	13	7.1
CONSTIPATION	23	12.6	11	6.0
DRY MOUTH	23	12.6	11	6.0
TREMOR	22	12.1	1	0.5
DECREASED APPETITE	19	10.4	2	1.1
LIBIDO DECREASED	18	9.9	5	2.7
SWEATING	18	9.9	2	1.1
YAWN	15	8.2	0	0.0
IMPOTENCE *	10	7.9	2	1.7
INCREASED APPETITE	13	7.1	5	2.7
FEMALE GENITAL DISORDERS **	4	7.1	0	0.0
INFECTION	12	6.6	8	4.3
RESPIRATORY DISORDER	10	5.5	22	12.0
MYALGIA	10	5.5	7	3.8
MYOCLONUS	10	5.5	2	1.1
VOMITING	9	4.9	4	2.2
SINUSITIS	8	4.4	9	4.9
DYSPEPSIA	8	4.4	7	3.8
FLATULENCE	8	4.4	7	3.8
ABDOMINAL PAIN	7	3.8	7	3.8
ANXIETY	7	3.8	5	2.7
CONCENTRATION IMPAIRED	7	3.8	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

	Paroxetine (N=182)		Placebo (N=184)	
Preferred Term	n	%	n	%
TASTE PERVERSION	7	3.8	1	0.5
VASODILATATION	7	3.8	0	0.0
URINARY FREQUENCY	6	3.3	6	3.3
TRAUMA	6	3.3	3	1.6
FEVER	6	3.3	1	0.5
URINATION IMPAIRED	6	3.3	0	0.0
PARESTHESIA	5	2.7	5	2.7
RHINITIS	5	2.7	5	2.7
RASH	5	2.7	3	1.6
ABNORMAL DREAMS	5	2.7	2	1.1
HYPERTONIA	5	2.7	2	1.1
ABNORMAL VISION	5	2.7	1	0.5
PHARYNGITIS	4	2.2	7	3.8
ARTHRALGIA	4	2.2	6	3.3
PAIN	4	2.2	6	3.3
COUGH INCREASED	4	2.2	3	1.6
DEPERSONALIZATION	4	2.2	2	1.1
DYSTONIA	4	2.2	2	1.1
PALPITATION	4	2.2	2	1.1
HYPERKINESIA	4	2.2	1	0.5
MYASTHENIA	4	2.2	0	0.0
DYSMENORRHEA **	1	1.8	4	5.8
BACK PAIN	3	1.6	9	4.9
DEPRESSION	3	1.6	8	4.3
AGITATION	3	1.6	3	1.6
LIVER FUNCTION TESTS ABNORMAL	3	1.6	3	1.6
PRURITUS	3	1.6	2	1.1
DYSURIA	3	1.6	1	0.5
AMNESIA	3	1.6	0	0.0
CHILLS	3	1.6	0	0.0
CONTACT DERMATITIS	3	1.6	0	0.0
HYPESTHESIA	3	1.6	0	0.0
URINARY RETENTION	3	1.6	0	0.0
WEIGHT GAIN	2	1.1	2	1.1
EAR DISORDER	2	1.1	1	0.5
HYPERTENSION	2	1.1	1	0.5
TINNITUS	2	1.1	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

	Paroxetine (N=182)		Placebo (N=184)	
Preferred Term	n	%	n	%
URINARY TRACT INFECTION	2	1.1	1	0.5
BRUXISM	2	1.1	0	0.0
DYSPHAGIA	2	1.1	0	0.0
HYPERCHOLESTEREMIA	2	1.1	0	0.0
MALAISE	2	1.1	0	0.0
MYDRIASIS	2	1.1	0	0.0
SYNCOPE	2	1.1	0	0.0
URTICARIA	2	1.1	0	0.0
PROSTATE DISORDER *	1	0.8	0	0.0
TOOTH DISORDER	1	0.5	3	1.6
BRONCHITIS	1	0.5	2	1.1
CHEST PAIN	1	0.5	2	1.1
CONJUNCTIVITIS	1	0.5	2	1.1
DYSPNEA	1	0.5	2	1.1
HERPES SIMPLEX	1	0.5	2	1.1
TACHYCARDIA	1	0.5	2	1.1
ULCERATIVE STOMATITIS	1	0.5	2	1.1
VERTIGO	1	0.5	2	1.1
ACNE	1	0.5	1	0.5
CONFUSION	1	0.5	1	0.5
CYSTITIS	1	0.5	1	0.5
GINGIVITIS	1	0.5	1	0.5
HOSTILITY	1	0.5	1	0.5
LARYNX DISORDER	1	0.5	1	0.5
NEOPLASM	1	0.5	1	0.5
NEUROSIS	1	0.5	1	0.5
OTITIS MEDIA	1	0.5	1	0.5
PARALYSIS	1	0.5	1	0.5
SGPT INCREASED	1	0.5	1	0.5
ANEMIA	1	0.5	0	0.0
ARRHYTHMIA	1	0.5	0	0.0
ATAXIA	1	0.5	0	0.0
BLEPHARITIS	1	0.5	0	0.0
BONE DISORDER	1	0.5	0	0.0
BRAIN EDEMA	1	0.5	0	0.0
EUPHORIA	1	0.5	0	0.0
EYE DISORDER	1	0.5	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

	Paroxetine (N=182)		Placebo (N=184)	
Preferred Term	n	%	n	%
GASTROINTESTINAL DISORDER	1	0.5	0	0.0
HERPES ZOSTER	1	0.5	0	0.0
HICCUP	1	0.5	0	0.0
KERATOCONJUNCTIVITIS	1	0.5	0	0.0
KIDNEY CALCULUS	1	0.5	0	0.0
LYMPHADENOPATHY	1	0.5	0	0.0
MACULOPAPULAR RASH	1	0.5	0	0.0
NOCTURIA	1	0.5	0	0.0
PHOTOPHOBIA	1	0.5	0	0.0
PURPURA	1	0.5	0	0.0
PUSTULAR RASH	1	0.5	0	0.0
SKIN DISORDER	1	0.5	0	0.0
STOMATITIS	1	0.5	0	0.0
SWEAT GLAND DISORDER	1	0.5	0	0.0
WEIGHT LOSS	1	0.5	0	0.0
ALLERGIC REACTION	0	0.0	3	1.6
EMOTIONAL LABILITY	0	0.0	3	1.6
BREAST CARCINOMA **	0	0.0	1	1.4
MENORRHAGIA **	0	0.0	1	1.4
OVARY DISORDER **	0	0.0	1	1.4
HAEMATURIA	0	0.0	2	1.1
HYPERLIPEMIA	0	0.0	2	1.1
ALBUMINURIA	0	0.0	1	0.5
ALCOHOL ABUSE	0	0.0	1	0.5
CARDIOVASCULAR DISORDER	0	0.0	1	0.5
COLITIS	0	0.0	1	0.5
DIGESTIVE SYSTEM DISORDER	0	0.0	1	0.5
DYSKINESIA	0	0.0	1	0.5
EDEMA	0	0.0	1	0.5
EOSINOPHILIA	0	0.0	1	0.5
EYE PAIN	0	0.0	1	0.5
GASTRITIS	0	0.0	1	0.5
GASTROENTERITIS	0	0.0	1	0.5
HEMOPTYSIS	0	0.0	1	0.5
HIRSUTISM	0	0.0	1	0.5
HYPERTHYROIDISM	0	0.0	1	0.5
HYPOTENSION	0	0.0	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 1.43
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
By Dosage
Adult Placebo Controlled Trials - Fixed Dosed Studies
Randomised Phase

Dose Level 60 mg

Preferred Term	Paroxetine (N=182) n	%	Placebo (N=184) n	%
INCREASED SALIVATION	0	0.0	1	0.5
MIGRAINE	0	0.0	1	0.5
PERIPHERAL EDEMA	0	0.0	1	0.5
PLEURA DISORDER	0	0.0	1	0.5
SKIN HYPERTROPHY	0	0.0	1	0.5
SWEATING DECREASED	0	0.0	1	0.5
TENDINOUS DISORDER	0	0.0	1	0.5
THINKING ABNORMAL	0	0.0	1	0.5
TOOTH CARIES	0	0.0	1	0.5
URINE ABNORMALITY	0	0.0	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 1.44
Change from Baseline in HAMD Total Score and HAMD Non-Suicide Sub-scale Score by Treatment Group
Adult Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
HAMD Total Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	2963	21.7	5.72	1741	20.7	6.81				
Change from Baseline to:										
Week 1	2517	-3.5	0.09	1478	-3.2	0.12				
Week 2	2306	-6.5	0.11	1388	-5.3	0.15				
Week 3	1978	-8.5	0.13	1046	-7.0	0.19				
Week 4	2056	-9.3	0.13	1179	-7.7	0.18				
Week 6	1777	-11.2	0.15	961	-8.8	0.21	-2.34	-2.85	-1.84	<0.001
LOCF	2654	-10.2	0.14	1585	-7.1	0.19	-3.10	-3.56	-2.64	<0.001

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.44
Change from Baseline in HAMD Total Score and HAMD Non-Suicide Sub-scale Score by Treatment Group
Adult Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
HAMD Non-Suicide Sub-scale Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	2963	20.7	5.38	1741	19.7	6.42				
Change from Baseline to:										
Week 1	2517	-3.2	0.08	1478	-3.0	0.11				
Week 2	2306	-6.0	0.11	1388	-4.9	0.14				
Week 3	1978	-7.9	0.13	1046	-6.5	0.18				
Week 4	2056	-8.6	0.13	1179	-7.2	0.17				
Week 6	1777	-10.5	0.15	961	-8.3	0.20	-2.16	-2.64	-1.68	<0.001
LOCF	2654	-9.6	0.14	1585	-6.7	0.18	-2.89	-3.32	-2.45	<0.001

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.45
Change from Baseline in HAMD Total Score and HAMD Non-Suicide Sub-scale Score by Treatment Group
Young Adult Placebo Controlled Trials (Aged 18-29 Inclusive), Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
HAMD Total Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	491	22.1	4.73	271	21.5	5.48				
Change from Baseline to:										
Week 1	398	-3.7	0.23	226	-3.7	0.30				
Week 2	362	-6.6	0.28	208	-5.7	0.38				
Week 3	317	-8.5	0.33	171	-7.8	0.45				
Week 4	302	-9.5	0.35	172	-8.0	0.46				
Week 6	256	-11.4	0.40	149	-9.6	0.52	-1.89	-3.19	-0.60	0.004
LOCF	427	-10.1	0.36	245	-8.3	0.47	-1.76	-2.93	-0.60	0.003

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.45
Change from Baseline in HAMD Total Score and HAMD Non-Suicide Sub-scale Score by Treatment Group
Young Adult Placebo Controlled Trials (Aged 18-29 Inclusive), Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
HAMD Non-Suicide Sub-scale Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	491	21.1	4.45	271	20.4	5.21				
Change from Baseline to:										
Week 1	398	-3.2	0.21	226	-3.3	0.28				
Week 2	362	-6.0	0.27	208	-5.2	0.35				
Week 3	317	-7.8	0.32	171	-7.2	0.43				
Week 4	302	-8.8	0.33	172	-7.3	0.44				
Week 6	256	-10.7	0.38	149	-8.9	0.50	-1.80	-3.03	-0.57	0.004
LOCF	427	-9.4	0.34	245	-7.7	0.45	-1.68	-2.78	-0.58	0.003

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.46
Change from Baseline in HAMD Total Score and HAMD Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
HAMD Total Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	93	19.4	4.83	88	19.5	4.98				
Change from Baseline to:										
Week 1	80	-3.7	0.46	82	-3.0	0.46				
Week 2	78	-6.2	0.60	78	-5.1	0.60				
Week 3	79	-8.6	0.64	74	-6.7	0.67				
Week 4	75	-9.4	0.61	71	-8.3	0.63				
Week 6	76	-11.3	0.66	73	-9.9	0.68	-1.41	-3.28	0.46	0.138
LOCF	87	-10.3	0.77	87	-9.2	0.77	-1.16	-3.31	0.98	0.287

Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.46
Change from Baseline in HAMD Total Score and HAMD Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
HAMD Non-Suicide Sub-scale Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	93	18.6	4.52	88	18.3	4.76				
Change from Baseline to:										
Week 1	80	-3.4	0.44	82	-2.6	0.43				
Week 2	78	-5.8	0.57	78	-4.6	0.57				
Week 3	79	-8.1	0.61	74	-6.2	0.63				
Week 4	75	-8.8	0.58	71	-7.6	0.59				
Week 6	76	-10.7	0.62	73	-9.3	0.63	-1.43	-3.18	0.33	0.110
LOCF	87	-9.8	0.73	87	-8.5	0.73	-1.35	-3.40	0.70	0.196

Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.47
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Adult Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
MADRS Total Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	1323	28.4	7.01	870	27.9	7.53				
Change from Baseline to:										
Week 1	1061	-3.9	0.17	665	-2.8	0.22				
Week 2	1037	-7.3	0.23	716	-5.1	0.27				
Week 3	806	-10.7	0.29	454	-7.6	0.39				
Week 4	880	-11.5	0.29	532	-8.4	0.37				
Week 6	710	-13.1	0.35	418	-9.7	0.45	-3.49	-4.61	-2.37	<0.001
LOCF	1195	-11.4	0.29	800	-7.4	0.35	-3.95	-4.84	-3.06	<0.001

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.47
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Adult Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
MADRS Non-Suicide Sub-scale Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	1323	26.7	6.59	870	26.2	7.09				
Change from Baseline to:										
Week 1	1061	-3.4	0.16	665	-2.5	0.20				
Week 2	1037	-6.7	0.21	716	-4.6	0.25				
Week 3	806	-9.8	0.27	454	-7.0	0.36				
Week 4	880	-10.6	0.27	532	-7.7	0.34				
Week 6	710	-12.2	0.33	418	-8.9	0.42	-3.23	-4.28	-2.18	<0.001
LOCF	1195	-10.5	0.27	800	-6.9	0.33	-3.60	-4.43	-2.77	<0.001

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.48
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Young Adult Placebo Controlled Trials (Aged 18-29 Inclusive), Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
MADRS Total Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	260	27.4	8.12	167	27.2	9.28				
Change from Baseline to:										
Week 1	177	-3.6	0.42	97	-2.9	0.56				
Week 2	183	-6.7	0.56	131	-4.8	0.67				
Week 3	148	-10.0	0.69	75	-8.4	0.98				
Week 4	139	-10.1	0.75	84	-8.9	0.96				
Week 6	116	-11.9	0.90	76	-9.1	1.11	-2.83	-5.66	-0.01	0.049
LOCF	224	-8.8	0.67	150	-6.9	0.82	-1.86	-3.96	0.23	0.081

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.48
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Young Adult Placebo Controlled Trials (Aged 18-29 Inclusive), Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
MADRS Non-Suicide Sub-scale Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	260	25.6	7.61	167	25.3	8.75				
Change from Baseline to:										
Week 1	177	-3.2	0.38	97	-2.7	0.52				
Week 2	183	-6.0	0.52	131	-4.4	0.61				
Week 3	148	-9.2	0.64	75	-7.7	0.91				
Week 4	139	-9.3	0.69	84	-8.2	0.89				
Week 6	116	-11.1	0.84	76	-8.2	1.03	-2.83	-5.46	-0.21	0.035
LOCF	224	-8.0	0.62	150	-6.4	0.76	-1.66	-3.59	0.26	0.090

Includes paroxetine and placebo data from multiple arm trials with active controls
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.49
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
MADRS Total Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	181	25.9	6.04	95	25.9	5.93				
Change from Baseline to:										
Week 1	177	-3.4	0.35	87	-3.0	0.50				
Week 2	168	-5.6	0.48	89	-5.7	0.67				
Week 3	156	-8.0	0.57	86	-7.1	0.76				
Week 4	156	-9.9	0.60	78	-9.3	0.85				
Week 6	143	-11.9	0.67	74	-11.5	0.93	-0.43	-2.69	1.82	0.705
LOCF	179	-13.6	0.73	91	-12.7	1.02	-0.89	-3.36	1.58	0.479

Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.49
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
MADRS Non-Suicide Sub-scale Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	181	24.2	5.40	95	24.2	5.37				
Change from Baseline to:										
Week 1	177	-2.9	0.34	87	-2.7	0.48				
Week 2	168	-5.1	0.46	89	-5.2	0.63				
Week 3	156	-7.3	0.53	86	-6.5	0.71				
Week 4	156	-9.1	0.55	78	-8.6	0.78				
Week 6	143	-11.0	0.61	74	-10.6	0.85	-0.45	-2.51	1.61	0.667
LOCF	179	-12.7	0.67	91	-11.7	0.94	-1.01	-3.29	1.27	0.384

Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.50
Change from Baseline in CDRS-R Total Score and CDRS-R Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
CDRS-R Total Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	104	60.7	9.31	102	62.6	8.96				
Change from Baseline to:										
Week 1	97	-9.1	1.06	100	-7.3	1.04				
Week 2	90	-14.6	1.12	91	-12.9	1.11				
Week 3	88	-18.4	1.30	86	-19.0	1.32				
Week 4	75	-22.2	1.34	86	-22.4	1.25				
Week 6	69	-23.5	1.39	80	-24.1	1.29	0.58	-3.17	4.33	0.761
LOCF	101	-21.8	1.36	100	-22.7	1.36	0.92	-2.89	4.72	0.635

Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.50
Change from Baseline in CDRS-R Total Score and CDRS-R Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF

	Paroxetine			Placebo			Treatment Comparisons*			
CDRS-R Non-Suicide Sub-scale Score	N used in Analysis	Least Square Mean+	S.E.+	N used in Analysis	Least Square Mean+	S.E.+	Difference	Lower 95% CI Limit	Upper 95% CI Limit	P-value
Baseline	104	59.0	9.00	102	60.5	8.53				
Change from Baseline to:										
Week 1	97	-8.9	1.03	100	-6.9	1.02				
Week 2	90	-14.3	1.10	91	-12.4	1.09				
Week 3	88	-18.0	1.28	86	-18.3	1.29				
Week 4	75	-21.8	1.32	86	-21.8	1.23				
Week 6	69	-23.0	1.38	80	-23.5	1.28	0.54	-3.17	4.26	0.773
LOCF	101	-21.5	1.33	100	-22.2	1.34	0.76	-2.97	4.49	0.687

Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.51
Change from Baseline in HAMD Items 19 and 20 by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.
Item 19: Depersonalisation and Derealisation	PAROXETINE	1908	-0.22	0.01	-0.08	(-0.11,-0.04)
	PLACEBO	1224	-0.14	0.01		
Item 20: Paranoid Symptoms	PAROXETINE	1908	-0.17	0.01	-0.05	(-0.08,-0.02)
	PLACEBO	1224	-0.12	0.01		

Includes paroxetine and placebo data from multiple arm trials with active controls where 21 or 28 item HAMD scale was used
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.52
Change from Baseline in HAMD Items 19 and 20 by Treatment Group
Adult Active Control Trials
Randomised Phase LOCF

HAM-D item	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.
Item 19: Depersonalisation and Derealisation	PAROXETINE	3676	-0.28	0.01	-0.03	(-0.06,-0.01)
	COMPARATOR	2631	-0.25	0.01		
Item 20: Paranoid Symptoms	PAROXETINE	3675	-0.22	0.01	-0.03	(-0.05,-0.01)
	COMPARATOR	2631	-0.19	0.01		

Includes paroxetine and active control data from multiple arm trials with placebo where 21 or 28 item HAMD scale was used
Treatment differences are Paroxetine minus Comparator
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Overall	N	8481	5808	14289
	SD	12.78	12.88	12.82
	Mean	40.8	40.8	40.8
	Median	39	39	39
	Mode	37	38	38
	Minimum	16	16	16
	Maximum	88	85	88
Study 001	N	25	25	50
	SD	11.7	13.13	12.33
	Mean	42.6	44.2	43.4
	Median	42	43	42.5
	Mode	35	31	31
	Minimum	20	24	20
	Maximum	65	64	65
Study 002	N	170	171	341
	SD	11.59	12.67	12.17
	Mean	40.5	42.5	41.5
	Median	39.5	40	40
	Mode	40	45	30
	Minimum	18	18	18
	Maximum	77	73	77
Study 003	N	241	244	485
	SD	11.28	11.92	11.6
	Mean	40.3	40.4	40.4
	Median	39	38	39
	Mode	39	38	34
	Minimum	18	19	18
	Maximum	69	70	70
Study 007	N	13	12	25
	SD	11.61	7.69	10.06
	Mean	40	45.1	42.4
	Median	36	46	41
	Mode	36	46	36
	Minimum	24	34	24
	Maximum	68	58	68
Study 009	N	421	53	474
	SD	13.17	10.45	12.88
	Mean	41.1	40.6	41
	Median	38	39	38
	Mode	32	39	32
	Minimum	18	23	18
	Maximum	85	70	85

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 057	N	131	136	267
	SD	10.58	12.19	11.41
	Mean	34.2	34.6	34.4
	Median	33	32	32
	Mode	34	32	32
	Minimum	18	18	18
	Maximum	74	70	74
Study 076	N	4	4	8
	SD	11.15	17.41	13.61
	Mean	49.3	46.5	47.9
	Median	49.5	47.5	49.5
	Mode	.	.	56
	Minimum	37	26	26
	Maximum	61	65	65
Study 083	N	68	67	135
	SD	9.03	8.43	8.78
	Mean	45.9	48.3	47.1
	Median	45.5	49	48
	Mode	44	52	52
	Minimum	23	26	23
	Maximum	65	64	65
Study 106	N	18	18	36
	SD	7.4	7.47	7.37
	Mean	28.9	30.4	29.7
	Median	27	30	29
	Mode	24	28	29
	Minimum	21	18	18
	Maximum	48	44	48
Study 108	N	60	60	120
	SD	10.42	9.1	9.75
	Mean	37.7	37	37.3
	Median	36	35.5	36
	Mode	34	45	34
	Minimum	23	21	21
	Maximum	69	57	69
Study 115	N	283	117	400
	SD	12.53	11.67	12.27
	Mean	41.8	41.5	41.7
	Median	41	40	41
	Mode	29	31	43
	Minimum	18	19	18
	Maximum	86	71	86

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 116	N	259	89	348
	SD	13.84	12.32	13.49
	Mean	40.8	43.1	41.4
	Median	39	44	40
	Mode	38	46	40
	Minimum	16	20	16
	Maximum	78	73	78
Study 118	N	82	77	159
	SD	11.69	10.71	11.48
	Mean	41.3	36.3	38.9
	Median	39	35	37
	Mode	36	26	36
	Minimum	19	16	16
	Maximum	77	67	77
Study 120	N	209	69	278
	SD	9.97	10.36	10.06
	Mean	36.1	37.3	36.4
	Median	35	36	35
	Mode	29	39	29
	Minimum	18	19	18
	Maximum	65	63	65
Study 128	N	357	140	497
	SD	12.7	12.17	12.55
	Mean	41.8	42.8	42.1
	Median	40	42	40
	Mode	36	52	36
	Minimum	18	20	18
	Maximum	82	76	82
Study 136	N	201	99	300
	SD	12.07	12.39	12.16
	Mean	37.8	37.8	37.8
	Median	36	36	36
	Mode	31	36	26
	Minimum	17	19	17
	Maximum	72	74	74
Study 187	N	123	123	246
	SD	9.27	8.86	9.05
	Mean	34.6	34.9	34.8
	Median	34	34	34
	Mode	27	34	27
	Minimum	19	18	18
	Maximum	66	62	66

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 190	N	61	64	125
	SD	11.49	11.31	11.43
	Mean	45.5	42.8	44.1
	Median	44	43	44
	Mode	39	39	39
	Minimum	20	22	20
	Maximum	74	70	74
Study 201	N	57	60	117
	SD	9.19	8.83	9.03
	Mean	41.8	39.6	40.7
	Median	41	37.5	38
	Mode	33	30	33
	Minimum	23	26	23
	Maximum	60	62	62
Study 223	N	76	71	147
	SD	11.1	11.9	11.45
	Mean	39.2	39	39.1
	Median	38	37	38
	Mode	33	32	36
	Minimum	22	19	19
	Maximum	74	67	74
Study 251	N	125	129	254
	SD	11.17	10.56	10.84
	Mean	41.3	41.3	41.3
	Median	41	41	41
	Mode	41	30	46
	Minimum	19	18	18
	Maximum	65	71	71
Study 274	N	22	23	45
	SD	13.2	11.84	12.41
	Mean	41.6	43.3	42.5
	Median	42	45	42
	Mode	58	33	58
	Minimum	18	22	18
	Maximum	64	60	64
Study 275	N	4	3	7
	SD	8.83	3.51	6.6
	Mean	55	56.3	55.6
	Median	58.5	56	57
	Mode	.	.	60
	Minimum	42	53	42
	Maximum	61	60	61

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 276	N	20	21	41
	SD	12.75	12.68	12.58
	Mean	45.1	43.4	44.2
	Median	46	43	44
	Mode	27	.	27
	Minimum	22	22	22
	Maximum	62	64	64
Study 279	N	21	10	31
	SD	18.32	17.25	18.42
	Mean	40.8	51.6	44.3
	Median	38	56.5	42
	Mode	20	67	20
	Minimum	20	23	20
	Maximum	75	71	75
Study 327	N	81	85	166
	SD	10.68	11.5	11.11
	Mean	40.8	42.6	41.7
	Median	41	42	41
	Mode	52	41	41
	Minimum	22	22	22
	Maximum	73	77	77
Study 352	N	35	43	78
	SD	10.15	10.66	10.42
	Mean	42.5	40.4	41.3
	Median	42	41	41
	Mode	37	41	37
	Minimum	24	21	21
	Maximum	66	66	66
Study 382	N	94	93	187
	SD	10.1	13.19	11.71
	Mean	35.9	36.7	36.3
	Median	34	34	34
	Mode	26	26	26
	Minimum	18	18	18
	Maximum	59	76	76
Study 400	N	31	17	48
	SD	6.05	5.65	5.87
	Mean	36	34.9	35.6
	Median	36	35	35
	Mode	35	29	35
	Minimum	23	24	23
	Maximum	45	44	45

Paroxetine EMEA LOQs

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 427	N	29	9	38
	SD	6.67	5.65	6.51
	Mean	36	32.8	35.2
	Median	37	32	36.5
	Mode	37	26	37
	Minimum	19	26	19
	Maximum	46	40	46
Study 448	N	212	103	315
	SD	10.66	10.04	10.46
	Mean	39.3	38.4	39
	Median	39.5	39	39
	Mode	43	27	43
	Minimum	18	19	18
	Maximum	62	64	64
Study 449	N	223	110	333
	SD	11.6	11.56	11.57
	Mean	41.3	40.7	41.1
	Median	42	40	42
	Mode	45	33	45
	Minimum	18	19	18
	Maximum	71	63	71
Study 454	N	289	95	384
	SD	9.98	10.41	10.15
	Mean	37.7	34.7	37
	Median	38	35	37
	Mode	32	21	38
	Minimum	20	18	18
	Maximum	70	65	70
Study 487	N	214	109	323
	SD	6.32	5.4	6.03
	Mean	70.2	69.4	69.9
	Median	70	70	70
	Mode	67	60	71
	Minimum	60	60	60
	Maximum	88	82	88
Study 494	N	141	148	289
	SD	10.06	10.25	10.17
	Mean	38.1	36.7	37.4
	Median	38	36	37
	Mode	28	25	25
	Minimum	19	20	19
	Maximum	63	61	63

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 495	N	162	165	327
	SD	10.15	10.64	10.38
	Mean	36.4	36.5	36.5
	Median	35	35	35
	Mode	35	23	33
	Minimum	18	19	18
	Maximum	62	72	72
Study 497	N	149	144	293
	SD	10.42	10.67	10.56
	Mean	38.2	39.8	39
	Median	38	40	39
	Mode	26	43	26
	Minimum	20	19	19
	Maximum	65	64	65
Study 502	N	139	151	290
	SD	11.56	11.44	11.55
	Mean	34.7	37.3	36.1
	Median	32	35	34.5
	Mode	26	33	27
	Minimum	18	18	18
	Maximum	67	85	85
Study 595	N	162	161	323
	SD	11.12	11.68	11.39
	Mean	38.1	38.2	38.2
	Median	36.5	38	38
	Mode	36	26	43
	Minimum	19	18	18
	Maximum	66	71	71
Study 625	N	112	117	229
	SD	11.39	10.51	10.95
	Mean	64.3	65.6	64.9
	Median	67	67	67
	Mode	68	78	68
	Minimum	22	38	22
	Maximum	85	82	85
Study 627	N	160	162	322
	SD	11.62	11.65	11.62
	Mean	39.5	38.9	39.2
	Median	38	38.5	38
	Mode	38	46	38
	Minimum	18	18	18
	Maximum	75	72	75

Paroxetine EMEA LOQs

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 637	N	187	185	372
	SD	14.93	15	14.96
	Mean	46.5	45.4	46
	Median	45	42	44
	Mode	45	33	33
	Minimum	18	18	18
	Maximum	78	78	78
Study 641	N	386	180	566
	SD	12.69	12.6	12.65
	Mean	40.4	40.8	40.5
	Median	40	40	40
	Mode	26	44	26
	Minimum	18	18	18
	Maximum	74	74	74
Study 642	N	164	166	330
	SD	11.99	12.32	12.15
	Mean	39.6	41	40.3
	Median	39	41	40
	Mode	24	43	42
	Minimum	19	19	19
	Maximum	69	80	80
Study 646	N	278	288	566
	SD	12.9	13.06	12.97
	Mean	43.1	43.7	43.4
	Median	42.5	42	42
	Mode	37	37	37
	Minimum	20	18	18
	Maximum	83	78	83
Study 648	N	163	160	323
	SD	11.17	12.11	11.66
	Mean	41.5	39.7	40.6
	Median	41	39.5	41
	Mode	38	49	49
	Minimum	19	18	18
	Maximum	69	78	78
Study 650	N	88	88	176
	SD	13.86	12.05	12.95
	Mean	42.9	42.5	42.7
	Median	42.5	42	42
	Mode	55	43	37
	Minimum	18	18	18
	Maximum	82	72	82

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 651	N	375	188	563
	SD	11.54	11.86	11.64
	Mean	41.6	41.4	41.6
	Median	43	42	42
	Mode	43	33	33
	Minimum	18	18	18
	Maximum	74	77	77
Study 677	N	212	109	321
	SD	5.72	6.15	5.87
	Mean	35.7	35	35.4
	Median	36	36	36
	Mode	40	40	40
	Minimum	19	20	19
	Maximum	45	45	45
Study 688	N	242	119	361
	SD	4.77	5.27	4.94
	Mean	37	36.6	36.9
	Median	38	37	38
	Mode	41	39	41
	Minimum	20	24	20
	Maximum	46	46	46
Study 689	N	246	125	371
	SD	5.49	5.8	5.6
	Mean	36.4	35.9	36.2
	Median	37	36	37
	Mode	39	38	39
	Minimum	20	19	19
	Maximum	45	45	45
Study 785	N	197	105	302
	SD	12.19	11.36	11.9
	Mean	41.3	40.4	41
	Median	43	40	41
	Mode	45	50	50
	Minimum	18	18	18
	Maximum	65	63	65
Study 790	N	186	184	370
	SD	10.5	11.52	11.01
	Mean	38.7	39	38.8
	Median	39	40	39
	Mode	45	24	45
	Minimum	18	18	18
	Maximum	69	67	69

EMEA LOQs Table 1.53
Summary of Age by Treatment Group and Study
Adult Placebo Controlled Trials

		Treatment Group		
		Paroxetine	Placebo	Total
Study 791	N	167	166	333
	SD	13.6	13.72	13.65
	Mean	38.6	39.5	39.1
	Median	37	38	37
	Mode	37	26	26
	Minimum	18	18	18
	Maximum	76	81	81
Study 810	N	306	148	454
	SD	11.53	11.78	11.6
	Mean	38.9	38.5	38.8
	Median	38	37	38
	Mode	38	26	37
	Minimum	18	18	18
	Maximum	74	65	74

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Overall	N	6522	4969	11491
	SD	14.99	15.36	15.15
	Mean	45.4	45.8	45.6
	Median	44	44	44
	Mode	40	46	46
	Minimum	17	16	16
	Maximum	98	97	98
Study 003	N	241	241	482
	SD	11.28	12.1	11.69
	Mean	40.3	39.6	40
	Median	39	38	39
	Mode	39	42	34
	Minimum	18	19	18
	Maximum	69	74	74
Study 006	N	33	33	66
	SD	5.16	5.54	5.45
	Mean	65.9	68.3	67.1
	Median	65	66	66
	Mode	60	65	65
	Minimum	60	60	60
	Maximum	82	78	82
Study 007	N	13	13	26
	SD	11.61	11.74	11.68
	Mean	40	44.6	42.3
	Median	36	45	40.5
	Mode	36	.	33
	Minimum	24	26	24
	Maximum	68	66	68
Study 011	N	103	103	206
	SD	6.02	5.4	5.71
	Mean	68.7	68.1	68.4
	Median	67	67	67
	Mode	67	66	67
	Minimum	60	60	60
	Maximum	85	82	85
Study 019	N	31	35	66
	SD	10.78	11.23	11.01
	Mean	33.6	36.2	35
	Median	35	35	35
	Mode	36	34	40
	Minimum	17	17	17
	Maximum	65	64	65

Paroxetine EMEA LOQs

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 020	N	24	24	48
	SD	11.2	15.18	13.39
	Mean	53.7	49.2	51.4
	Median	54.5	49	53
	Mode	40	29	40
	Minimum	33	23	23
	Maximum	73	78	78
Study 022	N	16	17	33
	SD	16.58	12.26	14.29
	Mean	42.1	42.3	42.2
	Median	39.5	43	42
	Mode	25	.	25
	Minimum	17	21	17
	Maximum	66	62	66
Study 025	N	4	4	8
	SD	10.72	12.28	11.6
	Mean	52.3	43.8	48
	Median	55	44.5	47.5
	Mode	.	.	.
	Minimum	38	28	28
	Maximum	61	58	61
Study 026	N	30	30	60
	SD	6.3	4.79	5.68
	Mean	73.6	76	74.8
	Median	73.5	76	75
	Mode	65	73	72
	Minimum	65	65	65
	Maximum	87	87	87
Study 027	N	17	15	32
	SD	15.29	17.29	16
	Mean	47.2	45.8	46.6
	Median	47	45	46
	Mode	67	29	67
	Minimum	23	20	20
	Maximum	67	67	67
Study 028	N	8	6	14
	SD	4.07	5.13	4.37
	Mean	69	69.5	69.2
	Median	69	68	69
	Mode	69	65	69
	Minimum	62	65	62
	Maximum	76	78	78

Paroxetine EMEA LOQs

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 029	N	4	5	9
	SD	10.24	16.63	13.43
	Mean	48.3	45.2	46.6
	Median	49	49	49
	Mode	49	.	49
	Minimum	35	26	26
	Maximum	60	64	64
Study 030	N	21	19	40
	SD	11.75	11.87	11.83
	Mean	44	47.9	45.8
	Median	41	49	45
	Mode	32	39	38
	Minimum	29	25	25
	Maximum	70	68	70
Study 032	N	30	30	60
	SD	11.6	11.81	11.72
	Mean	42.9	46.2	44.6
	Median	42	42.5	42.5
	Mode	39	42	42
	Minimum	21	26	21
	Maximum	68	72	72
Study 035	N	3	4	7
	SD	5.69	11.09	8.79
	Mean	53.7	49.5	51.3
	Median	52	51	52
	Mode	.	.	60
	Minimum	49	36	36
	Maximum	60	60	60
Study 038	N	32	29	61
	SD	11.17	11.7	11.34
	Mean	42.3	41.3	41.8
	Median	41.5	39	40
	Mode	33	34	36
	Minimum	26	19	19
	Maximum	69	63	69
Study 043	N	15	18	33
	SD	11.87	10.33	10.91
	Mean	35.3	37	36.2
	Median	35	36	35
	Mode	18	38	38
	Minimum	18	23	18
	Maximum	60	61	61

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 046	N	21	22	43
	SD	4.98	5.76	5.4
	Mean	72.8	74.5	73.7
	Median	72	74	73
	Mode	70	68	80
	Minimum	65	65	65
	Maximum	81	83	83
Study 047	N	46	49	95
	SD	12.85	13.36	13.24
	Mean	45.3	40.9	43.1
	Median	44	38	42
	Mode	63	38	38
	Minimum	19	19	19
	Maximum	65	64	65
Study 049	N	62	32	94
	SD	5.62	9.61	7.19
	Mean	72.2	71.4	71.9
	Median	72	72.5	72
	Mode	72	73	66
	Minimum	62	43	43
	Maximum	91	93	93
Study 059	N	72	71	143
	SD	11.45	11.41	11.43
	Mean	48.1	46.1	47.1
	Median	50	48	49
	Mode	32	49	47
	Minimum	22	20	20
	Maximum	65	64	65
Study 060	N	44	47	91
	SD	5.87	5.58	5.69
	Mean	71	71.3	71.2
	Median	68.5	71	69
	Mode	68	65	65
	Minimum	63	64	63
	Maximum	84	82	84
Study 061	N	54	52	106
	SD	5.93	6.37	6.13
	Mean	74.2	73.7	74
	Median	75	73	75
	Mode	78	65	78
	Minimum	61	65	61
	Maximum	85	85	85

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 063	N	21	19	40
	SD	10.86	11.71	11.13
	Mean	41.7	42.5	42.1
	Median	42	46	42.5
	Mode	42	46	42
	Minimum	24	21	21
	Maximum	61	62	62
Study 064	N	49	50	99
	SD	12.1	12.36	12.17
	Mean	44.6	44.1	44.3
	Median	45	44	44
	Mode	34	44	34
	Minimum	18	22	18
	Maximum	65	66	66
Study 065	N	28	32	60
	SD	11.46	12.88	12.14
	Mean	40.4	40.5	40.4
	Median	39.5	39.5	39.5
	Mode	31	57	57
	Minimum	19	20	19
	Maximum	63	63	63
Study 069	N	45	46	91
	SD	7.36	6.56	6.94
	Mean	71.8	70.8	71.3
	Median	73	72.5	73
	Mode	73	61	73
	Minimum	60	60	60
	Maximum	85	84	85
Study 070	N	32	30	62
	SD	8.59	11.56	10.06
	Mean	72.2	73.1	72.6
	Median	73.5	73.5	73.5
	Mode	81	83	60
	Minimum	59	50	50
	Maximum	87	90	90
Study 071	N	9	9	18
	SD	4.72	2.79	4.31
	Mean	68.6	64.4	66.5
	Median	67	64	66
	Mode	67	62	61
	Minimum	61	61	61
	Maximum	75	69	75

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 073	N	6	4	10
	SD	12.48	7.41	12.97
	Mean	40.8	56.3	47
	Median	44.5	54.5	50
	Mode	.	.	50
	Minimum	20	50	20
	Maximum	53	66	66
Study 074	N	20	20	40
	SD	11.38	11.07	11.15
	Mean	44.4	46.8	45.6
	Median	48	49	48.5
	Mode	55	50	55
	Minimum	23	26	23
	Maximum	57	62	62
Study 076	N	4	4	8
	SD	11.15	6.61	8.61
	Mean	49.3	46.5	47.9
	Median	49.5	49	49
	Mode	.	51	37
	Minimum	37	37	37
	Maximum	61	51	61
Study 077	N	46	46	92
	SD	12.22	10.88	11.52
	Mean	43.5	44.7	44.1
	Median	41	44	42.5
	Mode	37	36	36
	Minimum	22	20	20
	Maximum	64	68	68
Study 078	N	155	153	308
	SD	13.69	11.87	12.8
	Mean	48.8	49.3	49
	Median	48.5	50	49
	Mode	48	44	43
	Minimum	20	21	20
	Maximum	77	76	77
Study 079	N	45	45	90
	SD	12.55	11.93	12.21
	Mean	37.8	39.6	38.7
	Median	37	42	39
	Mode	20	20	20
	Minimum	19	19	19
	Maximum	62	65	65

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 080	N	10	13	23
	SD	10.54	6.91	8.46
	Mean	49.1	48.5	48.8
	Median	50.5	49	49
	Mode	.	41	38
	Minimum	30	38	30
	Maximum	64	60	64
Study 082	N	37	34	71
	SD	12.2	11.23	11.71
	Mean	43.6	45.6	44.5
	Median	43	45	44
	Mode	39	57	39
	Minimum	19	20	19
	Maximum	65	63	65
Study 084	N	6	5	11
	SD	8.21	4.55	6.67
	Mean	80.2	83.2	81.5
	Median	83.5	84	84
	Mode	.	.	88
	Minimum	68	78	68
	Maximum	88	88	88
Study 086	N	271	275	546
	SD	12.47	11.97	12.21
	Mean	44.2	44.6	44.4
	Median	45	46	45
	Mode	41	50	53
	Minimum	18	18	18
	Maximum	66	71	71
Study 088	N	16	15	31
	SD	8.57	11.01	10
	Mean	53.8	48.6	51.3
	Median	57	49	52
	Mode	42	29	62
	Minimum	35	29	29
	Maximum	65	65	65
Study 089	N	26	34	60
	SD	9.5	11.99	10.89
	Mean	52	52.1	52
	Median	48	53	49.5
	Mode	41	65	44
	Minimum	37	28	28
	Maximum	69	69	69

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 090	N	79	78	157
	SD	12.69	10.47	11.65
	Mean	44.8	42.8	43.8
	Median	45	42	43
	Mode	45	32	48
	Minimum	18	20	18
	Maximum	69	68	69
Study 095	N	134	68	202
	SD	8.19	9.63	8.7
	Mean	43.9	42.7	43.5
	Median	44	41.5	43.5
	Mode	47	34	39
	Minimum	24	22	22
	Maximum	63	65	65
Study 109	N	65	67	132
	SD	12.95	11.97	12.44
	Mean	48.7	50.3	49.5
	Median	50.5	53	52
	Mode	39	54	62
	Minimum	20	25	20
	Maximum	69	70	70
Study 112	N	55	65	120
	SD	11.54	9.88	10.63
	Mean	43.8	43.3	43.5
	Median	44	42	43
	Mode	28	36	28
	Minimum	20	27	20
	Maximum	65	64	65
Study 115	N	283	288	571
	SD	12.53	11.23	11.89
	Mean	41.8	41.1	41.5
	Median	41	41	41
	Mode	29	36	36
	Minimum	18	20	18
	Maximum	86	76	86
Study 118	N	82	82	164
	SD	11.69	11.37	11.81
	Mean	41.3	36	38.7
	Median	39	32.5	37
	Mode	36	25	36
	Minimum	19	17	17
	Maximum	77	66	77

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 128	N	357	351	708
	SD	12.7	11.58	12.18
	Mean	41.8	40	40.9
	Median	40	39	39.5
	Mode	36	44	34
	Minimum	18	19	18
	Maximum	82	79	82
Study 131	N	100	99	199
	SD	10.8	10.71	10.74
	Mean	40	40.9	40.5
	Median	39.5	40	40
	Mode	28	30	45
	Minimum	18	20	18
	Maximum	65	63	65
Study 135	N	60	62	122
	SD	11	10.69	11.04
	Mean	43.1	38.5	40.8
	Median	43.5	39.5	41
	Mode	37	39	41
	Minimum	20	19	19
	Maximum	68	65	68
Study 136	N	201	99	300
	SD	12.07	12.34	12.14
	Mean	37.8	38.4	38
	Median	36	38	37
	Mode	31	46	31
	Minimum	17	16	16
	Maximum	72	70	72
Study 184	N	14	14	28
	SD	10.89	10.85	10.97
	Mean	35.2	40.3	37.8
	Median	36	38.5	36.5
	Mode	36	26	36
	Minimum	19	26	19
	Maximum	56	62	62
Study 187	N	123	122	245
	SD	9.27	9.36	9.3
	Mean	34.6	35.2	34.9
	Median	34	35	34
	Mode	27	29	29
	Minimum	19	19	19
	Maximum	66	57	66

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 197	N	99	99	198
	SD	9.62	8.81	9.2
	Mean	76.6	76.6	76.6
	Median	76	78	77
	Mode	83	73	83
	Minimum	59	59	59
	Maximum	98	97	98
Study 223	N	76	77	153
	SD	11.1	12.48	11.78
	Mean	39.2	39.5	39.3
	Median	38	40	39
	Mode	33	29	24
	Minimum	22	18	18
	Maximum	74	71	74
Study 239	N	1766	402	2168
	SD	12.44	12.75	12.5
	Mean	41.7	40.9	41.5
	Median	41	40	40
	Mode	45	46	37
	Minimum	18	18	18
	Maximum	91	80	91
Study 245	N	517	510	1027
	SD	13.1	12.51	12.82
	Mean	43.2	42	42.6
	Median	43	42	43
	Mode	40	46	29
	Minimum	18	18	18
	Maximum	70	70	70
Study 256	N	39	34	73
	SD	11.45	11.88	11.66
	Mean	52.6	49.8	51.3
	Median	53	50	52
	Mode	47	42	42
	Minimum	26	28	26
	Maximum	73	74	74
Study 260	N	21	23	44
	SD	12.12	14.24	13.18
	Mean	62.9	60.3	61.6
	Median	64	62	63
	Mode	70	72	70
	Minimum	35	25	25
	Maximum	85	80	85

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 261	N	62	58	120
	SD	11.32	11.54	11.38
	Mean	48.4	48.6	48.5
	Median	47	50	49
	Mode	34	45	45
	Minimum	24	22	22
	Maximum	67	69	69
Study 272	N	5	3	8
	SD	5.73	5.57	5.26
	Mean	55.4	55	55.3
	Median	55	54	55
	Mode	55	.	55
	Minimum	47	50	47
	Maximum	63	61	63
Study 275	N	4	4	8
	SD	8.83	8.1	7.9
	Mean	55	56.8	55.9
	Median	58.5	59	58.5
	Mode	.	63	63
	Minimum	42	46	42
	Maximum	61	63	63
Study 279	N	21	16	37
	SD	18.32	18.42	18.13
	Mean	40.8	42.7	41.6
	Median	38	46	42
	Mode	20	52	20
	Minimum	20	17	17
	Maximum	75	72	75
Study 281	N	106	98	204
	SD	13.52	13.26	13.43
	Mean	41.6	38.9	40.3
	Median	42	37	39
	Mode	46	32	46
	Minimum	18	18	18
	Maximum	67	65	67
Study 289	N	42	44	86
	SD	11.76	11.15	11.39
	Mean	45.3	45.4	45.4
	Median	47	46	47
	Mode	44	58	58
	Minimum	22	21	21
	Maximum	65	62	65

Paroxetine EMEA LOQs

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 290	N	40	39	79
	SD	5.27	6.05	5.67
	Mean	69.3	68.1	68.7
	Median	70.5	68	69
	Mode	75	60	74
	Minimum	60	60	60
	Maximum	75	83	83
Study 291	N	41	42	83
	SD	8.01	8.86	8.42
	Mean	71.1	70.2	70.6
	Median	71	69	69
	Mode	62	75	65
	Minimum	60	57	57
	Maximum	87	96	96
Study 292	N	46	44	90
	SD	12.85	12.83	12.85
	Mean	48.3	45.3	46.8
	Median	48	46	48
	Mode	48	49	49
	Minimum	18	19	18
	Maximum	72	69	72
Study 308	N	10	12	22
	SD	11.97	12.1	11.8
	Mean	43.3	45.3	44.4
	Median	46	44.5	46
	Mode	47	38	47
	Minimum	27	28	27
	Maximum	64	66	66
Study 309	N	11	10	21
	SD	11.3	10.75	11.01
	Mean	41.5	36.9	39.3
	Median	43	33.5	37
	Mode	56	31	31
	Minimum	25	20	20
	Maximum	56	56	56
Study 310	N	9	10	19
	SD	11.73	9.15	10.24
	Mean	39.1	41.8	40.5
	Median	43	43	43
	Mode	30	.	28
	Minimum	25	28	25
	Maximum	61	56	61

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 312	N	2	2	4
	SD	14.85	1.41	10.21
	Mean	46.5	37	41.8
	Median	46.5	37	37
	Mode	.	.	36
	Minimum	36	36	36
	Maximum	57	38	57
Study 314	N	10	8	18
	SD	13.41	11.73	12.65
	Mean	47.9	41.8	45
	Median	54	42	50
	Mode	54	.	54
	Minimum	23	23	23
	Maximum	62	58	62
Study 316	N	9	8	17
	SD	14.15	11.67	13.04
	Mean	47.2	41	44.3
	Median	51	37.5	42
	Mode	.	.	35
	Minimum	24	29	24
	Maximum	70	57	70
Study 318	N	9	12	21
	SD	10.14	8.22	8.89
	Mean	47.3	50.1	49
	Median	42.5	48	45.5
	Mode	.	43	43
	Minimum	36	37	36
	Maximum	65	62	65
Study 319	N	1	1	2
	SD	.	.	0.71
	Mean	51	52	51.5
	Median	51	52	51.5
	Mode	51	52	.
	Minimum	51	52	51
	Maximum	51	52	52
Study 331	N	41	40	81
	SD	10.95	12.69	11.77
	Mean	57.8	58	57.9
	Median	58	62	59
	Mode	52	62	67
	Minimum	40	34	34
	Maximum	84	78	84

EMEA LOQs Table 1.54
Summary of Age by Treatment Group and Study
Adult Active Control Trials

		Treatment Group		
		Paroxetine	Comparator	Total
Study 352	N	35	39	74
	SD	10.15	11.09	10.58
	Mean	42.5	41.9	42.2
	Median	42	44	43
	Mode	37	35	35
	Minimum	24	21	21
	Maximum	66	71	71
Study 785	N	197	206	403
	SD	12.19	11.14	11.71
	Mean	41.3	38.9	40.1
	Median	43	38	40
	Mode	45	37	40
	Minimum	18	18	18
	Maximum	65	64	65

Paroxetine EMEA LOQs

EMEA LOQs Table 1.55
Change from Baseline in HAMD Total Score By Study
20mg Fixed Dose Depression Studies

Study	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Overall*	PAROXETINE	247	11.87	0.48	2.61	(1.18, 4.03)	<0.001
	PLACEBO	193	9.26	0.57			
Study 009	PAROXETINE	104	10.95	0.75	2.86	(0.27, 5.44)	0.03
	PLACEBO	51	8.09	1.07			
Study 810	PAROXETINE	143	12.66	0.62	2.50	(0.77, 4.22)	0.005
	PLACEBO	142	10.16	0.62			

* Overall is adjusted for fixed study effect
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

EMEA LOQs Table 1.56
Change from Baseline in HAMD Total Score By Study
Flexible Dose Depression Studies

Study	Treatment group	Number in analysis	LS Mean	Std. Error	Estimated treatment difference	95% C.I.	P-value
Overall*	PAROXETINE	1935	10.04	0.31	2.55	(2.01, 3.10)	<0.001
	PLACEBO	1256	7.48	0.33			
Study 001	PAROXETINE	24	11.23	1.25	1.49	(-2.08, 5.07)	0.4
	PLACEBO	24	9.73	1.25			
Study 002	PAROXETINE	162	10.05	0.63	3.96	(2.21, 5.71)	<0.001
	PLACEBO	162	6.09	0.63			
Study 003	PAROXETINE	234	8.91	0.48	3.74	(2.40, 5.08)	<0.001
	PLACEBO	234	5.17	0.48			
Study 007	PAROXETINE	12	10.09	2.63	-0.28	(-8.26, 7.71)	0.94
	PLACEBO	11	10.36	2.75			
Study 115	PAROXETINE	272	9.18	0.44	0.89	(-0.74, 2.52)	0.28
	PLACEBO	111	8.29	0.70			
Study 128	PAROXETINE	347	10.63	0.42	2.44	(0.88, 4.00)	0.002
	PLACEBO	135	8.19	0.67			
Study 251	PAROXETINE	120	9.04	0.67	1.69	(-0.16, 3.54)	0.07
	PLACEBO	123	7.35	0.66			
Study 275	PAROXETINE	4	5.77	4.42	0.80	(-18.6,20.24)	0.91
	PLACEBO	3	4.97	5.15			
Study 279	PAROXETINE	19	8.07	1.38	1.51	(-3.33, 6.35)	0.53
	PLACEBO	10	6.56	1.91			
Study 327	PAROXETINE	77	7.35	0.72	2.72	(0.73, 4.71)	0.008
	PLACEBO	82	4.63	0.70			
Study 352	PAROXETINE	33	10.16	1.31	2.26	(-1.22, 5.74)	0.2
	PLACEBO	43	7.90	1.14			
Study 448	PAROXETINE	206	12.00	0.56	2.08	(0.16, 3.99)	0.03
	PLACEBO	101	9.92	0.80			
Study 449	PAROXETINE	218	12.81	0.52	2.54	(0.76, 4.32)	0.005
	PLACEBO	110	10.27	0.74			
Study 487	PAROXETINE	207	12.02	0.48	2.69	(1.07, 4.31)	0.001
	PLACEBO	107	9.33	0.67			

* Overall is adjusted for fixed study effect
Treatment differences are Paroxetine minus Placebo
Negative differences correspond to Paroxetine treatment benefit

Paroxetine EMEA LOQs

EMEA LOQs Table 1.57
Emergent Suicidal Ideation (MADRS item 10) by CGI Response and Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	17/1660	1.0	0.72	[0.35, 1.49]	0.37
	Placebo	13/917	1.4			
Non-responder	Paroxetine	27/725	3.7	0.87	[0.53, 1.44]	0.59
	Placebo	39/917	4.3			

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.58
Emergent Suicidal Ideation (MADRS item 10) by CGI Response and Treatment Group
Adult Active Control Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	3/716	0.4	1.40	[0.23, 8.38]	0.71
	Comparator	2/666	0.3			
Non-responder	Paroxetine	16/342	4.7	0.85	[0.42, 1.72]	0.66
	Comparator	17/313	5.4			

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.59
Emergent Suicidal Ideation (MADRS item 10) by CGI Response and Treatment Group
Paediatric Placebo Controlled Trials, Study 377
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	2/67	3.0	0.42	[0.06, 3.10]	0.39
	Placebo	2/29	6.9			
Non-responder	Paroxetine	2/12	16.7	0.80	[0.11, 5.77]	0.82
	Placebo	3/15	20.0			

Paroxetine EMEA LOQs

EMEA LOQs Table 1.60
Emergent Suicidal Ideation (HAM-D item 3) by CGI Response and Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	14/1410	1.0	1.99	[0.57, 6.93]	0.28
	Placebo	3/597	0.5			
Non-responder	Paroxetine	15/827	1.8	1.16	[0.55, 2.46]	0.69
	Placebo	13/832	1.6			

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.61
Emergent Suicidal Ideation (HAM-D item 3) by CGI Response and Treatment Group
Adult Active Control Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	8/1554	0.5	0.68	[0.25, 1.88]	0.46
	Comparator	7/926	0.8			
Non-responder	Paroxetine	14/659	2.1	1.01	[0.46, 2.25]	0.98
	Comparator	11/524	2.1			

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.62
Emergent Suicidal Ideation (HAM-D item 3) by CGI Response and Treatment Group
Paediatric Placebo Controlled Trials, Studies 329 and 453
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	1/95	1.1	0.81	[0.05,13.14]	0.88
	Placebo	1/77	1.3			
Non-responder	Paroxetine	4/59	6.8		-	0.04
	Placebo	0/69	0			

Paroxetine EMEA LOQs

EMEA LOQs Table 1.63
Declining Suicidal Ideation (MADRS item 10) by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Paroxetine	181/305	59.3	1.99	[1.40, 2.85]	<0.001
Placebo	90/213	42.3			

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.64
Declining Suicidal Ideation (MADRS item 10) by Treatment Group
Adult Active Control Trials
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Paroxetine	205/327	62.7	1.02	[0.74, 1.40]	0.93
Comparator	192/308	62.3			

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.65
Declining Suicidal Ideation (MADRS item 10) by Treatment Group
Paediatric Placebo Controlled Trials, Study 377
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Paroxetine	25/52	48.1	0.44	[0.16, 1.19]	0.10
Placebo	17/25	68.0			

Paroxetine EMEA LOQs

EMEA LOQs Table 1.66
Declining Suicidal Ideation (HAM-D item 3) by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Paroxetine	78/116	67.2	1.48	[0.78, 2.80]	0.23
Placebo	36/62	58.1			

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.67
Declining Suicidal Ideation (HAM-D item 3) by Treatment Group
Adult Active Control Trials
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Paroxetine	281/367	76.6	1.17	[0.81, 1.69]	0.39
Comparator	192/261	73.6			

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.68
Declining Suicidal Ideation (HAM-D item 3) by Treatment Group
Paediatric Placebo Controlled Trials, Studies 329 and 453
Randomised Phase

Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Paroxetine	4/5	80.0	0.67	[0.03,14.03]	0.79
Placebo	6/7	85.7			

Paroxetine EMEA LOQs

EMEA LOQs Table 1.69
Declining Suicidal Ideation (MADRS item 10) by CGI response and Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	143/157	91.1	3.52	[1.68, 7.37]	<0.001
	Placebo	61/82	74.4			
Non-responder	Paroxetine	38/148	25.7	1.22	[0.70, 2.11]	0.49
	Placebo	29/131	22.1			

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.70
Declining Suicidal Ideation (MADRS item 10) by CGI response and Treatment Group
Adult Active Control Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	153/173	88.4	0.73	[0.35, 1.51]	0.39
	Comparator	137/150	91.3			
Non-responder	Paroxetine	42/137	30.7	1.23	[0.72, 2.08]	0.45
	Comparator	35/132	26.5			

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.71
Declining Suicidal Ideation (MADRS item 10) by CGI response and Treatment Group
Paediatric Placebo Controlled Trials, Study 377
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	20/22	90.9		-	0.51
	Placebo	14/14	100.0			
Non-responder	Paroxetine	5/28	17.9	0.58	[0.11, 2.99]	0.52
	Placebo	3/11	27.3			

Paroxetine EMEA LOQs

EMEA LOQs Table 1.72
Declining Suicidal Ideation (HAM-D item 3) by CGI response and Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	62/66	93.9		-	0.57
	Placebo	25/25	100.0			
Non-responder	Paroxetine	12/43	27.9	1.02	[0.35, 2.91]	0.98
	Placebo	8/29	27.6			

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.73
Declining Suicidal Ideation (HAM-D item 3) by CGI response and Treatment Group
Adult Active Control Trials
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	168/175	96.0	1.01	[0.25, 4.03]	0.98
	Comparator	71/74	95.9			
Non-responder	Paroxetine	39/82	47.6	1.33	[0.70, 2.54]	0.39
	Comparator	28/69	40.6			

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.74
Declining Suicidal Ideation (HAM-D item 3) by CGI response and Treatment Group
Paediatric Placebo Controlled Trials, Studies 329 and 453
Randomised Phase

CGI response	Treatment group	(n/N)	(%)	Odds ratio	95% CI	P-value
Responder	Paroxetine	3/3	100.0			
	Placebo	3/3	100.0			
Non-responder	Paroxetine	1/2	50.0	0.33	[0.01,11.94]	0.55
	Placebo	3/4	75.0			

Paroxetine EMEA LOQs

EMEA LOQs Table 1.75
Probability of a Patient Responding (CGI Response) to a Dose of Paroxetine IR Given Non-Response at Lower Doses
Paroxetine Studies 448 & 449
Randomised Phase
Intention to Treat Population

IR Dose	Point Estimate	n/N	Lower 95% C.I. Limit	Upper 95% C.I. Limit
20 mg	0.23	46/204	0.17	0.28
30 mg	0.35	49/139	0.27	0.43
40 mg	0.28	22/79	0.18	0.38
50 mg	0.51	23/45	0.37	0.66

Definition of n/N: n = Number of patients responding at that dose who had not responded at all lower doses
N = Number of patients with a CGI assessment at that dose

Paroxetine EMEA LOQs

EMEA LOQs Table 1.76
Mean and Median Daily Dose (mg) of Paroxetine IR
Paroxetine Studies 448 & 449
Randomised Phase
Intention to Treat Population

Treatment Group	Mean Dose (mg)	Median Dose (mg)
PAROXETINE IR	33.6	30

EMEA LOQs Table 1.77
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Adult Placebo Controlled Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	131/8481 (1.5%)	117/5808 (2.0%)	0.76 (0.59, 0.98)	0.04
Study 276(02DEC1982)	n/N (%)	0/20 (0.0%)	0/21 (0.0%)		
Study 279(02JUN1983)	n/N (%)	2/21 (9.5%)	1/10 (10.0%)	0.95 (0.08, 11.87)	1.00
Study 274(20JUN1983)	n/N (%)	0/22 (0.0%)	0/23 (0.0%)		
Study 275(24AUG1983)	n/N (%)	0/4 (0.0%)	0/3 (0.0%)		
Study 001(03APR1984)	n/N (%)	0/25 (0.0%)	0/25 (0.0%)		
Study 002(25APR1985)	n/N (%)	2/170 (1.2%)	4/171 (2.3%)	0.5 (0.09, 2.75)	0.68
Study 009(25APR1985)	n/N (%)	8/421 (1.9%)	1/53 (1.9%)	1.01 (0.12, 8.22)	1.00
Study 003(01MAY1985)	n/N (%)	3/241 (1.2%)	5/244 (2.0%)	0.6 (0.14, 2.55)	0.72
Study 007(01NOV1986)	n/N (%)	0/13 (0.0%)	0/12 (0.0%)		
Study 201(30NOV1988)	n/N (%)	0/57 (0.0%)	0/60 (0.0%)		
Study 083(17DEC1988)	n/N (%)	1/68 (1.5%)	2/67 (3.0%)	0.49 (0.04, 5.48)	0.62
Study 076(04JUL1989)	n/N (%)	1/4 (25.0%)	0/4 (0.0%)		1.00
Study 057(19MAY1990)	n/N (%)	36/131 (27.5%)	40/136 (29.4%)	0.91 (0.53, 1.55)	0.79
Study 106(25JUN1990)	n/N (%)	8/18 (44.4%)	5/18 (27.8%)	2.08 (0.52, 8.34)	0.49
Study 108(03JAN1991)	n/N (%)	0/60 (0.0%)	0/60 (0.0%)		
Study 115(20MAR1991)	n/N (%)	6/283 (2.1%)	2/117 (1.7%)	1.25 (0.25, 6.26)	1.00
Study 128(17MAY1991)	n/N (%)	10/357 (2.8%)	7/140 (5.0%)	0.55 (0.2, 1.47)	0.27
Study 116(06AUG1991)	n/N (%)	2/259 (0.8%)	1/89 (1.1%)	0.68 (0.06, 7.64)	1.00
Study 118(12SEP1991)	n/N (%)	0/82 (0.0%)	1/77 (1.3%)		0.48
Study 187(17OCT1991)	n/N (%)	0/123 (0.0%)	3/123 (2.4%)		0.25
Study 136(26OCT1991)	n/N (%)	2/201 (1.0%)	7/99 (7.1%)	0.13 (0.03, 0.65)	0.007
Study 251(20MAY1992)	n/N (%)	3/125 (2.4%)	1/129 (0.8%)	3.15 (0.32, 30.66)	0.36
Study 120(02NOV1992)	n/N (%)	2/209 (1.0%)	0/69 (0.0%)		1.00

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.77
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Adult Placebo Controlled Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Study 223(01DEC1992)	n/N (%)	0/76 (0.0%)	1/71 (1.4%)		0.48
Study 190(22SEP1993)	n/N (%)	0/61 (0.0%)	1/64 (1.6%)		1.00
Study 327(01MAR1994)	n/N (%)	3/81 (3.7%)	0/85 (0.0%)		0.11
Study 352(05APR1994)	n/N (%)	1/35 (2.9%)	0/43 (0.0%)		0.45
Study 400(27DEC1994)	n/N (%)	0/31 (0.0%)	0/17 (0.0%)		
Study 382(02MAY1995)	n/N (%)	0/94 (0.0%)	1/93 (1.1%)		0.50
Study 427(04JAN1996)	n/N (%)	0/29 (0.0%)	0/9 (0.0%)		
Study 448(10SEP1996)	n/N (%)	3/212 (1.4%)	1/103 (1.0%)	1.46 (0.15, 14.25)	1.00
Study 449(26SEP1996)	n/N (%)	6/223 (2.7%)	3/110 (2.7%)	0.99 (0.24, 4.02)	1.00
Study 487(24OCT1996)	n/N (%)	4/214 (1.9%)	1/109 (0.9%)	2.06 (0.23, 18.63)	0.67
Study 495(19NOV1996)	n/N (%)	0/162 (0.0%)	0/165 (0.0%)		
Study 494(22NOV1996)	n/N (%)	0/141 (0.0%)	0/148 (0.0%)		
Study 497(03DEC1996)	n/N (%)	0/149 (0.0%)	0/144 (0.0%)		
Study 502(13DEC1996)	n/N (%)	2/139 (1.4%)	1/151 (0.7%)	2.19 (0.2, 24.42)	0.61
Study 454(18JAN1997)	n/N (%)	0/289 (0.0%)	0/95 (0.0%)		
Study 595(11JUN1998)	n/N (%)	0/162 (0.0%)	1/161 (0.6%)		0.50
Study 627(08JUL1998)	n/N (%)	6/160 (3.8%)	7/162 (4.3%)	0.86 (0.28, 2.63)	1.00
Study 625(29AUG1998)	n/N (%)	2/112 (1.8%)	1/117 (0.9%)	2.11 (0.19, 23.59)	0.62
Study 637(11NOV1998)	n/N (%)	1/187 (0.5%)	0/185 (0.0%)		1.00
Study 641(21NOV1998)	n/N (%)	1/386 (0.3%)	0/180 (0.0%)		1.00
Study 642(08JAN1999)	n/N (%)	1/164 (0.6%)	1/166 (0.6%)	1.01 (0.06, 16.32)	1.00
Study 651(04FEB1999)	n/N (%)	3/375 (0.8%)	6/188 (3.2%)	0.24 (0.06, 0.99)	0.07
Study 648(09FEB1999)	n/N (%)	2/163 (1.2%)	4/160 (2.5%)	0.48 (0.09, 2.68)	0.45
Study 650(03MAR1999)	n/N (%)	4/88 (4.5%)	0/88 (0.0%)		0.12

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.77
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Adult Placebo Controlled Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Study 646(10MAR1999)	n/N (%)	0/278 (0.0%)	0/288 (0.0%)		
Study 689(03FEB2000)	n/N (%)	0/246 (0.0%)	0/125 (0.0%)		
Study 677(25FEB2000)	n/N (%)	0/212 (0.0%)	0/109 (0.0%)		
Study 688(29MAR2000)	n/N (%)	0/242 (0.0%)	0/119 (0.0%)		
Study 785(11APR2001)	n/N (%)	3/197 (1.5%)	4/105 (3.8%)	0.39 (0.09, 1.78)	0.24
Study 791(08AUG2001)	n/N (%)	1/167 (0.6%)	2/166 (1.2%)	0.49 (0.04, 5.5)	0.62
Study 810(28AUG2001)	n/N (%)	2/306 (0.7%)	2/148 (1.4%)	0.48 (0.07, 3.44)	0.60
Study 790(27NOV2001)	n/N (%)	0/186 (0.0%)	0/184 (0.0%)		

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 1.78
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Adult Active Control Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	96/6522 (1.5%)	98/4969 (2.0%)	0.74 (0.56, 0.99)	0.04
Study 260(17OCT1980)	n/N (%)	0/21 (0.0%)	0/23 (0.0%)		
Study 310(17SEP1981)	n/N (%)	0/9 (0.0%)	1/10 (10.0%)		1.00
Study 308(30SEP1981)	n/N (%)	1/10 (10.0%)	0/12 (0.0%)		0.45
Study 309(13MAR1982)	n/N (%)	1/11 (9.1%)	0/10 (0.0%)		1.00
Study 319(25AUG1982)	n/N (%)	0/1 (0.0%)	0/1 (0.0%)		
Study 318(22SEP1982)	n/N (%)	0/9 (0.0%)	1/12 (8.3%)		1.00
Study 316(05OCT1982)	n/N (%)	2/9 (22.2%)	1/8 (12.5%)	2 (0.15, 27.45)	1.00
Study 314(07MAR1983)	n/N (%)	0/10 (0.0%)	0/8 (0.0%)		
Study 281(14MAR1983)	n/N (%)	3/106 (2.8%)	0/98 (0.0%)		0.25
Study 279(02JUN1983)	n/N (%)	2/21 (9.5%)	0/16 (0.0%)		0.50
Study 275(24AUG1983)	n/N (%)	0/4 (0.0%)	0/4 (0.0%)		
Study 312(08OCT1983)	n/N (%)	0/2 (0.0%)	0/2 (0.0%)		
Study 256(21OCT1983)	n/N (%)	0/39 (0.0%)	0/34 (0.0%)		
Study 022(04NOV1983)	n/N (%)	0/16 (0.0%)	0/17 (0.0%)		
Study 272(19JAN1984)	n/N (%)	0/5 (0.0%)	0/3 (0.0%)		
Study 020(19JUN1984)	n/N (%)	0/24 (0.0%)	0/24 (0.0%)		
Study 289(25JUN1984)	n/N (%)	0/42 (0.0%)	1/44 (2.3%)		1.00
Study 292(14AUG1984)	n/N (%)	0/46 (0.0%)	0/44 (0.0%)		
Study 035(20AUG1984)	n/N (%)	0/3 (0.0%)	0/4 (0.0%)		
Study 261(17APR1985)	n/N (%)	0/62 (0.0%)	0/58 (0.0%)		
Study 003(01MAY1985)	n/N (%)	3/241 (1.2%)	3/241 (1.2%)	1 (0.2, 5)	1.00
Study 027(05JUN1985)	n/N (%)	0/17 (0.0%)	1/15 (6.7%)		0.47
Study 038(18JUN1985)	n/N (%)	0/32 (0.0%)	0/29 (0.0%)		

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.78
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Adult Active Control Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Study 028(20JUN1985)	n/N (%)	0/8 (0.0%)	0/6 (0.0%)		
Study 030(09JUL1985)	n/N (%)	1/21 (4.8%)	1/19 (5.3%)	0.9 (0.05, 15.47)	1.00
Study 026(10JUL1985)	n/N (%)	0/30 (0.0%)	0/30 (0.0%)		
Study 032(19JUL1985)	n/N (%)	0/30 (0.0%)	0/30 (0.0%)		
Study 025(27AUG1985)	n/N (%)	0/4 (0.0%)	0/4 (0.0%)		
Study 029(11SEP1985)	n/N (%)	0/4 (0.0%)	0/5 (0.0%)		
Study 043(09DEC1985)	n/N (%)	0/15 (0.0%)	0/18 (0.0%)		
Study 088(19DEC1985)	n/N (%)	0/16 (0.0%)	1/15 (6.7%)		0.48
Study 019(24JAN1986)	n/N (%)	1/31 (3.2%)	1/35 (2.9%)	1.13 (0.07, 18.92)	1.00
Study 007(01NOV1986)	n/N (%)	0/13 (0.0%)	0/13 (0.0%)		
Study 006(19NOV1986)	n/N (%)	0/33 (0.0%)	1/33 (3.0%)		1.00
Study 089(28JAN1987)	n/N (%)	2/26 (7.7%)	3/34 (8.8%)	0.86 (0.13, 5.57)	1.00
Study 290(17FEB1987)	n/N (%)	0/40 (0.0%)	0/39 (0.0%)		
Study 071(09APR1987)	n/N (%)	0/9 (0.0%)	0/9 (0.0%)		
Study 291(23JUN1987)	n/N (%)	0/41 (0.0%)	0/42 (0.0%)		
Study 011(08SEP1987)	n/N (%)	2/103 (1.9%)	1/103 (1.0%)	2.02 (0.18, 22.63)	1.00
Study 046(16SEP1987)	n/N (%)	1/21 (4.8%)	0/22 (0.0%)		0.49
Study 047(30SEP1987)	n/N (%)	2/46 (4.3%)	1/49 (2.0%)	2.18 (0.19, 24.91)	0.61
Study 184(30SEP1987)	n/N (%)	0/14 (0.0%)	0/14 (0.0%)		
Study 049(04DEC1987)	n/N (%)	0/62 (0.0%)	0/32 (0.0%)		
Study 060(29APR1988)	n/N (%)	3/44 (6.8%)	1/47 (2.1%)	3.37 (0.34, 33.63)	0.35
Study 059(30APR1988)	n/N (%)	5/72 (6.9%)	7/71 (9.9%)	0.68 (0.21, 2.26)	0.56
Study 069(16MAY1988)	n/N (%)	2/45 (4.4%)	1/46 (2.2%)	2.09 (0.18, 23.93)	0.62
Study 077(09JUL1988)	n/N (%)	1/46 (2.2%)	1/46 (2.2%)	1 (0.06, 16.48)	1.00

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.78
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Adult Active Control Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Study 070(13JUL1988)	n/N (%)	1/32 (3.1%)	0/30 (0.0%)		1.00
Study 065(01OCT1988)	n/N (%)	1/28 (3.6%)	3/32 (9.4%)	0.36 (0.04, 3.65)	0.62
Study 090(04OCT1988)	n/N (%)	1/79 (1.3%)	1/78 (1.3%)	0.99 (0.06, 16.07)	1.00
Study 078(24OCT1988)	n/N (%)	0/155 (0.0%)	0/153 (0.0%)		
Study 074(28OCT1988)	n/N (%)	0/20 (0.0%)	1/20 (5.0%)		1.00
Study 063(14NOV1988)	n/N (%)	0/21 (0.0%)	0/19 (0.0%)		
Study 073(24JAN1989)	n/N (%)	1/6 (16.7%)	0/4 (0.0%)		1.00
Study 064(01FEB1989)	n/N (%)	0/49 (0.0%)	0/50 (0.0%)		
Study 061(14FEB1989)	n/N (%)	4/54 (7.4%)	3/52 (5.8%)	1.31 (0.28, 6.14)	1.00
Study 079(16FEB1989)	n/N (%)	0/45 (0.0%)	1/45 (2.2%)		1.00
Study 076(04JUL1989)	n/N (%)	1/4 (25.0%)	0/4 (0.0%)		1.00
Study 080(17JUL1989)	n/N (%)	1/10 (10.0%)	0/13 (0.0%)		0.43
Study 082(24NOV1989)	n/N (%)	0/37 (0.0%)	0/34 (0.0%)		
Study 086(31MAR1990)	n/N (%)	2/271 (0.7%)	3/275 (1.1%)	0.67 (0.11, 4.07)	1.00
Study 095(01OCT1990)	n/N (%)	0/134 (0.0%)	0/68 (0.0%)		
Study 115(20MAR1991)	n/N (%)	6/283 (2.1%)	6/288 (2.1%)	1.02 (0.32, 3.19)	1.00
Study 084(03APR1991)	n/N (%)	0/6 (0.0%)	0/5 (0.0%)		
Study 128(17MAY1991)	n/N (%)	10/357 (2.8%)	14/351 (4.0%)	0.69 (0.3, 1.58)	0.41
Study 112(11JUL1991)	n/N (%)	0/55 (0.0%)	1/65 (1.5%)		1.00
Study 118(12SEP1991)	n/N (%)	0/82 (0.0%)	0/82 (0.0%)		
Study 135(27SEP1991)	n/N (%)	0/60 (0.0%)	2/62 (3.2%)		0.50
Study 187(17OCT1991)	n/N (%)	0/123 (0.0%)	2/122 (1.6%)		0.25
Study 136(26OCT1991)	n/N (%)	2/201 (1.0%)	2/99 (2.0%)	0.49 (0.07, 3.51)	0.60
Study 131(27DEC1991)	n/N (%)	3/100 (3.0%)	6/99 (6.1%)	0.48 (0.12, 1.97)	0.33

Includes paroxetine and active control data from multiple arm trials with placebo

EMEA LOQs Table 1.78
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Adult Active Control Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Study 109(03JUL1992)	n/N (%)	1/65 (1.5%)	1/67 (1.5%)	1.03 (0.06, 16.84)	1.00
Study 245(28OCT1992)	n/N (%)	9/517 (1.7%)	13/510 (2.5%)	0.68 (0.29, 1.6)	0.40
Study 239(20NOV1992)	n/N (%)	14/1766 (0.8%)	4/402 (1.0%)	0.79 (0.26, 2.43)	0.76
Study 223(01DEC1992)	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
Study 197(29DEC1993)	n/N (%)	2/99 (2.0%)	3/99 (3.0%)	0.66 (0.11, 4.04)	1.00
Study 331(11MAR1994)	n/N (%)	1/41 (2.4%)	0/40 (0.0%)		1.00
Study 352(05APR1994)	n/N (%)	1/35 (2.9%)	0/39 (0.0%)		0.47
Study 785(11APR2001)	n/N (%)	3/197 (1.5%)	5/206 (2.4%)	0.62 (0.15, 2.64)	0.72

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 1.79
Incidence of Suicidality 'Composite' Definition by Treatment Group and Study
Paediatric Placebo Controlled Trials
Studies Ordered By Study Start Date

Study (Study Start Date)		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	27/738 (3.7%)	13/647 (2.0%)	1.85 (0.95, 3.62)	0.08
Study 329(20APR1994)	n/N (%)	10/93 (10.8%)	3/88 (3.4%)	3.41 (0.91, 12.84)	0.08
Study 377(18MAY1995)	n/N (%)	11/181 (6.1%)	9/95 (9.5%)	0.62 (0.25, 1.55)	0.33
Study 453(23JAN1997)	n/N (%)	1/96 (1.0%)	0/98 (0.0%)		0.49
Study 676(30NOV1999)	n/N (%)	3/165 (1.8%)	0/157 (0.0%)		0.25
Study 704(20JAN2000)	n/N (%)	1/99 (1.0%)	0/107 (0.0%)		0.48
Study 701(20MAR2000)	n/N (%)	1/104 (1.0%)	1/102 (1.0%)	0.98 (0.06, 15.89)	1.00

Paroxetine EMEA LOQs

EMEA LOQs Table 1.80
Study Phase at onset of Possibly suicide-related AEs by Treatment Group
Paediatric Studies - 329, 377, 453, 676, 701 & 704

Study Phase	Paroxetine (N=738)	Placebo (N=647)
Total no. of pts with event	25	8
Treatment	17 (68.0%)	6 (75.0%)
Taper	1 (4.0%)	1 (12.5%)
Follow-Up	7 (28.0%)	1 (12.5%)

Paroxetine EMEA LOQs

EMEA LOQs Table 1.81
Incidence of Possibly Suicide-Related AEs by Treatment Group and Prior Exposure to Paroxetine
Adult Placebo Control Trials
On-Therapy

Pre rand. Paroxetine use		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	66/8481 (0.8%)	55/5808 (0.9%)	0.82 (0.57, 1.18)	0.31
No/Unknown	n/N (%)	66/7694 (0.9%)	51/5057 (1.0%)	0.85 (0.59, 1.23)	0.39
Yes	n/N (%)	0/787 (0.0%)	4/751 (0.5%)		0.057

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.82
Incidence of Possibly Suicide-Related AEs by Treatment Group and Prior Exposure to Paroxetine
Adult Active Control Trials
On-Therapy

Pre rand. Paroxetine use		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	55/6522 (0.8%)	63/4969 (1.3%)	0.66 (0.46, 0.95)	0.031
No/Unknown	n/N (%)	55/6510 (0.8%)	63/4958 (1.3%)	0.66 (0.46, 0.95)	0.031
Yes	n/N (%)	0/12 (0.0%)	0/11 (0.0%)		

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.83
Incidence of Possibly Suicide-Related AEs by Treatment Group and Prior Exposure to Paroxetine
Paediatric Placebo Controlled Trials
On-Therapy

Pre rand. Paroxetine use		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	18/738 (2.4%)	7/647 (1.1%)	2.29 (0.95, 5.51)	0.069
No/Unknown	n/N (%)	18/626 (2.9%)	7/535 (1.3%)	2.23 (0.93, 5.39)	0.071
Yes	n/N (%)	0/112 (0.0%)	0/112 (0.0%)		

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.84
Incidence of Possibly Suicide-Related AEs by Treatment Group and Prior Exposure to SSRIs
Adult Placebo Control Trials
On-Therapy

Pre rand. SSRI use		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	66/8481 (0.8%)	55/5808 (0.9%)	0.82 (0.57, 1.18)	0.31
No/Unknown	n/N (%)	60/7134 (0.8%)	50/4652 (1.1%)	0.78 (0.54, 1.14)	0.20
Yes	n/N (%)	6/1347 (0.4%)	5/1156 (0.4%)	1.03 (0.31, 3.38)	1.00

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.85
Incidence of Possibly Suicide-Related AEs by Treatment Group and Prior Exposure to SSRIs
Adult Active Control Trials
On-Therapy

Pre rand. SSRI use		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	55/6522 (0.8%)	63/4969 (1.3%)	0.66 (0.46, 0.95)	0.031
No/Unknown	n/N (%)	55/6438 (0.9%)	63/4898 (1.3%)	0.66 (0.46, 0.95)	0.031
Yes	n/N (%)	0/84 (0.0%)	0/71 (0.0%)		

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 1.86
Incidence of Possibly Suicide-Related AEs by Treatment Group and Prior Exposure to SSRIs
Paediatric Placebo Controlled Trials
On-Therapy

Pre rand. SSRI use		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	18/738 (2.4%)	7/647 (1.1%)	2.29 (0.95, 5.51)	0.069
No/Unknown	n/N (%)	17/587 (2.9%)	7/496 (1.4%)	2.08 (0.86, 5.07)	0.15
Yes	n/N (%)	1/151 (0.7%)	0/151 (0.0%)		1.00

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.87
Incidence of Possibly Suicide-Related AEs by Treatment Group, Prior Exposure to Paroxetine and Modified Age Group
Paediatric Placebo Controlled Trials
On-Therapy

Pre rand. Paroxetine use	Modified Age Group		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	18/738 (2.4%)	7/647 (1.1%)	2.29 (0.95, 5.51)	0.07
	< 12 years	n/N (%)	0/205 (0.0%)	0/194 (0.0%)		
	12-15 years	n/N (%)	10/329 (3.0%)	5/269 (1.9%)	1.66 (0.56, 4.9)	0.44
	>=16 years	n/N (%)	8/204 (3.9%)	2/184 (1.1%)	3.71 (0.78, 17.72)	0.11
No/Unknown	Overall	n/N (%)	18/626 (2.9%)	7/535 (1.3%)	2.23 (0.93, 5.39)	0.07
	< 12 years	n/N (%)	0/151 (0.0%)	0/145 (0.0%)		
	12-15 years	n/N (%)	10/288 (3.5%)	5/222 (2.3%)	1.56 (0.53, 4.63)	0.60
	>=16 years	n/N (%)	8/187 (4.3%)	2/168 (1.2%)	3.71 (0.78, 17.72)	0.11
Yes	Overall	n/N (%)	0/112 (0.0%)	0/112 (0.0%)		
	< 12 years	n/N (%)	0/54 (0.0%)	0/49 (0.0%)		
	12-15 years	n/N (%)	0/41 (0.0%)	0/47 (0.0%)		
	>=16 years	n/N (%)	0/17 (0.0%)	0/16 (0.0%)		

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.88

Incidence of Possibly Suicide-Related AEs by Treatment Group, Prior Exposure to SSRIs and Modified Age Group

Paediatric Placebo Controlled Trials

On-Therapy

Pre rand. SSRI use	Modified Age Group		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	18/738 (2.4%)	7/647 (1.1%)	2.29 (0.95, 5.51)	0.07
	< 12 years	n/N (%)	0/205 (0.0%)	0/194 (0.0%)		
	12-15 years	n/N (%)	10/329 (3.0%)	5/269 (1.9%)	1.66 (0.56, 4.9)	0.44
	>=16 years	n/N (%)	8/204 (3.9%)	2/184 (1.1%)	3.71 (0.78, 17.72)	0.11
No/Unknown	Overall	n/N (%)	17/587 (2.9%)	7/496 (1.4%)	2.08 (0.86, 5.07)	0.15
	< 12 years	n/N (%)	0/139 (0.0%)	0/133 (0.0%)		
	12-15 years	n/N (%)	9/272 (3.3%)	5/198 (2.5%)	1.32 (0.44, 4)	0.79
	>=16 years	n/N (%)	8/176 (4.5%)	2/165 (1.2%)	3.88 (0.81, 18.55)	0.11
Yes	Overall	n/N (%)	1/151 (0.7%)	0/151 (0.0%)		1.00
	< 12 years	n/N (%)	0/66 (0.0%)	0/61 (0.0%)		
	12-15 years	n/N (%)	1/57 (1.8%)	0/71 (0.0%)		0.45
	>=16 years	n/N (%)	0/28 (0.0%)	0/19 (0.0%)		

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.89
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Overall	N	8481	5808
	Pre rand. Paroxetine use	787 (9.28%)	751 (12.93%)
Study 001	N	25	25
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 002	N	170	171
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 003	N	241	244
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 007	N	13	12
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 009	N	421	53
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 057	N	131	136
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 076	N	4	4
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 083	N	68	67
	Pre rand. Paroxetine use	68 (100.00%)	67 (100.00%)
Study 106	N	18	18
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 108	N	60	60
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 115	N	283	117
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 116	N	259	89
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 118	N	82	77
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 120	N	209	69
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 128	N	357	140
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.89
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Study 136	N	201	99
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 187	N	123	123
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 190	N	61	64
	Pre rand. Paroxetine use	61 (100.00%)	64 (100.00%)
Study 201	N	57	60
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 223	N	76	71
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 251	N	125	129
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 274	N	22	23
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 275	N	4	3
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 276	N	20	21
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 279	N	21	10
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 327	N	81	85
	Pre rand. Paroxetine use	1 (1.23%)	2 (2.35%)
Study 352	N	35	43
	Pre rand. Paroxetine use	3 (8.57%)	4 (9.30%)
Study 382	N	94	93
	Pre rand. Paroxetine use	0 (0.00%)	1 (1.08%)
Study 400	N	31	17
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 427	N	29	9
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 448	N	212	103
	Pre rand. Paroxetine use	12 (5.66%)	6 (5.83%)

EMEA LOQs Table 1.89
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Study 449	N	223	110
	Pre rand. Paroxetine use	20 (8.97%)	7 (6.36%)
Study 454	N	289	95
	Pre rand. Paroxetine use	3 (1.04%)	0 (0.00%)
Study 487	N	214	109
	Pre rand. Paroxetine use	13 (6.07%)	5 (4.59%)
Study 494	N	141	148
	Pre rand. Paroxetine use	8 (5.67%)	7 (4.73%)
Study 495	N	162	165
	Pre rand. Paroxetine use	8 (4.94%)	10 (6.06%)
Study 497	N	149	144
	Pre rand. Paroxetine use	7 (4.70%)	8 (5.56%)
Study 502	N	139	151
	Pre rand. Paroxetine use	7 (5.04%)	5 (3.31%)
Study 595	N	162	161
	Pre rand. Paroxetine use	162 (100.00%)	161 (100.00%)
Study 625	N	112	117
	Pre rand. Paroxetine use	4 (3.57%)	1 (0.85%)
Study 627	N	160	162
	Pre rand. Paroxetine use	5 (3.13%)	5 (3.09%)
Study 637	N	187	185
	Pre rand. Paroxetine use	1 (0.53%)	5 (2.70%)
Study 641	N	386	180
	Pre rand. Paroxetine use	0 (0.00%)	2 (1.11%)
Study 642	N	164	166
	Pre rand. Paroxetine use	0 (0.00%)	3 (1.81%)
Study 646	N	278	288
	Pre rand. Paroxetine use	278 (100.00%)	288 (100.00%)
Study 648	N	163	160
	Pre rand. Paroxetine use	2 (1.23%)	2 (1.25%)
Study 650	N	88	88
	Pre rand. Paroxetine use	88 (100.00%)	88 (100.00%)

EMEA LOQs Table 1.89
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Study 651	N	375	188
	Pre rand. Paroxetine use	9 (2.40%)	2 (1.06%)
Study 677	N	212	109
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 688	N	242	119
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 689	N	246	125
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 785	N	197	105
	Pre rand. Paroxetine use	7 (3.55%)	2 (1.90%)
Study 790	N	186	184
	Pre rand. Paroxetine use	3 (1.61%)	0 (0.00%)
Study 791	N	167	166
	Pre rand. Paroxetine use	4 (2.40%)	4 (2.41%)
Study 810	N	306	148
	Pre rand. Paroxetine use	13 (4.25%)	2 (1.35%)

Paroxetine EMEA LOQs

EMEA LOQs Table 1.90
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Overall	N	6522	4969
	Pre rand. Paroxetine use	12 (0.18%)	11 (0.22%)
Study 003	N	241	241
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 006	N	33	33
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 007	N	13	13
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 011	N	103	103
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 019	N	31	35
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 020	N	24	24
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 022	N	16	17
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 025	N	4	4
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 026	N	30	30
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 027	N	17	15
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 028	N	8	6
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 029	N	4	5
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 030	N	21	19
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 032	N	30	30
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 035	N	3	4
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.90
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 038	N	32	29
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 043	N	15	18
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 046	N	21	22
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 047	N	46	49
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 049	N	62	32
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 059	N	72	71
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 060	N	44	47
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 061	N	54	52
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 063	N	21	19
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 064	N	49	50
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 065	N	28	32
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 069	N	45	46
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 070	N	32	30
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 071	N	9	9
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 073	N	6	4
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 074	N	20	20
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.90
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 076	N	4	4
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 077	N	46	46
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 078	N	155	153
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 079	N	45	45
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 080	N	10	13
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 082	N	37	34
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 084	N	6	5
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 086	N	271	275
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 088	N	16	15
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 089	N	26	34
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 090	N	79	78
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 095	N	134	68
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 109	N	65	67
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 112	N	55	65
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 115	N	283	288
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 118	N	82	82
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.90
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 128	N	357	351
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 131	N	100	99
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 135	N	60	62
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 136	N	201	99
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 184	N	14	14
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 187	N	123	122
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 197	N	99	99
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 223	N	76	77
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 239	N	1766	402
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 245	N	517	510
	Pre rand. Paroxetine use	0 (0.00%)	1 (0.20%)
Study 256	N	39	34
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 260	N	21	23
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 261	N	62	58
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 272	N	5	3
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 275	N	4	4
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 279	N	21	16
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.90
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 281	N	106	98
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 289	N	42	44
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 290	N	40	39
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 291	N	41	42
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 292	N	46	44
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 308	N	10	12
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 309	N	11	10
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 310	N	9	10
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 312	N	2	2
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 314	N	10	8
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 316	N	9	8
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 318	N	9	12
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 319	N	1	1
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 331	N	41	40
	Pre rand. Paroxetine use	2 (4.88%)	1 (2.50%)
Study 352	N	35	39
	Pre rand. Paroxetine use	3 (8.57%)	4 (10.26%)
Study 785	N	197	206
	Pre rand. Paroxetine use	7 (3.55%)	5 (2.43%)

EMEA LOQs Table 1.91
Summary of Prior exposure to Paroxetine by Treatment Group and Study
Paediatric Placebo Controlled Trials

		Treatment Group	
		Paroxetine	Placebo
Overall	N	738	647
	Pre rand. Paroxetine use	112 (15.18%)	112 (17.31%)
Study 329	N	93	88
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 377	N	181	95
	Pre rand. Paroxetine use	0 (0.00%)	0 (0.00%)
Study 453	N	96	98
	Pre rand. Paroxetine use	96 (100.00%)	98 (100.00%)
Study 676	N	165	157
	Pre rand. Paroxetine use	4 (2.42%)	6 (3.82%)
Study 701	N	104	102
	Pre rand. Paroxetine use	6 (5.77%)	3 (2.94%)
Study 704	N	99	107
	Pre rand. Paroxetine use	6 (6.06%)	5 (4.67%)

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

EMEA LOQs Table 1.92
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Overall	N	8481	5808
	Pre rand. SSRI use	1347 (15.88%)	1156 (19.90%)
Study 001	N	25	25
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 002	N	170	171
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 003	N	241	244
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 007	N	13	12
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 009	N	421	53
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 057	N	131	136
	Pre rand. SSRI use	3 (2.29%)	2 (1.47%)
Study 076	N	4	4
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 083	N	68	67
	Pre rand. SSRI use	68 (100.00%)	67 (100.00%)
Study 106	N	18	18
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 108	N	60	60
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 115	N	283	117
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 116	N	259	89
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 118	N	82	77
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 120	N	209	69
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 128	N	357	140
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.92
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Study 136	N	201	99
	Pre rand. SSRI use	9 (4.48%)	3 (3.03%)
Study 187	N	123	123
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 190	N	61	64
	Pre rand. SSRI use	61 (100.00%)	64 (100.00%)
Study 201	N	57	60
	Pre rand. SSRI use	2 (3.51%)	0 (0.00%)
Study 223	N	76	71
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 251	N	125	129
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 274	N	22	23
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 275	N	4	3
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 276	N	20	21
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 279	N	21	10
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 327	N	81	85
	Pre rand. SSRI use	27 (33.33%)	30 (35.29%)
Study 352	N	35	43
	Pre rand. SSRI use	19 (54.29%)	21 (48.84%)
Study 382	N	94	93
	Pre rand. SSRI use	4 (4.26%)	3 (3.23%)
Study 400	N	31	17
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 427	N	29	9
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 448	N	212	103
	Pre rand. SSRI use	96 (45.28%)	48 (46.60%)

EMEA LOQs Table 1.92
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Study 449	N	223	110
	Pre rand. SSRI use	93 (41.70%)	46 (41.82%)
Study 454	N	289	95
	Pre rand. SSRI use	22 (7.61%)	5 (5.26%)
Study 487	N	214	109
	Pre rand. SSRI use	72 (33.64%)	33 (30.28%)
Study 494	N	141	148
	Pre rand. SSRI use	36 (25.53%)	34 (22.97%)
Study 495	N	162	165
	Pre rand. SSRI use	34 (20.99%)	56 (33.94%)
Study 497	N	149	144
	Pre rand. SSRI use	29 (19.46%)	31 (21.53%)
Study 502	N	139	151
	Pre rand. SSRI use	31 (22.30%)	27 (17.88%)
Study 595	N	162	161
	Pre rand. SSRI use	162 (100.00%)	161 (100.00%)
Study 625	N	112	117
	Pre rand. SSRI use	8 (7.14%)	9 (7.69%)
Study 627	N	160	162
	Pre rand. SSRI use	27 (16.88%)	29 (17.90%)
Study 637	N	187	185
	Pre rand. SSRI use	11 (5.88%)	9 (4.86%)
Study 641	N	386	180
	Pre rand. SSRI use	18 (4.66%)	10 (5.56%)
Study 642	N	164	166
	Pre rand. SSRI use	5 (3.05%)	11 (6.63%)
Study 646	N	278	288
	Pre rand. SSRI use	278 (100.00%)	288 (100.00%)
Study 648	N	163	160
	Pre rand. SSRI use	12 (7.36%)	7 (4.38%)
Study 650	N	88	88
	Pre rand. SSRI use	88 (100.00%)	88 (100.00%)

EMEA LOQs Table 1.92
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Placebo Control Trials

		Treatment Group	
		Paroxetine	Placebo
Study 651	N	375	188
	Pre rand. SSRI use	38 (10.13%)	18 (9.57%)
Study 677	N	212	109
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 688	N	242	119
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 689	N	246	125
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 785	N	197	105
	Pre rand. SSRI use	20 (10.15%)	11 (10.48%)
Study 790	N	186	184
	Pre rand. SSRI use	20 (10.75%)	14 (7.61%)
Study 791	N	167	166
	Pre rand. SSRI use	11 (6.59%)	16 (9.64%)
Study 810	N	306	148
	Pre rand. SSRI use	43 (14.05%)	15 (10.14%)

EMEA LOQs Table 1.93
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Overall	N	6522	4969
	Pre rand. SSRI use	84 (1.29%)	71 (1.43%)
Study 003	N	241	241
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 006	N	33	33
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 007	N	13	13
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 011	N	103	103
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 019	N	31	35
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 020	N	24	24
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 022	N	16	17
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 025	N	4	4
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 026	N	30	30
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 027	N	17	15
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 028	N	8	6
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 029	N	4	5
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 030	N	21	19
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 032	N	30	30
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 035	N	3	4
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.93
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 038	N	32	29
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 043	N	15	18
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 046	N	21	22
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 047	N	46	49
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 049	N	62	32
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 059	N	72	71
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 060	N	44	47
	Pre rand. SSRI use	0 (0.00%)	1 (2.13%)
Study 061	N	54	52
	Pre rand. SSRI use	1 (1.85%)	1 (1.92%)
Study 063	N	21	19
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 064	N	49	50
	Pre rand. SSRI use	1 (2.04%)	1 (2.00%)
Study 065	N	28	32
	Pre rand. SSRI use	1 (3.57%)	0 (0.00%)
Study 069	N	45	46
	Pre rand. SSRI use	0 (0.00%)	1 (2.17%)
Study 070	N	32	30
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 071	N	9	9
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 073	N	6	4
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 074	N	20	20
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.93
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 076	N	4	4
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 077	N	46	46
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 078	N	155	153
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 079	N	45	45
	Pre rand. SSRI use	1 (2.22%)	0 (0.00%)
Study 080	N	10	13
	Pre rand. SSRI use	1 (10.00%)	0 (0.00%)
Study 082	N	37	34
	Pre rand. SSRI use	0 (0.00%)	1 (2.94%)
Study 084	N	6	5
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 086	N	271	275
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 088	N	16	15
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 089	N	26	34
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 090	N	79	78
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 095	N	134	68
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 109	N	65	67
	Pre rand. SSRI use	5 (7.69%)	1 (1.49%)
Study 112	N	55	65
	Pre rand. SSRI use	1 (1.82%)	1 (1.54%)
Study 115	N	283	288
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 118	N	82	82
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.93
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 128	N	357	351
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 131	N	100	99
	Pre rand. SSRI use	5 (5.00%)	1 (1.01%)
Study 135	N	60	62
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 136	N	201	99
	Pre rand. SSRI use	9 (4.48%)	2 (2.02%)
Study 184	N	14	14
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 187	N	123	122
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 197	N	99	99
	Pre rand. SSRI use	1 (1.01%)	1 (1.01%)
Study 223	N	76	77
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 239	N	1766	402
	Pre rand. SSRI use	4 (0.23%)	1 (0.25%)
Study 245	N	517	510
	Pre rand. SSRI use	7 (1.35%)	9 (1.76%)
Study 256	N	39	34
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 260	N	21	23
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 261	N	62	58
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 272	N	5	3
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 275	N	4	4
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 279	N	21	16
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)

EMEA LOQs Table 1.93
Summary of Prior exposure to SSRIs by Treatment Group and Study
Adult Active Control Trials

		Treatment Group	
		Paroxetine	Comparator
Study 281	N	106	98
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 289	N	42	44
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 290	N	40	39
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 291	N	41	42
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 292	N	46	44
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 308	N	10	12
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 309	N	11	10
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 310	N	9	10
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 312	N	2	2
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 314	N	10	8
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 316	N	9	8
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 318	N	9	12
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 319	N	1	1
	Pre rand. SSRI use	0 (0.00%)	0 (0.00%)
Study 331	N	41	40
	Pre rand. SSRI use	8 (19.51%)	5 (12.50%)
Study 352	N	35	39
	Pre rand. SSRI use	19 (54.29%)	23 (58.97%)
Study 785	N	197	206
	Pre rand. SSRI use	20 (10.15%)	22 (10.68%)

EMEA LOQs Table 1.94
Summary of Prior exposure to SSRIs by Treatment Group and Study
Paediatric Placebo Controlled Trials

		Treatment Group	
		Paroxetine	Placebo
Overall	N	738	647
	Pre rand. SSRI use	151 (20.46%)	151 (23.34%)
Study 329	N	93	88
	Pre rand. SSRI use	2 (2.15%)	1 (1.14%)
Study 377	N	181	95
	Pre rand. SSRI use	2 (1.10%)	0 (0.00%)
Study 453	N	96	98
	Pre rand. SSRI use	96 (100.00%)	98 (100.00%)
Study 676	N	165	157
	Pre rand. SSRI use	10 (6.06%)	12 (7.64%)
Study 701	N	104	102
	Pre rand. SSRI use	23 (22.12%)	16 (15.69%)
Study 704	N	99	107
	Pre rand. SSRI use	18 (18.18%)	24 (22.43%)

Includes studies 329, 377, 676, 701, 704 and placebo controlled phase of 453

Paroxetine EMEA LOQs

EMEA LOQs Table 1.95
Incidence of Possibly Suicide-Related AEs by Treatment Group and Age Group
Adult Fluoxetine Controlled Trials
On-Therapy

Age Group		Paroxetine	Fluoxetine	Odds Ratio (95% CI)	P value
Overall	n/N (%)	13/948 (1.4%)	20/947 (2.1%)	0.64 (0.32, 1.3)	0.23
18-29 years	n/N (%)	3/150 (2.0%)	6/172 (3.5%)	0.56 (0.14, 2.3)	0.51
30-39 years	n/N (%)	3/270 (1.1%)	6/257 (2.3%)	0.47 (0.12, 1.9)	0.33
40-49 years	n/N (%)	3/251 (1.2%)	4/276 (1.4%)	0.82 (0.18, 3.71)	1.00
50-59 years	n/N (%)	1/141 (0.7%)	2/136 (1.5%)	0.48 (0.04, 5.34)	0.62
60-69 years	n/N (%)	1/80 (1.3%)	2/64 (3.1%)	0.39 (0.03, 4.43)	0.59
>=70 years	n/N (%)	2/56 (3.6%)	0/42 (0.0%)		0.51

Includes paroxetine and fluoxetine control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 3.01
Number % of patients with Possibly Suicide-Related Adverse Events by Body System and Preferred Term
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.7	0	0.0
Nervous System	TOTAL	2	0.7	0	0.0
	EMOTIONAL LABILITY	2	0.7	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 3.02
Number % of patients with Adverse Events by Body System and Preferred Term
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

		Paroxetine N=(268)		Placebo N=(182)	
Body System	Preferred Term	n	%	n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	17	6.3	17	9.3
Body as a Whole	TOTAL	5	1.9	6	3.3
	ASTHENIA	1	0.4	3	1.6
	CHILLS	0	0.0	1	0.5
	HEADACHE	4	1.5	2	1.1
Digestive System	TOTAL	4	1.5	6	3.3
	DIARRHEA	1	0.4	2	1.1
	NAUSEA	3	1.1	5	2.7
	VOMITING	0	0.0	2	1.1
Nervous System	TOTAL	11	4.1	7	3.8
	ABNORMAL DREAMS	2	0.7	0	0.0
	AGITATION	1	0.4	0	0.0
	ANXIETY	0	0.0	2	1.1
	CONFUSION	1	0.4	1	0.5
	DIZZINESS	6	2.2	2	1.1
	INSOMNIA	2	0.7	1	0.5
	NERVOUSNESS	1	0.4	1	0.5
	SOMNOLENCE	1	0.4	0	0.0
	TREMOR	1	0.4	1	0.5
	VERTIGO	1	0.4	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0
	SWEATING	1	0.4	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 3.03
Number % of patients with Anti-Cholinergic Adverse Events by Body System and Preferred Term
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	66	24.6	17	9.3
Cardiovascular System	TOTAL	25	9.3	5	2.7
	BRADYCARDIA	4	1.5	0	0.0
	HYPOTENSION	17	6.3	4	2.2
	POSTURAL HYPOTENSION	3	1.1	1	0.5
	VASODILATATION	1	0.4	1	0.5
Digestive System	TOTAL	23	8.6	9	4.9
	DRY MOUTH	23	8.6	9	4.9
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0
	THIRST	1	0.4	0	0.0
Nervous System	TOTAL	14	5.2	2	1.1
	EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.5
	TREMOR	14	5.2	1	0.5
Skin and Appendages	TOTAL	17	6.3	1	0.5
	SWEATING	17	6.3	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 3.04

Number % of patients with Possibly Suicide-Related Adverse Events by Body System and Preferred Term and by Maximum Severity

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Maximum Severity : Mild

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	0.4	0	0.0
Nervous System	TOTAL	1	0.4	0	0.0
	EMOTIONAL LABILITY	1	0.4	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 3.04

Number % of patients with Possibly Suicide-Related Adverse Events by Body System and Preferred Term and by Maximum Severity

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Maximum Severity : Severe

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	0.4	0	0.0
Nervous System	TOTAL	1	0.4	0	0.0
	EMOTIONAL LABILITY	1	0.4	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 3.05
Number % of patients with Adverse Events by Body System and Preferred Term and by Maximum Severity
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Maximum Severity : Mild

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	13	4.9	12	6.6
Body as a Whole	TOTAL	4	1.5	3	1.6
	ASTHENIA	0	0.0	2	1.1
	CHILLS	0	0.0	0	0.0
	HEADACHE	4	1.5	1	0.5
Digestive System	TOTAL	2	0.7	5	2.7
	DIARRHEA	0	0.0	2	1.1
	NAUSEA	2	0.7	3	1.6
	VOMITING	0	0.0	1	0.5
Nervous System	TOTAL	7	2.6	4	2.2
	ABNORMAL DREAMS	1	0.4	0	0.0
	AGITATION	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0
	CONFUSION	1	0.4	0	0.0
	DIZZINESS	3	1.1	2	1.1
	INSOMNIA	1	0.4	1	0.5
	NERVOUSNESS	0	0.0	0	0.0
	SOMNOLENCE	1	0.4	0	0.0
	TREMOR	1	0.4	1	0.5
	VERTIGO	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0
	SWEATING	1	0.4	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 3.05
Number % of patients with Adverse Events by Body System and Preferred Term and by Maximum Severity
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Maximum Severity : Moderate

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	7	2.6	8	4.4
Body as a Whole	TOTAL	1	0.4	2	1.1
	ASTHENIA	1	0.4	1	0.5
	CHILLS	0	0.0	1	0.5
	HEADACHE	0	0.0	0	0.0
Digestive System	TOTAL	2	0.7	3	1.6
	DIARRHEA	1	0.4	0	0.0
	NAUSEA	1	0.4	2	1.1
	VOMITING	0	0.0	1	0.5
Nervous System	TOTAL	5	1.9	4	2.2
	ABNORMAL DREAMS	1	0.4	0	0.0
	AGITATION	1	0.4	0	0.0
	ANXIETY	0	0.0	2	1.1
	CONFUSION	0	0.0	1	0.5
	DIZZINESS	3	1.1	0	0.0
	INSOMNIA	1	0.4	0	0.0
	NERVOUSNESS	1	0.4	1	0.5
	SOMNOLENCE	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0
	VERTIGO	1	0.4	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 3.05
Number % of patients with Adverse Events by Body System and Preferred Term and by Maximum Severity
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Maximum Severity : Severe

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	1	0.5
Body as a Whole	TOTAL	0	0.0	1	0.5
	ASTHENIA	0	0.0	0	0.0
	CHILLS	0	0.0	0	0.0
	HEADACHE	0	0.0	1	0.5
Digestive System	TOTAL	0	0.0	0	0.0
	DIARRHEA	0	0.0	0	0.0
	NAUSEA	0	0.0	0	0.0
	VOMITING	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0
	ABNORMAL DREAMS	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0
	DIZZINESS	0	0.0	0	0.0
	INSOMNIA	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	0	0.0
	SOMNOLENCE	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0
	VERTIGO	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 3.06
Number % of patients with Anti-Cholinergic Adverse Events by Body System and Preferred Term and by Maximum Severity
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Maximum Severity : Mild

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	50	18.7	11	6.0
Cardiovascular System	TOTAL	19	7.1	2	1.1
	BRADYCARDIA	4	1.5	0	0.0
	HYPOTENSION	13	4.9	1	0.5
	POSTURAL HYPOTENSION	2	0.7	1	0.5
	VASODILATATION	0	0.0	0	0.0
Digestive System	TOTAL	15	5.6	8	4.4
	DRY MOUTH	15	5.6	8	4.4
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0
Nervous System	TOTAL	9	3.4	1	0.5
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0
	TREMOR	9	3.4	1	0.5
Skin and Appendages	TOTAL	13	4.9	0	0.0
	SWEATING	13	4.9	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 3.06
Number % of patients with Anti-Cholinergic Adverse Events by Body System and Preferred Term and by Maximum Severity
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Maximum Severity : Moderate

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	19	7.1	6	3.3
Cardiovascular System	TOTAL	6	2.2	3	1.6
	BRADYCARDIA	0	0.0	0	0.0
	HYPOTENSION	4	1.5	3	1.6
	POSTURAL HYPOTENSION	1	0.4	0	0.0
	VASODILATATION	1	0.4	1	0.5
Digestive System	TOTAL	6	2.2	1	0.5
	DRY MOUTH	6	2.2	1	0.5
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0
	THIRST	1	0.4	0	0.0
Nervous System	TOTAL	5	1.9	1	0.5
	EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.5
	TREMOR	5	1.9	0	0.0
Skin and Appendages	TOTAL	4	1.5	1	0.5
	SWEATING	4	1.5	1	0.5

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 3.06
Number % of patients with Anti-Cholinergic Adverse Events by Body System and Preferred Term and by Maximum Severity
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Maximum Severity : Severe

Body System	Preferred Term	Paroxetine N=(268) n	%	Placebo N=(182) n	%
TOTAL	Total Male Subjects *	132	100.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	111	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.7	0	0.0
Cardiovascular System	TOTAL	0	0.0	0	0.0
	BRADYCARDIA	0	0.0	0	0.0
	HYPOTENSION	0	0.0	0	0.0
	POSTURAL HYPOTENSION	0	0.0	0	0.0
	VASODILATATION	0	0.0	0	0.0
Digestive System	TOTAL	2	0.7	0	0.0
	DRY MOUTH	2	0.7	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: HYPERTENSION

Body System	Preferred Term	Paroxetine Condition=N N=247 n	%	Paroxetine Condition=Y N=21 n	%	Placebo Condition=N N=166 n	%	Placebo Condition=Y N=16 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	71	100.0	0	0.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	119	100.0	17	100.0	95	100.0	16	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: DIABETES MELLITUS

Body System	Preferred Term	Paroxetine Condition=N N=235 n	%	Paroxetine Condition=Y N=33 n	%	Placebo Condition=N N=157 n	%	Placebo Condition=Y N=25 n	%
TOTAL	Total Male Subjects *	113	100.0	19	100.0	58	100.0	13	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	122	100.0	14	100.0	99	100.0	12	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.9	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.9	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.9	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: ARTHROPATHY

Body System	Preferred Term	Paroxetine Condition=N N=239 n	%	Paroxetine Condition=Y N=29 n	%	Placebo Condition=N N=160 n	%	Placebo Condition=Y N=22 n	%
TOTAL	Total Male Subjects *	119	100.0	13	100.0	69	100.0	2	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	120	100.0	16	100.0	91	100.0	20	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: CEREBROVASCULAR DIS

Body System	Preferred Term	Paroxetine Condition=N N=249 n	%	Paroxetine Condition=Y N=19 n	%	Placebo Condition=N N=160 n	%	Placebo Condition=Y N=22 n	%
TOTAL	Total Male Subjects *	121	100.0	11	100.0	62	100.0	9	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	128	100.0	8	100.0	98	100.0	13	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: OSTEOARTHROSIS

Body System	Preferred Term	Paroxetine Condition=N N=242 n	%	Paroxetine Condition=Y N=26 n	%	Placebo Condition=N N=170 n	%	Placebo Condition=Y N=12 n	%
TOTAL	Total Male Subjects *	120	100.0	12	100.0	66	100.0	5	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	122	100.0	14	100.0	104	100.0	7	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: HEADACHE

Body System	Preferred Term	Paroxetine Condition=N N=244 n	%	Paroxetine Condition=Y N=24 n	%	Placebo Condition=N N=169 n	%	Placebo Condition=Y N=13 n	%
TOTAL	Total Male Subjects *	118	100.0	14	100.0	67	100.0	4	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	126	100.0	10	100.0	102	100.0	9	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	0.4	1	4.2	0	0.0	0	0.0
Nervous System	TOTAL	1	0.4	1	4.2	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	0.4	1	4.2	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: HYPOTHYROIDISM

Body System	Preferred Term	Paroxetine Condition=N N=247 n	%	Paroxetine Condition=Y N=21 n	%	Placebo Condition=N N=166 n	%	Placebo Condition=Y N=16 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	71	100.0	0	0.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	119	100.0	17	100.0	95	100.0	16	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: CHOLEST/TRIGLYCERIDE, ELEVATED

Body System	Preferred Term	Paroxetine Condition=N N=251 n	%	Paroxetine Condition=Y N=17 n	%	Placebo Condition=N N=164 n	%	Placebo Condition=Y N=18 n	%
TOTAL	Total Male Subjects *	127	100.0	5	100.0	64	100.0	7	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	124	100.0	12	100.0	100	100.0	11	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: INSOMNIA

Body System	Preferred Term	Paroxetine Condition=N N=254 n	%	Paroxetine Condition=Y N=14 n	%	Placebo Condition=N N=165 n	%	Placebo Condition=Y N=17 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	66	100.0	5	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	126	100.0	10	100.0	99	100.0	12	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.07

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: PROSTATE DISORD

Body System	Preferred Term	Paroxetine Condition=N N=254 n	%	Paroxetine Condition=Y N=14 n	%	Placebo Condition=N N=169 n	%	Placebo Condition=Y N=13 n	%
TOTAL	Total Male Subjects *	118	100.0	14	100.0	58	100.0	13	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	0	0.0	111	100.0	0	0.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	0.8	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	0.8	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	2	0.8	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: HYPERTENSION

Body System	Preferred Term	Paroxetine Condition=N N=247 n	%	Paroxetine Condition=Y N=21 n	%	Placebo Condition=N N=166 n	%	Placebo Condition=Y N=16 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	71	100.0	0	0.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	119	100.0	17	100.0	95	100.0	16	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	13	5.3	4	19.0	14	8.4	3	18.8
Body as a Whole	TOTAL	5	2.0	0	0.0	5	3.0	1	6.3
	ASTHENIA	1	0.4	0	0.0	3	1.8	0	0.0
	CHILLS	0	0.0	0	0.0	0	0.0	1	6.3
	HEADACHE	4	1.6	0	0.0	2	1.2	0	0.0
Digestive System	TOTAL	3	1.2	1	4.8	5	3.0	1	6.3
	DIARRHEA	1	0.4	0	0.0	2	1.2	0	0.0
	NAUSEA	2	0.8	1	4.8	4	2.4	1	6.3
	VOMITING	0	0.0	0	0.0	2	1.2	0	0.0
Nervous System	TOTAL	8	3.2	3	14.3	5	3.0	2	12.5
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	1	0.6	1	6.3
	CONFUSION	0	0.0	1	4.8	1	0.6	0	0.0
	DIZZINESS	4	1.6	2	9.5	1	0.6	1	6.3
	INSOMNIA	2	0.8	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	0	0.0	1	4.8	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: DIABETES MELLITUS

Body System	Preferred Term	Paroxetine Condition=N N=235 n	%	Paroxetine Condition=Y N=33 n	%	Placebo Condition=N N=157 n	%	Placebo Condition=Y N=25 n	%
TOTAL	Total Male Subjects *	113	100.0	19	100.0	58	100.0	13	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	122	100.0	14	100.0	99	100.0	12	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	15	6.4	2	6.1	15	9.6	2	8.0
Body as a Whole	TOTAL	4	1.7	1	3.0	5	3.2	1	4.0
	ASTHENIA	1	0.4	0	0.0	3	1.9	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	3	1.3	1	3.0	1	0.6	1	4.0
Digestive System	TOTAL	3	1.3	1	3.0	6	3.8	0	0.0
	DIARRHEA	1	0.4	0	0.0	2	1.3	0	0.0
	NAUSEA	2	0.9	1	3.0	5	3.2	0	0.0
	VOMITING	0	0.0	0	0.0	2	1.3	0	0.0
Nervous System	TOTAL	11	4.7	0	0.0	6	3.8	1	4.0
	ABNORMAL DREAMS	2	0.9	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.3	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	6	2.6	0	0.0	1	0.6	1	4.0
	INSOMNIA	2	0.9	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: ARTHROPATHY

Body System	Preferred Term	Paroxetine Condition=N N=239 n	%	Paroxetine Condition=Y N=29 n	%	Placebo Condition=N N=160 n	%	Placebo Condition=Y N=22 n	%
TOTAL	Total Male Subjects *	119	100.0	13	100.0	69	100.0	2	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	120	100.0	16	100.0	91	100.0	20	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	15	6.3	2	6.9	14	8.8	3	13.6
Body as a Whole	TOTAL	4	1.7	1	3.4	6	3.8	0	0.0
	ASTHENIA	0	0.0	1	3.4	3	1.9	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	4	1.7	0	0.0	2	1.3	0	0.0
Digestive System	TOTAL	4	1.7	0	0.0	5	3.1	1	4.5
	DIARRHEA	1	0.4	0	0.0	2	1.3	0	0.0
	NAUSEA	3	1.3	0	0.0	4	2.5	1	4.5
	VOMITING	0	0.0	0	0.0	2	1.3	0	0.0
Nervous System	TOTAL	10	4.2	1	3.4	5	3.1	2	9.1
	ABNORMAL DREAMS	1	0.4	1	3.4	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.3	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	6	2.5	0	0.0	1	0.6	1	4.5
	INSOMNIA	1	0.4	1	3.4	0	0.0	1	4.5
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: CEREBROVASCULAR DIS

		Paroxetine Condition=N N=249		Paroxetine Condition=Y N=19		Placebo Condition=N N=160		Placebo Condition=Y N=22	
Body System	Preferred Term	n	%	n	%	n	%	n	%
TOTAL	Total Male Subjects *	121	100.0	11	100.0	62	100.0	9	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	128	100.0	8	100.0	98	100.0	13	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	17	6.8	0	0.0	15	9.4	2	9.1
Body as a Whole	TOTAL	5	2.0	0	0.0	5	3.1	1	4.5
	ASTHENIA	1	0.4	0	0.0	3	1.9	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	4	1.6	0	0.0	1	0.6	1	4.5
Digestive System	TOTAL	4	1.6	0	0.0	5	3.1	1	4.5
	DIARRHEA	1	0.4	0	0.0	2	1.3	0	0.0
	NAUSEA	3	1.2	0	0.0	4	2.5	1	4.5
	VOMITING	0	0.0	0	0.0	2	1.3	0	0.0
Nervous System	TOTAL	11	4.4	0	0.0	7	4.4	0	0.0
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.3	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	6	2.4	0	0.0	2	1.3	0	0.0
	INSOMNIA	2	0.8	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: OSTEOARTHROSIS

Body System	Preferred Term	Paroxetine Condition=N N=242 n	%	Paroxetine Condition=Y N=26 n	%	Placebo Condition=N N=170 n	%	Placebo Condition=Y N=12 n	%
TOTAL	Total Male Subjects *	120	100.0	12	100.0	66	100.0	5	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	122	100.0	14	100.0	104	100.0	7	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	15	6.2	2	7.7	14	8.2	3	25.0
Body as a Whole	TOTAL	4	1.7	1	3.8	4	2.4	2	16.7
	ASTHENIA	1	0.4	0	0.0	2	1.2	1	8.3
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	3	1.2	1	3.8	1	0.6	1	8.3
Digestive System	TOTAL	4	1.7	0	0.0	5	2.9	1	8.3
	DIARRHEA	1	0.4	0	0.0	1	0.6	1	8.3
	NAUSEA	3	1.2	0	0.0	4	2.4	1	8.3
	VOMITING	0	0.0	0	0.0	2	1.2	0	0.0
Nervous System	TOTAL	9	3.7	2	7.7	6	3.5	1	8.3
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	4	1.7	2	7.7	2	1.2	0	0.0
	INSOMNIA	2	0.8	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	0	0.0	1	8.3
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: HEADACHE

Body System	Preferred Term	Paroxetine Condition=N N=244 n	%	Paroxetine Condition=Y N=24 n	%	Placebo Condition=N N=169 n	%	Placebo Condition=Y N=13 n	%
TOTAL	Total Male Subjects *	118	100.0	14	100.0	67	100.0	4	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	126	100.0	10	100.0	102	100.0	9	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	17	7.0	0	0.0	15	8.9	2	15.4
Body as a Whole	TOTAL	5	2.0	0	0.0	6	3.6	0	0.0
	ASTHENIA	1	0.4	0	0.0	3	1.8	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	4	1.6	0	0.0	2	1.2	0	0.0
Digestive System	TOTAL	4	1.6	0	0.0	5	3.0	1	7.7
	DIARRHEA	1	0.4	0	0.0	2	1.2	0	0.0
	NAUSEA	3	1.2	0	0.0	4	2.4	1	7.7
	VOMITING	0	0.0	0	0.0	2	1.2	0	0.0
Nervous System	TOTAL	11	4.5	0	0.0	6	3.6	1	7.7
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	6	2.5	0	0.0	1	0.6	1	7.7
	INSOMNIA	2	0.8	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: HYPOTHYROIDISM

Body System	Preferred Term	Paroxetine Condition=N N=247 n	%	Paroxetine Condition=Y N=21 n	%	Placebo Condition=N N=166 n	%	Placebo Condition=Y N=16 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	71	100.0	0	0.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	119	100.0	17	100.0	95	100.0	16	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	13	5.3	4	19.0	14	8.4	3	18.8
Body as a Whole	TOTAL	5	2.0	0	0.0	5	3.0	1	6.3
	ASTHENIA	1	0.4	0	0.0	3	1.8	0	0.0
	CHILLS	0	0.0	0	0.0	0	0.0	1	6.3
	HEADACHE	4	1.6	0	0.0	2	1.2	0	0.0
Digestive System	TOTAL	3	1.2	1	4.8	5	3.0	1	6.3
	DIARRHEA	1	0.4	0	0.0	2	1.2	0	0.0
	NAUSEA	2	0.8	1	4.8	4	2.4	1	6.3
	VOMITING	0	0.0	0	0.0	2	1.2	0	0.0
Nervous System	TOTAL	8	3.2	3	14.3	5	3.0	2	12.5
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	1	0.6	1	6.3
	CONFUSION	0	0.0	1	4.8	1	0.6	0	0.0
	DIZZINESS	4	1.6	2	9.5	1	0.6	1	6.3
	INSOMNIA	2	0.8	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	0	0.0	1	4.8	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: CHOLEST/TRIGLYCERIDE, ELEVATED

		Paroxetine Condition=N N=251		Paroxetine Condition=Y N=17		Placebo Condition=N N=164		Placebo Condition=Y N=18	
Body System	Preferred Term	n	%	n	%	n	%	n	%
TOTAL	Total Male Subjects *	127	100.0	5	100.0	64	100.0	7	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	124	100.0	12	100.0	100	100.0	11	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	16	6.4	1	5.9	14	8.5	3	16.7
Body as a Whole	TOTAL	5	2.0	0	0.0	5	3.0	1	5.6
	ASTHENIA	1	0.4	0	0.0	3	1.8	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	4	1.6	0	0.0	1	0.6	1	5.6
Digestive System	TOTAL	4	1.6	0	0.0	6	3.7	0	0.0
	DIARRHEA	1	0.4	0	0.0	2	1.2	0	0.0
	NAUSEA	3	1.2	0	0.0	5	3.0	0	0.0
	VOMITING	0	0.0	0	0.0	2	1.2	0	0.0
Nervous System	TOTAL	10	4.0	1	5.9	5	3.0	2	11.1
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	6	2.4	0	0.0	1	0.6	1	5.6
	INSOMNIA	2	0.8	0	0.0	0	0.0	1	5.6
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	1	5.9	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: INSOMNIA

Body System	Preferred Term	Paroxetine Condition=N N=254 n	%	Paroxetine Condition=Y N=14 n	%	Placebo Condition=N N=165 n	%	Placebo Condition=Y N=17 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	66	100.0	5	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	126	100.0	10	100.0	99	100.0	12	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	17	6.7	0	0.0	16	9.7	1	5.9
Body as a Whole	TOTAL	5	2.0	0	0.0	6	3.6	0	0.0
	ASTHENIA	1	0.4	0	0.0	3	1.8	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	4	1.6	0	0.0	2	1.2	0	0.0
Digestive System	TOTAL	4	1.6	0	0.0	5	3.0	1	5.9
	DIARRHEA	1	0.4	0	0.0	2	1.2	0	0.0
	NAUSEA	3	1.2	0	0.0	4	2.4	1	5.9
	VOMITING	0	0.0	0	0.0	2	1.2	0	0.0
Nervous System	TOTAL	11	4.3	0	0.0	7	4.2	0	0.0
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	6	2.4	0	0.0	2	1.2	0	0.0
	INSOMNIA	2	0.8	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	1	0.6	0	0.0
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.08
Number % of patients with Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Medical Condition: PROSTATE DISORD

Body System	Preferred Term	Paroxetine Condition=N N=254 n	%	Paroxetine Condition=Y N=14 n	%	Placebo Condition=N N=169 n	%	Placebo Condition=Y N=13 n	%
TOTAL	Total Male Subjects *	118	100.0	14	100.0	58	100.0	13	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	0	0.0	111	100.0	0	0.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	15	5.9	2	14.3	14	8.3	3	23.1
Body as a Whole	TOTAL	3	1.2	2	14.3	6	3.6	0	0.0
	ASTHENIA	1	0.4	0	0.0	3	1.8	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6	0	0.0
	HEADACHE	2	0.8	2	14.3	2	1.2	0	0.0
Digestive System	TOTAL	4	1.6	0	0.0	4	2.4	2	15.4
	DIARRHEA	1	0.4	0	0.0	2	1.2	0	0.0
	NAUSEA	3	1.2	0	0.0	4	2.4	1	7.7
	VOMITING	0	0.0	0	0.0	1	0.6	1	7.7
Nervous System	TOTAL	11	4.3	0	0.0	6	3.6	1	7.7
	ABNORMAL DREAMS	2	0.8	0	0.0	0	0.0	0	0.0
	AGITATION	1	0.4	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2	0	0.0
	CONFUSION	1	0.4	0	0.0	1	0.6	0	0.0
	DIZZINESS	6	2.4	0	0.0	2	1.2	0	0.0
	INSOMNIA	2	0.8	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	1	0.4	0	0.0	0	0.0	1	7.7
	SOMNOLENCE	1	0.4	0	0.0	0	0.0	0	0.0
	TREMOR	1	0.4	0	0.0	1	0.6	0	0.0
	VERTIGO	1	0.4	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	SWEATING	1	0.4	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: HYPERTENSION

Body System	Preferred Term	Paroxetine Condition=N N=247 n	%	Paroxetine Condition=Y N=21 n	%	Placebo Condition=N N=166 n	%	Placebo Condition=Y N=16 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	71	100.0	0	0.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	119	100.0	17	100.0	95	100.0	16	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	54	21.9	12	57.1	14	8.4	3	18.8
Cardiovascular System	TOTAL	19	7.7	6	28.6	5	3.0	0	0.0
	BRADYCARDIA	3	1.2	1	4.8	0	0.0	0	0.0
	HYPOTENSION	12	4.9	5	23.8	4	2.4	0	0.0
	POSTURAL HYPOTENSION	3	1.2	0	0.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	20	8.1	3	14.3	6	3.6	3	18.8
	DRY MOUTH	20	8.1	3	14.3	6	3.6	3	18.8
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	4.8	0	0.0	0	0.0
	THIRST	0	0.0	1	4.8	0	0.0	0	0.0
Nervous System	TOTAL	13	5.3	1	4.8	2	1.2	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	13	5.3	1	4.8	1	0.6	0	0.0
Skin and Appendages	TOTAL	14	5.7	3	14.3	1	0.6	0	0.0
	SWEATING	14	5.7	3	14.3	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.09

Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Medical Condition: DIABETES MELLITUS

Body System	Preferred Term	Paroxetine Condition=N N=235 n	%	Paroxetine Condition=Y N=33 n	%	Placebo Condition=N N=157 n	%	Placebo Condition=Y N=25 n	%
TOTAL	Total Male Subjects *	113	100.0	19	100.0	58	100.0	13	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	122	100.0	14	100.0	99	100.0	12	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	59	25.1	7	21.2	16	10.2	1	4.0
Cardiovascular System	TOTAL	20	8.5	5	15.2	5	3.2	0	0.0
	BRADYCARDIA	4	1.7	0	0.0	0	0.0	0	0.0
	HYPOTENSION	13	5.5	4	12.1	4	2.5	0	0.0
	POSTURAL HYPOTENSION	2	0.9	1	3.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	23	9.8	0	0.0	8	5.1	1	4.0
	DRY MOUTH	23	9.8	0	0.0	8	5.1	1	4.0
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	12	5.1	2	6.1	2	1.3	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	12	5.1	2	6.1	1	0.6	0	0.0
Skin and Appendages	TOTAL	14	6.0	3	9.1	1	0.6	0	0.0
	SWEATING	14	6.0	3	9.1	1	0.6	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: ARTHROPATHY

Body System	Preferred Term	Paroxetine Condition=N N=239 n	%	Paroxetine Condition=Y N=29 n	%	Placebo Condition=N N=160 n	%	Placebo Condition=Y N=22 n	%
TOTAL	Total Male Subjects *	119	100.0	13	100.0	69	100.0	2	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	120	100.0	16	100.0	91	100.0	20	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	60	25.1	6	20.7	14	8.8	3	13.6
Cardiovascular System	TOTAL	22	9.2	3	10.3	3	1.9	2	9.1
	BRADYCARDIA	4	1.7	0	0.0	0	0.0	0	0.0
	HYPOTENSION	14	5.9	3	10.3	2	1.3	2	9.1
	POSTURAL HYPOTENSION	3	1.3	0	0.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	21	8.8	2	6.9	8	5.0	1	4.5
	DRY MOUTH	21	8.8	2	6.9	8	5.0	1	4.5
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	14	5.9	0	0.0	2	1.3	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	14	5.9	0	0.0	1	0.6	0	0.0
Skin and Appendages	TOTAL	16	6.7	1	3.4	1	0.6	0	0.0
	SWEATING	16	6.7	1	3.4	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: CEREBROVASCULAR DIS

Body System	Preferred Term	Paroxetine Condition=N N=249 n	%	Paroxetine Condition=Y N=19 n	%	Placebo Condition=N N=160 n	%	Placebo Condition=Y N=22 n	%
TOTAL	Total Male Subjects *	121	100.0	11	100.0	62	100.0	9	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	128	100.0	8	100.0	98	100.0	13	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	65	26.1	1	5.3	16	10.0	1	4.5
Cardiovascular System	TOTAL	24	9.6	1	5.3	5	3.1	0	0.0
	BRADYCARDIA	3	1.2	1	5.3	0	0.0	0	0.0
	HYPOTENSION	17	6.8	0	0.0	4	2.5	0	0.0
	POSTURAL HYPOTENSION	3	1.2	0	0.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	23	9.2	0	0.0	8	5.0	1	4.5
	DRY MOUTH	23	9.2	0	0.0	8	5.0	1	4.5
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	14	5.6	0	0.0	2	1.3	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	14	5.6	0	0.0	1	0.6	0	0.0
Skin and Appendages	TOTAL	17	6.8	0	0.0	1	0.6	0	0.0
	SWEATING	17	6.8	0	0.0	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: OSTEOARTHROSIS

Body System	Preferred Term	Paroxetine Condition=N N=242 n	%	Paroxetine Condition=Y N=26 n	%	Placebo Condition=N N=170 n	%	Placebo Condition=Y N=12 n	%
TOTAL	Total Male Subjects *	120	100.0	12	100.0	66	100.0	5	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	122	100.0	14	100.0	104	100.0	7	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	59	24.4	7	26.9	15	8.8	2	16.7
Cardiovascular System	TOTAL	23	9.5	2	7.7	5	2.9	0	0.0
	BRADYCARDIA	4	1.7	0	0.0	0	0.0	0	0.0
	HYPOTENSION	15	6.2	2	7.7	4	2.4	0	0.0
	POSTURAL HYPOTENSION	3	1.2	0	0.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	20	8.3	3	11.5	8	4.7	1	8.3
	DRY MOUTH	20	8.3	3	11.5	8	4.7	1	8.3
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	13	5.4	1	3.8	1	0.6	1	8.3
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0	1	8.3
	TREMOR	13	5.4	1	3.8	1	0.6	0	0.0
Skin and Appendages	TOTAL	16	6.6	1	3.8	1	0.6	0	0.0
	SWEATING	16	6.6	1	3.8	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: HEADACHE

		Paroxetine Condition=N N=244		Paroxetine Condition=Y N=24		Placebo Condition=N N=169		Placebo Condition=Y N=13	
Body System	Preferred Term	n	%	n	%	n	%	n	%
TOTAL	Total Male Subjects *	118	100.0	14	100.0	67	100.0	4	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	126	100.0	10	100.0	102	100.0	9	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	61	25.0	5	20.8	15	8.9	2	15.4
Cardiovascular System	TOTAL	23	9.4	2	8.3	5	3.0	0	0.0
	BRADYCARDIA	3	1.2	1	4.2	0	0.0	0	0.0
	HYPOTENSION	16	6.6	1	4.2	4	2.4	0	0.0
	POSTURAL HYPOTENSION	3	1.2	0	0.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	20	8.2	3	12.5	7	4.1	2	15.4
	DRY MOUTH	20	8.2	3	12.5	7	4.1	2	15.4
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	14	5.7	0	0.0	2	1.2	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	14	5.7	0	0.0	1	0.6	0	0.0
Skin and Appendages	TOTAL	17	7.0	0	0.0	1	0.6	0	0.0
	SWEATING	17	7.0	0	0.0	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: HYPOTHYROIDISM

Body System	Preferred Term	Paroxetine Condition=N N=247 n	%	Paroxetine Condition=Y N=21 n	%	Placebo Condition=N N=166 n	%	Placebo Condition=Y N=16 n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	71	100.0	0	0.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	119	100.0	17	100.0	95	100.0	16	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	54	21.9	12	57.1	14	8.4	3	18.8
Cardiovascular System	TOTAL	19	7.7	6	28.6	5	3.0	0	0.0
	BRADYCARDIA	3	1.2	1	4.8	0	0.0	0	0.0
	HYPOTENSION	12	4.9	5	23.8	4	2.4	0	0.0
	POSTURAL HYPOTENSION	3	1.2	0	0.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	20	8.1	3	14.3	6	3.6	3	18.8
	DRY MOUTH	20	8.1	3	14.3	6	3.6	3	18.8
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	4.8	0	0.0	0	0.0
	THIRST	0	0.0	1	4.8	0	0.0	0	0.0
Nervous System	TOTAL	13	5.3	1	4.8	2	1.2	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	13	5.3	1	4.8	1	0.6	0	0.0
Skin and Appendages	TOTAL	14	5.7	3	14.3	1	0.6	0	0.0
	SWEATING	14	5.7	3	14.3	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: CHOLEST/TRIGLYCERIDE, ELEVATED

		Paroxetine Condition=N N=251		Paroxetine Condition=Y N=17		Placebo Condition=N N=164		Placebo Condition=Y N=18	
Body System	Preferred Term	n	%	n	%	n	%	n	%
TOTAL	Total Male Subjects *	127	100.0	5	100.0	64	100.0	7	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	124	100.0	12	100.0	100	100.0	11	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	59	23.5	7	41.2	15	9.1	2	11.1
Cardiovascular System	TOTAL	22	8.8	3	17.6	4	2.4	1	5.6
	BRADYCARDIA	4	1.6	0	0.0	0	0.0	0	0.0
	HYPOTENSION	15	6.0	2	11.8	4	2.4	0	0.0
	POSTURAL HYPOTENSION	2	0.8	1	5.9	0	0.0	1	5.6
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	20	8.0	3	17.6	9	5.5	0	0.0
	DRY MOUTH	20	8.0	3	17.6	9	5.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	13	5.2	1	5.9	2	1.2	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	13	5.2	1	5.9	1	0.6	0	0.0
Skin and Appendages	TOTAL	17	6.8	0	0.0	0	0.0	1	5.6
	SWEATING	17	6.8	0	0.0	0	0.0	1	5.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: INSOMNIA

		Paroxetine Condition=N N=254		Paroxetine Condition=Y N=14		Placebo Condition=N N=165		Placebo Condition=Y N=17	
Body System	Preferred Term	n	%	n	%	n	%	n	%
TOTAL	Total Male Subjects *	128	100.0	4	100.0	66	100.0	5	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	126	100.0	10	100.0	99	100.0	12	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	64	25.2	2	14.3	15	9.1	2	11.8
Cardiovascular System	TOTAL	24	9.4	1	7.1	5	3.0	0	0.0
	BRADYCARDIA	4	1.6	0	0.0	0	0.0	0	0.0
	HYPOTENSION	17	6.7	0	0.0	4	2.4	0	0.0
	POSTURAL HYPOTENSION	3	1.2	0	0.0	1	0.6	0	0.0
	VASODILATATION	0	0.0	1	7.1	1	0.6	0	0.0
Digestive System	TOTAL	21	8.3	2	14.3	8	4.8	1	5.9
	DRY MOUTH	21	8.3	2	14.3	8	4.8	1	5.9
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	14	5.5	0	0.0	1	0.6	1	5.9
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0	1	5.9
	TREMOR	14	5.5	0	0.0	1	0.6	0	0.0
Skin and Appendages	TOTAL	16	6.3	1	7.1	1	0.6	0	0.0
	SWEATING	16	6.3	1	7.1	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

EMEA LOQs Table 3.09
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medical Condition^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Medical Condition: PROSTATE DISORD

Body System	Preferred Term	Paroxetine Condition=N N=254 n	%	Paroxetine Condition=Y N=14 n	%	Placebo Condition=N N=169 n	%	Placebo Condition=Y N=13 n	%
TOTAL	Total Male Subjects *	118	100.0	14	100.0	58	100.0	13	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	136	100.0	0	0.0	111	100.0	0	0.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	63	24.8	3	21.4	17	10.1	0	0.0
Cardiovascular System	TOTAL	24	9.4	1	7.1	5	3.0	0	0.0
	BRADYCARDIA	4	1.6	0	0.0	0	0.0	0	0.0
	HYPOTENSION	16	6.3	1	7.1	4	2.4	0	0.0
	POSTURAL HYPOTENSION	3	1.2	0	0.0	1	0.6	0	0.0
	VASODILATATION	1	0.4	0	0.0	1	0.6	0	0.0
Digestive System	TOTAL	23	9.1	0	0.0	9	5.3	0	0.0
	DRY MOUTH	23	9.1	0	0.0	9	5.3	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	0.4	0	0.0	0	0.0	0	0.0
	THIRST	1	0.4	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	13	5.1	1	7.1	2	1.2	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6	0	0.0
	TREMOR	13	5.1	1	7.1	1	0.6	0	0.0
Skin and Appendages	TOTAL	16	6.3	1	7.1	1	0.6	0	0.0
	SWEATING	16	6.3	1	7.1	1	0.6	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently occurring medical conditions across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: ACETYLSALICYLIC ACID

Body System	Preferred Term	Med taken N=84 Med < AE n	%	Med taken N=84 Med >= AE n	%	None taken N=184 n	%
TOTAL	Total Male Subjects *	48	100.0	48	100.0	84	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	36	100.0	36	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	1.1
Nervous System	TOTAL	0	0.0	0	0.0	2	1.1
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	1.1

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: ACETYLSALICYLIC ACID

Body System	Preferred Term	Med taken N=56 Med < AE n	%	Med taken N=56 Med >= AE n	%	None taken N=126 n	%
TOTAL	Total Male Subjects *	20	100.0	20	100.0	51	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	36	100.0	36	100.0	75	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: PARACETAMOL

Body System	Preferred Term	Med taken N=50 Med < AE n	%	Med taken N=50 Med >= AE n	%	None taken N=218 n	%
TOTAL	Total Male Subjects *	22	100.0	22	100.0	110	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	28	100.0	28	100.0	108	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	1	2.0	1	0.5
Nervous System	TOTAL	0	0.0	1	2.0	1	0.5
	EMOTIONAL LABILITY	0	0.0	1	2.0	1	0.5

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: PARACETAMOL

Body System	Preferred Term	Med taken N=21 Med < AE n	%	Med taken N=21 Med >= AE n	%	None taken N=161 n	%
TOTAL	Total Male Subjects *	5	100.0	5	100.0	66	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	16	100.0	16	100.0	95	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: VITAMIN NOS

Body System	Preferred Term	Med taken N=35 Med < AE n	%	Med taken N=35 Med >= AE n	%	None taken N=233 n	%
TOTAL	Total Male Subjects *	15	100.0	15	100.0	117	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	20	100.0	20	100.0	116	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.9
Nervous System	TOTAL	0	0.0	0	0.0	2	0.9
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.9

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: VITAMIN NOS

Body System	Preferred Term	Med taken N=21 Med < AE n	%	Med taken N=21 Med >= AE n	%	None taken N=161 n	%
TOTAL	Total Male Subjects *	7	100.0	7	100.0	64	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	97	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: HYDROCHLOROTHIAZIDE

Body System	Preferred Term	Med taken N=26 Med < AE n	%	Med taken N=26 Med >= AE n	%	None taken N=242 n	%
TOTAL	Total Male Subjects *	10	100.0	10	100.0	122	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	16	100.0	16	100.0	120	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.8
Nervous System	TOTAL	0	0.0	0	0.0	2	0.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.8

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: HYDROCHLOROTHIAZIDE

Body System	Preferred Term	Med taken N=23 Med < AE n	%	Med taken N=23 Med >= AE n	%	None taken N=159 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	62	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	97	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: IBUPROFEN

Body System	Preferred Term	Med taken N=19 Med < AE n	%	Med taken N=19 Med >= AE n	%	None taken N=249 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	10	100.0	10	100.0	126	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.8
Nervous System	TOTAL	0	0.0	0	0.0	2	0.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.8

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: IBUPROFEN

Body System	Preferred Term	Med taken N=17 Med < AE n	%	Med taken N=17 Med >= AE n	%	None taken N=165 n	%
TOTAL	Total Male Subjects *	6	100.0	6	100.0	65	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	11	100.0	11	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: PAROXETINE

Body System	Preferred Term	Med taken N=22 Med < AE n	%	Med taken N=22 Med >= AE n	%	None taken N=246 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	13	100.0	13	100.0	123	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.8
Nervous System	TOTAL	0	0.0	0	0.0	2	0.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.8

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: PAROXETINE

Body System	Preferred Term	Med taken N=13 Med < AE n	%	Med taken N=13 Med >= AE n	%	None taken N=169 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	67	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	9	100.0	9	100.0	102	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: RANITIDINE HYDROCHLORIDE

Body System	Preferred Term	Med taken N=26 Med < AE n	%	Med taken N=26 Med >= AE n	%	None taken N=242 n	%
TOTAL	Total Male Subjects *	12	100.0	12	100.0	120	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	122	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.8
Nervous System	TOTAL	0	0.0	0	0.0	2	0.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.8

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.10
Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: RANITIDINE HYDROCHLORIDE

Body System	Preferred Term	Med taken N=9 Med < AE n	%	Med taken N=9 Med >= AE n	%	None taken N=173 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	67	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	5	100.0	5	100.0	106	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: LEVOTHYROXINE SODIUM

Body System	Preferred Term	Med taken N=19 Med < AE n	%	Med taken N=19 Med >= AE n	%	None taken N=249 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	128	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	15	100.0	15	100.0	121	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.8
Nervous System	TOTAL	0	0.0	0	0.0	2	0.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.8

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.10
Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: LEVOTHYROXINE SODIUM

Body System	Preferred Term	Med taken N=15 Med < AE n	%	Med taken N=15 Med >= AE n	%	None taken N=167 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	15	100.0	15	100.0	96	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.10
Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: ESTROGENS CONJUGATED

Body System	Preferred Term	Med taken N=23 Med < AE n	%	Med taken N=23 Med >= AE n	%	None taken N=245 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	132	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	23	100.0	23	100.0	113	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.8
Nervous System	TOTAL	0	0.0	0	0.0	2	0.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.8

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: ESTROGENS CONJUGATED

Body System	Preferred Term	Med taken N=10 Med < AE n	%	Med taken N=10 Med >= AE n	%	None taken N=172 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	10	100.0	10	100.0	101	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: ENALAPRIL MALEATE

Body System	Preferred Term	Med taken N=16 Med < AE n	%	Med taken N=16 Med >= AE n	%	None taken N=252 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	7	100.0	7	100.0	129	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	2	0.8
Nervous System	TOTAL	0	0.0	0	0.0	2	0.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	2	0.8

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 3.10

Number % of patients with Possibly Suicide-Related Adverse Events by Body System, Preferred Term and Medication^

Patients over 65 years in Studies 487, 625, 637 and 646

On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: ENALAPRIL MALEATE

Body System	Preferred Term	Med taken N=16 Med < AE n	%	Med taken N=16 Med >= AE n	%	None taken N=166 n	%
TOTAL	Total Male Subjects *	5	100.0	5	100.0	66	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	11	100.0	11	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0

* Percentage calculated from the total number of males

** Percentage calculated from the total number of females

^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: ACETYLSALICYLIC ACID

Body System	Preferred Term	Med taken N=84 Med < AE n	%	Med taken N=84 Med >= AE n	%	None taken N=184 n	%
TOTAL	Total Male Subjects *	48	100.0	48	100.0	84	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	36	100.0	36	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	5	6.0	0	0.0	12	6.5
Body as a Whole	TOTAL	2	2.4	0	0.0	3	1.6
	ASTHENIA	0	0.0	0	0.0	1	0.5
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	2	2.4	0	0.0	2	1.1
Digestive System	TOTAL	0	0.0	0	0.0	4	2.2
	DIARRHEA	0	0.0	0	0.0	1	0.5
	NAUSEA	0	0.0	0	0.0	3	1.6
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	4	4.8	0	0.0	7	3.8
	ABNORMAL DREAMS	1	1.2	0	0.0	1	0.5
	AGITATION	0	0.0	0	0.0	1	0.5
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	1	1.2	0	0.0	0	0.0
	DIZZINESS	1	1.2	0	0.0	5	2.7
	INSOMNIA	2	2.4	0	0.0	0	0.0
	NERVOUSNESS	1	1.2	0	0.0	0	0.0
	SOMNOLENCE	1	1.2	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.5
	VERTIGO	0	0.0	0	0.0	1	0.5
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.5
	SWEATING	0	0.0	0	0.0	1	0.5

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: ACETYLSALICYLIC ACID

Body System	Preferred Term	Med taken N=56 Med < AE n	%	Med taken N=56 Med >= AE n	%	None taken N=126 n	%
TOTAL	Total Male Subjects *	20	100.0	20	100.0	51	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	36	100.0	36	100.0	75	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	4	7.1	0	0.0	13	10.3
Body as a Whole	TOTAL	2	3.6	0	0.0	4	3.2
	ASTHENIA	2	3.6	0	0.0	1	0.8
	CHILLS	0	0.0	0	0.0	1	0.8
	HEADACHE	0	0.0	0	0.0	2	1.6
Digestive System	TOTAL	0	0.0	0	0.0	6	4.8
	DIARRHEA	0	0.0	0	0.0	2	1.6
	NAUSEA	0	0.0	0	0.0	5	4.0
	VOMITING	0	0.0	0	0.0	2	1.6
Nervous System	TOTAL	2	3.6	0	0.0	5	4.0
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.6
	CONFUSION	0	0.0	0	0.0	1	0.8
	DIZZINESS	1	1.8	0	0.0	1	0.8
	INSOMNIA	1	1.8	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	0	0.0	1	0.8
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.8
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: PARACETAMOL

Body System	Preferred Term	Med taken N=50 Med < AE n	%	Med taken N=50 Med >= AE n	%	None taken N=218 n	%
TOTAL	Total Male Subjects *	22	100.0	22	100.0	110	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	28	100.0	28	100.0	108	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	7	14.0	2	4.0	9	4.1
Body as a Whole	TOTAL	2	4.0	2	4.0	1	0.5
	ASTHENIA	1	2.0	0	0.0	0	0.0
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	1	2.0	2	4.0	1	0.5
Digestive System	TOTAL	2	4.0	0	0.0	2	0.9
	DIARRHEA	0	0.0	0	0.0	1	0.5
	NAUSEA	2	4.0	0	0.0	1	0.5
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	3	6.0	1	2.0	7	3.2
	ABNORMAL DREAMS	1	2.0	0	0.0	1	0.5
	AGITATION	0	0.0	0	0.0	1	0.5
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.5
	DIZZINESS	2	4.0	1	2.0	3	1.4
	INSOMNIA	1	2.0	0	0.0	1	0.5
	NERVOUSNESS	1	2.0	0	0.0	0	0.0
	SOMNOLENCE	0	0.0	0	0.0	1	0.5
	TREMOR	0	0.0	0	0.0	1	0.5
	VERTIGO	1	2.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	2.0	0	0.0	0	0.0
	SWEATING	1	2.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: PARACETAMOL

Body System	Preferred Term	Med taken N=21 Med < AE n	%	Med taken N=21 Med >= AE n	%	None taken N=161 n	%
TOTAL	Total Male Subjects *	5	100.0	5	100.0	66	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	16	100.0	16	100.0	95	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	5	23.8	1	4.8	11	6.8
Body as a Whole	TOTAL	3	14.3	1	4.8	2	1.2
	ASTHENIA	2	9.5	0	0.0	1	0.6
	CHILLS	0	0.0	0	0.0	1	0.6
	HEADACHE	1	4.8	1	4.8	0	0.0
Digestive System	TOTAL	1	4.8	0	0.0	5	3.1
	DIARRHEA	1	4.8	0	0.0	1	0.6
	NAUSEA	1	4.8	0	0.0	4	2.5
	VOMITING	0	0.0	0	0.0	2	1.2
Nervous System	TOTAL	2	9.5	0	0.0	5	3.1
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	1	4.8	0	0.0	1	0.6
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	1	4.8	0	0.0	1	0.6
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	0	0.0	0	0.0	1	0.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	1	4.8	0	0.0	0	0.0
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: VITAMIN NOS

Body System	Preferred Term	Med taken N=35 Med < AE n	%	Med taken N=35 Med >= AE n	%	None taken N=233 n	%
TOTAL	Total Male Subjects *	15	100.0	15	100.0	117	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	20	100.0	20	100.0	116	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	3	8.6	0	0.0	14	6.0
Body as a Whole	TOTAL	2	5.7	0	0.0	3	1.3
	ASTHENIA	1	2.9	0	0.0	0	0.0
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	1	2.9	0	0.0	3	1.3
Digestive System	TOTAL	0	0.0	0	0.0	4	1.7
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	0	0.0	0	0.0	3	1.3
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	2	5.7	0	0.0	9	3.9
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.9
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.4
	DIZZINESS	0	0.0	0	0.0	6	2.6
	INSOMNIA	1	2.9	0	0.0	1	0.4
	NERVOUSNESS	1	2.9	0	0.0	0	0.0
	SOMNOLENCE	1	2.9	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.4
	SWEATING	0	0.0	0	0.0	1	0.4

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: VITAMIN NOS

Body System	Preferred Term	Med taken N=21 Med < AE n	%	Med taken N=21 Med >= AE n	%	None taken N=161 n	%
TOTAL	Total Male Subjects *	7	100.0	7	100.0	64	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	97	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	9.5	1	4.8	14	8.7
Body as a Whole	TOTAL	0	0.0	1	4.8	5	3.1
	ASTHENIA	0	0.0	1	4.8	2	1.2
	CHILLS	0	0.0	0	0.0	1	0.6
	HEADACHE	0	0.0	0	0.0	2	1.2
Digestive System	TOTAL	1	4.8	0	0.0	5	3.1
	DIARRHEA	1	4.8	0	0.0	1	0.6
	NAUSEA	1	4.8	0	0.0	4	2.5
	VOMITING	1	4.8	0	0.0	1	0.6
Nervous System	TOTAL	1	4.8	0	0.0	6	3.7
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	1	4.8	0	0.0	1	0.6
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	0	0.0	0	0.0	1	0.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: HYDROCHLOROTHIAZIDE

Body System	Preferred Term	Med taken N=26 Med < AE n	%	Med taken N=26 Med >= AE n	%	None taken N=242 n	%
TOTAL	Total Male Subjects *	10	100.0	10	100.0	122	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	16	100.0	16	100.0	120	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	17	7.0
Body as a Whole	TOTAL	0	0.0	0	0.0	5	2.1
	ASTHENIA	0	0.0	0	0.0	1	0.4
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	0	0.0	0	0.0	4	1.7
Digestive System	TOTAL	0	0.0	0	0.0	4	1.7
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	0	0.0	0	0.0	3	1.2
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	11	4.5
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.8
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.4
	DIZZINESS	0	0.0	0	0.0	6	2.5
	INSOMNIA	0	0.0	0	0.0	2	0.8
	NERVOUSNESS	0	0.0	0	0.0	1	0.4
	SOMNOLENCE	0	0.0	0	0.0	1	0.4
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.4
	SWEATING	0	0.0	0	0.0	1	0.4

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: HYDROCHLOROTHIAZIDE

Body System	Preferred Term	Med taken N=23 Med < AE n	%	Med taken N=23 Med >= AE n	%	None taken N=159 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	62	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	97	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	8.7	0	0.0	15	9.4
Body as a Whole	TOTAL	0	0.0	0	0.0	6	3.8
	ASTHENIA	0	0.0	0	0.0	3	1.9
	CHILLS	0	0.0	0	0.0	1	0.6
	HEADACHE	0	0.0	0	0.0	2	1.3
Digestive System	TOTAL	0	0.0	0	0.0	6	3.8
	DIARRHEA	0	0.0	0	0.0	2	1.3
	NAUSEA	0	0.0	0	0.0	5	3.1
	VOMITING	0	0.0	0	0.0	2	1.3
Nervous System	TOTAL	2	8.7	0	0.0	5	3.1
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	1	4.3	0	0.0	1	0.6
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	0	0.0	0	0.0	2	1.3
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	1	4.3	0	0.0	0	0.0
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	1	4.3	0	0.0	0	0.0
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: IBUPROFEN

Body System	Preferred Term	Med taken N=19 Med < AE n	%	Med taken N=19 Med >= AE n	%	None taken N=249 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	10	100.0	10	100.0	126	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	5.3	0	0.0	16	6.4
Body as a Whole	TOTAL	1	5.3	0	0.0	4	1.6
	ASTHENIA	0	0.0	0	0.0	1	0.4
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	1	5.3	0	0.0	3	1.2
Digestive System	TOTAL	0	0.0	0	0.0	4	1.6
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	0	0.0	0	0.0	3	1.2
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	11	4.4
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.8
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.4
	DIZZINESS	0	0.0	0	0.0	6	2.4
	INSOMNIA	0	0.0	0	0.0	2	0.8
	NERVOUSNESS	0	0.0	0	0.0	1	0.4
	SOMNOLENCE	0	0.0	0	0.0	1	0.4
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.4
	SWEATING	0	0.0	0	0.0	1	0.4

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: IBUPROFEN

Body System	Preferred Term	Med taken N=17 Med < AE n	%	Med taken N=17 Med >= AE n	%	None taken N=165 n	%
TOTAL	Total Male Subjects *	6	100.0	6	100.0	65	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	11	100.0	11	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	11.8	0	0.0	15	9.1
Body as a Whole	TOTAL	1	5.9	0	0.0	5	3.0
	ASTHENIA	1	5.9	0	0.0	2	1.2
	CHILLS	0	0.0	0	0.0	1	0.6
	HEADACHE	0	0.0	0	0.0	2	1.2
Digestive System	TOTAL	0	0.0	0	0.0	6	3.6
	DIARRHEA	0	0.0	0	0.0	2	1.2
	NAUSEA	0	0.0	0	0.0	5	3.0
	VOMITING	0	0.0	0	0.0	2	1.2
Nervous System	TOTAL	1	5.9	0	0.0	6	3.6
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	0	0.0	0	0.0	2	1.2
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	1	5.9	0	0.0	0	0.0
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: PAROXETINE

Body System	Preferred Term	Med taken N=22 Med < AE n	%	Med taken N=22 Med >= AE n	%	None taken N=246 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	13	100.0	13	100.0	123	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	4.5	2	9.1	14	5.7
Body as a Whole	TOTAL	0	0.0	0	0.0	5	2.0
	ASTHENIA	0	0.0	0	0.0	1	0.4
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	0	0.0	0	0.0	4	1.6
Digestive System	TOTAL	0	0.0	1	4.5	3	1.2
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	0	0.0	1	4.5	2	0.8
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	1	4.5	0	0.0	10	4.1
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.8
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.4
	DIZZINESS	0	0.0	0	0.0	6	2.4
	INSOMNIA	0	0.0	0	0.0	2	0.8
	NERVOUSNESS	0	0.0	0	0.0	1	0.4
	SOMNOLENCE	1	4.5	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	1	4.5	0	0.0
	SWEATING	0	0.0	1	4.5	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: PAROXETINE

Body System	Preferred Term	Med taken N=13 Med < AE n	%	Med taken N=13 Med >= AE n	%	None taken N=169 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	67	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	9	100.0	9	100.0	102	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	7.7	1	7.7	15	8.9
Body as a Whole	TOTAL	0	0.0	1	7.7	5	3.0
	ASTHENIA	0	0.0	1	7.7	2	1.2
	CHILLS	0	0.0	0	0.0	1	0.6
	HEADACHE	0	0.0	0	0.0	2	1.2
Digestive System	TOTAL	1	7.7	0	0.0	5	3.0
	DIARRHEA	0	0.0	0	0.0	2	1.2
	NAUSEA	1	7.7	0	0.0	4	2.4
	VOMITING	0	0.0	0	0.0	2	1.2
Nervous System	TOTAL	0	0.0	0	0.0	7	4.1
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	0	0.0	0	0.0	2	1.2
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	0	0.0	0	0.0	1	0.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: RANITIDINE HYDROCHLORIDE

Body System	Preferred Term	Med taken N=26 Med < AE n	%	Med taken N=26 Med >= AE n	%	None taken N=242 n	%
TOTAL	Total Male Subjects *	12	100.0	12	100.0	120	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	122	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	7.7	1	3.8	14	5.8
Body as a Whole	TOTAL	2	7.7	0	0.0	3	1.2
	ASTHENIA	0	0.0	0	0.0	1	0.4
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	2	7.7	0	0.0	2	0.8
Digestive System	TOTAL	0	0.0	1	3.8	3	1.2
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	0	0.0	1	3.8	2	0.8
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	1	3.8	0	0.0	10	4.1
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.8
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.4
	DIZZINESS	1	3.8	0	0.0	5	2.1
	INSOMNIA	0	0.0	0	0.0	2	0.8
	NERVOUSNESS	0	0.0	0	0.0	1	0.4
	SOMNOLENCE	0	0.0	0	0.0	1	0.4
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.4
	SWEATING	0	0.0	0	0.0	1	0.4

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: RANITIDINE HYDROCHLORIDE

Body System	Preferred Term	Med taken N=9 Med < AE n	%	Med taken N=9 Med >= AE n	%	None taken N=173 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	67	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	5	100.0	5	100.0	106	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	11.1	0	0.0	16	9.2
Body as a Whole	TOTAL	0	0.0	0	0.0	6	3.5
	ASTHENIA	0	0.0	0	0.0	3	1.7
	CHILLS	0	0.0	0	0.0	1	0.6
	HEADACHE	0	0.0	0	0.0	2	1.2
Digestive System	TOTAL	0	0.0	0	0.0	6	3.5
	DIARRHEA	0	0.0	0	0.0	2	1.2
	NAUSEA	0	0.0	0	0.0	5	2.9
	VOMITING	0	0.0	0	0.0	2	1.2
Nervous System	TOTAL	1	11.1	0	0.0	6	3.5
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	1	11.1	0	0.0	1	0.6
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	0	0.0	0	0.0	1	0.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: LEVOTHYROXINE SODIUM

Body System	Preferred Term	Med taken N=19 Med < AE n	%	Med taken N=19 Med >= AE n	%	None taken N=249 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	128	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	15	100.0	15	100.0	121	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	4	21.1	0	0.0	13	5.2
Body as a Whole	TOTAL	0	0.0	0	0.0	5	2.0
	ASTHENIA	0	0.0	0	0.0	1	0.4
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	0	0.0	0	0.0	4	1.6
Digestive System	TOTAL	1	5.3	0	0.0	3	1.2
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	1	5.3	0	0.0	2	0.8
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	3	15.8	0	0.0	8	3.2
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.8
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	1	5.3	0	0.0	0	0.0
	DIZZINESS	2	10.5	0	0.0	4	1.6
	INSOMNIA	0	0.0	0	0.0	2	0.8
	NERVOUSNESS	0	0.0	0	0.0	1	0.4
	SOMNOLENCE	1	5.3	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.4
	SWEATING	0	0.0	0	0.0	1	0.4

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: LEVOTHYROXINE SODIUM

Body System	Preferred Term	Med taken N=15 Med < AE n	%	Med taken N=15 Med >= AE n	%	None taken N=167 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	15	100.0	15	100.0	96	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	3	20.0	0	0.0	14	8.4
Body as a Whole	TOTAL	1	6.7	0	0.0	5	3.0
	ASTHENIA	0	0.0	0	0.0	3	1.8
	CHILLS	1	6.7	0	0.0	0	0.0
	HEADACHE	0	0.0	0	0.0	2	1.2
Digestive System	TOTAL	1	6.7	0	0.0	5	3.0
	DIARRHEA	0	0.0	0	0.0	2	1.2
	NAUSEA	1	6.7	0	0.0	4	2.4
	VOMITING	0	0.0	0	0.0	2	1.2
Nervous System	TOTAL	2	13.3	0	0.0	5	3.0
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	1	6.7	0	0.0	1	0.6
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	1	6.7	0	0.0	1	0.6
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	0	0.0	0	0.0	1	0.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: ESTROGENS CONJUGATED

Body System	Preferred Term	Med taken N=23 Med < AE n	%	Med taken N=23 Med >= AE n	%	None taken N=245 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	132	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	23	100.0	23	100.0	113	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	4.3	0	0.0	16	6.5
Body as a Whole	TOTAL	0	0.0	0	0.0	5	2.0
	ASTHENIA	0	0.0	0	0.0	1	0.4
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	0	0.0	0	0.0	4	1.6
Digestive System	TOTAL	0	0.0	0	0.0	4	1.6
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	0	0.0	0	0.0	3	1.2
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	1	4.3	0	0.0	10	4.1
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.8
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.4
	DIZZINESS	0	0.0	0	0.0	6	2.4
	INSOMNIA	0	0.0	0	0.0	2	0.8
	NERVOUSNESS	0	0.0	0	0.0	1	0.4
	SOMNOLENCE	1	4.3	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.4
	SWEATING	0	0.0	0	0.0	1	0.4

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: ESTROGENS CONJUGATED

Body System	Preferred Term	Med taken N=10 Med < AE n	%	Med taken N=10 Med >= AE n	%	None taken N=172 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	10	100.0	10	100.0	101	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	10.0	0	0.0	16	9.3
Body as a Whole	TOTAL	1	10.0	0	0.0	5	2.9
	ASTHENIA	0	0.0	0	0.0	3	1.7
	CHILLS	1	10.0	0	0.0	0	0.0
	HEADACHE	0	0.0	0	0.0	2	1.2
Digestive System	TOTAL	0	0.0	0	0.0	6	3.5
	DIARRHEA	0	0.0	0	0.0	2	1.2
	NAUSEA	0	0.0	0	0.0	5	2.9
	VOMITING	0	0.0	0	0.0	2	1.2
Nervous System	TOTAL	1	10.0	0	0.0	6	3.5
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	1	10.0	0	0.0	1	0.6
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	0	0.0	0	0.0	2	1.2
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	0	0.0	0	0.0	1	0.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PAROXETINE Medication: ENALAPRIL MALEATE

Body System	Preferred Term	Med taken N=16 Med < AE n	%	Med taken N=16 Med >= AE n	%	None taken N=252 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	7	100.0	7	100.0	129	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	17	6.7
Body as a Whole	TOTAL	0	0.0	0	0.0	5	2.0
	ASTHENIA	0	0.0	0	0.0	1	0.4
	CHILLS	0	0.0	0	0.0	0	0.0
	HEADACHE	0	0.0	0	0.0	4	1.6
Digestive System	TOTAL	0	0.0	0	0.0	4	1.6
	DIARRHEA	0	0.0	0	0.0	1	0.4
	NAUSEA	0	0.0	0	0.0	3	1.2
	VOMITING	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	11	4.4
	ABNORMAL DREAMS	0	0.0	0	0.0	2	0.8
	AGITATION	0	0.0	0	0.0	1	0.4
	ANXIETY	0	0.0	0	0.0	0	0.0
	CONFUSION	0	0.0	0	0.0	1	0.4
	DIZZINESS	0	0.0	0	0.0	6	2.4
	INSOMNIA	0	0.0	0	0.0	2	0.8
	NERVOUSNESS	0	0.0	0	0.0	1	0.4
	SOMNOLENCE	0	0.0	0	0.0	1	0.4
	TREMOR	0	0.0	0	0.0	1	0.4
	VERTIGO	0	0.0	0	0.0	1	0.4
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.4
	SWEATING	0	0.0	0	0.0	1	0.4

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.11
Number % of patients with Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
All AEs Identified as Potentially Withdrawal Events
Taper and Follow-up Phases

Treatment Group: PLACEBO Medication: ENALAPRIL MALEATE

Body System	Preferred Term	Med taken N=16 Med < AE n	%	Med taken N=16 Med >= AE n	%	None taken N=166 n	%
TOTAL	Total Male Subjects *	5	100.0	5	100.0	66	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	11	100.0	11	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	6.3	0	0.0	16	9.6
Body as a Whole	TOTAL	0	0.0	0	0.0	6	3.6
	ASTHENIA	0	0.0	0	0.0	3	1.8
	CHILLS	0	0.0	0	0.0	1	0.6
	HEADACHE	0	0.0	0	0.0	2	1.2
Digestive System	TOTAL	1	6.3	0	0.0	5	3.0
	DIARRHEA	0	0.0	0	0.0	2	1.2
	NAUSEA	0	0.0	0	0.0	5	3.0
	VOMITING	1	6.3	0	0.0	1	0.6
Nervous System	TOTAL	0	0.0	0	0.0	7	4.2
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0
	AGITATION	0	0.0	0	0.0	0	0.0
	ANXIETY	0	0.0	0	0.0	2	1.2
	CONFUSION	0	0.0	0	0.0	1	0.6
	DIZZINESS	0	0.0	0	0.0	2	1.2
	INSOMNIA	0	0.0	0	0.0	1	0.6
	NERVOUSNESS	0	0.0	0	0.0	1	0.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	0	0.0
	SWEATING	0	0.0	0	0.0	0	0.0

Potentially withdrawal event based on blinded manual review of all preferred terms
* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: ACETYLSALICYLIC ACID

Body System	Preferred Term	Med taken N=84 Med < AE n	%	Med taken N=84 Med >= AE n	%	None taken N=184 n	%
TOTAL	Total Male Subjects *	48	100.0	48	100.0	84	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	36	100.0	36	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	29	34.5	4	4.8	34	18.5
Cardiovascular System	TOTAL	13	15.5	0	0.0	12	6.5
	BRADYCARDIA	2	2.4	0	0.0	2	1.1
	HYPOTENSION	7	8.3	0	0.0	10	5.4
	POSTURAL HYPOTENSION	3	3.6	0	0.0	0	0.0
	VASODILATATION	1	1.2	0	0.0	0	0.0
Digestive System	TOTAL	10	11.9	3	3.6	10	5.4
	DRY MOUTH	10	11.9	3	3.6	10	5.4
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.5
	THIRST	0	0.0	0	0.0	1	0.5
Nervous System	TOTAL	4	4.8	0	0.0	10	5.4
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	4	4.8	0	0.0	10	5.4
Skin and Appendages	TOTAL	7	8.3	1	1.2	9	4.9
	SWEATING	7	8.3	1	1.2	9	4.9

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: ACETYLSALICYLIC ACID

Body System	Preferred Term	Med taken N=56 Med < AE n	%	Med taken N=56 Med >= AE n	%	None taken N=126 n	%
TOTAL	Total Male Subjects *	20	100.0	20	100.0	51	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	36	100.0	36	100.0	75	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	6	10.7	1	1.8	10	7.9
Cardiovascular System	TOTAL	0	0.0	1	1.8	4	3.2
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	0	0.0	1	1.8	3	2.4
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.8
	VASODILATATION	0	0.0	0	0.0	1	0.8
Digestive System	TOTAL	4	7.1	0	0.0	5	4.0
	DRY MOUTH	4	7.1	0	0.0	5	4.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	1	1.8	0	0.0	1	0.8
	EXTRAPYRAMIDAL SYNDROME	1	1.8	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.8
Skin and Appendages	TOTAL	1	1.8	0	0.0	0	0.0
	SWEATING	1	1.8	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: PARACETAMOL

Body System	Preferred Term	Med taken N=50 Med < AE n	%	Med taken N=50 Med >= AE n	%	None taken N=218 n	%
TOTAL	Total Male Subjects *	22	100.0	22	100.0	110	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	28	100.0	28	100.0	108	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	14	28.0	7	14.0	48	22.0
Cardiovascular System	TOTAL	6	12.0	2	4.0	17	7.8
	BRADYCARDIA	1	2.0	0	0.0	3	1.4
	HYPOTENSION	4	8.0	2	4.0	11	5.0
	POSTURAL HYPOTENSION	1	2.0	0	0.0	2	0.9
	VASODILATATION	0	0.0	0	0.0	1	0.5
Digestive System	TOTAL	3	6.0	4	8.0	16	7.3
	DRY MOUTH	3	6.0	4	8.0	16	7.3
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.5
	THIRST	0	0.0	0	0.0	1	0.5
Nervous System	TOTAL	3	6.0	3	6.0	8	3.7
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	3	6.0	3	6.0	8	3.7
Skin and Appendages	TOTAL	2	4.0	2	4.0	13	6.0
	SWEATING	2	4.0	2	4.0	13	6.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: PARACETAMOL

Body System	Preferred Term	Med taken N=21 Med < AE n	%	Med taken N=21 Med >= AE n	%	None taken N=161 n	%
TOTAL	Total Male Subjects *	5	100.0	5	100.0	66	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	16	100.0	16	100.0	95	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	5	23.8	1	4.8	11	6.8
Cardiovascular System	TOTAL	1	4.8	0	0.0	4	2.5
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	1	4.8	0	0.0	3	1.9
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	3	14.3	1	4.8	5	3.1
	DRY MOUTH	3	14.3	1	4.8	5	3.1
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	1	4.8	0	0.0	1	0.6
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	1	4.8	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: VITAMIN NOS

Body System	Preferred Term	Med taken N=35 Med < AE n	%	Med taken N=35 Med >= AE n	%	None taken N=233 n	%
TOTAL	Total Male Subjects *	15	100.0	15	100.0	117	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	20	100.0	20	100.0	116	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	11	31.4	0	0.0	55	23.6
Cardiovascular System	TOTAL	4	11.4	0	0.0	21	9.0
	BRADYCARDIA	0	0.0	0	0.0	4	1.7
	HYPOTENSION	4	11.4	0	0.0	13	5.6
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.3
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	6	17.1	0	0.0	17	7.3
	DRY MOUTH	6	17.1	0	0.0	17	7.3
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.4
	THIRST	0	0.0	0	0.0	1	0.4
Nervous System	TOTAL	2	5.7	0	0.0	12	5.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	2	5.7	0	0.0	12	5.2
Skin and Appendages	TOTAL	4	11.4	0	0.0	13	5.6
	SWEATING	4	11.4	0	0.0	13	5.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: VITAMIN NOS

Body System	Preferred Term	Med taken N=21 Med < AE n	%	Med taken N=21 Med >= AE n	%	None taken N=161 n	%
TOTAL	Total Male Subjects *	7	100.0	7	100.0	64	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	97	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	2	9.5	15	9.3
Cardiovascular System	TOTAL	0	0.0	1	4.8	4	2.5
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	0	0.0	1	4.8	3	1.9
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	0	0.0	1	4.8	8	5.0
	DRY MOUTH	0	0.0	1	4.8	8	5.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	2	1.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	0	0.0	0	0.0	1	0.6
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: HYDROCHLOROTHIAZIDE

Body System	Preferred Term	Med taken N=26 Med < AE n	%	Med taken N=26 Med >= AE n	%	None taken N=242 n	%
TOTAL	Total Male Subjects *	10	100.0	10	100.0	122	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	16	100.0	16	100.0	120	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	5	19.2	0	0.0	61	25.2
Cardiovascular System	TOTAL	1	3.8	0	0.0	24	9.9
	BRADYCARDIA	0	0.0	0	0.0	4	1.7
	HYPOTENSION	1	3.8	0	0.0	16	6.6
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.2
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	2	7.7	0	0.0	21	8.7
	DRY MOUTH	2	7.7	0	0.0	21	8.7
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.4
	THIRST	0	0.0	0	0.0	1	0.4
Nervous System	TOTAL	0	0.0	0	0.0	14	5.8
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	14	5.8
Skin and Appendages	TOTAL	2	7.7	0	0.0	15	6.2
	SWEATING	2	7.7	0	0.0	15	6.2

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: HYDROCHLOROTHIAZIDE

Body System	Preferred Term	Med taken N=23 Med < AE n	%	Med taken N=23 Med >= AE n	%	None taken N=159 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	62	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	97	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	8.7	0	0.0	15	9.4
Cardiovascular System	TOTAL	0	0.0	0	0.0	5	3.1
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	0	0.0	0	0.0	4	2.5
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	1	4.3	0	0.0	8	5.0
	DRY MOUTH	1	4.3	0	0.0	8	5.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	1	4.3	0	0.0	1	0.6
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	1	4.3	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: IBUPROFEN

Body System	Preferred Term	Med taken N=19 Med < AE n	%	Med taken N=19 Med >= AE n	%	None taken N=249 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	10	100.0	10	100.0	126	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	7	36.8	1	5.3	58	23.3
Cardiovascular System	TOTAL	1	5.3	1	5.3	23	9.2
	BRADYCARDIA	0	0.0	0	0.0	4	1.6
	HYPOTENSION	1	5.3	1	5.3	15	6.0
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.2
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	4	21.1	0	0.0	19	7.6
	DRY MOUTH	4	21.1	0	0.0	19	7.6
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.4
	THIRST	0	0.0	0	0.0	1	0.4
Nervous System	TOTAL	1	5.3	0	0.0	13	5.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	1	5.3	0	0.0	13	5.2
Skin and Appendages	TOTAL	1	5.3	0	0.0	16	6.4
	SWEATING	1	5.3	0	0.0	16	6.4

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: IBUPROFEN

Body System	Preferred Term	Med taken N=17 Med < AE n	%	Med taken N=17 Med >= AE n	%	None taken N=165 n	%
TOTAL	Total Male Subjects *	6	100.0	6	100.0	65	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	11	100.0	11	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	2	11.8	0	0.0	15	9.1
Cardiovascular System	TOTAL	1	5.9	0	0.0	4	2.4
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	1	5.9	0	0.0	3	1.8
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	1	5.9	0	0.0	8	4.8
	DRY MOUTH	1	5.9	0	0.0	8	4.8
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	2	1.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	0	0.0	0	0.0	1	0.6
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: PAROXETINE

Body System	Preferred Term	Med taken N=22 Med < AE n	%	Med taken N=22 Med >= AE n	%	None taken N=246 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	13	100.0	13	100.0	123	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	10	45.5	56	22.8
Cardiovascular System	TOTAL	0	0.0	4	18.2	21	8.5
	BRADYCARDIA	0	0.0	3	13.6	1	0.4
	HYPOTENSION	0	0.0	1	4.5	16	6.5
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.2
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	0	0.0	3	13.6	20	8.1
	DRY MOUTH	0	0.0	3	13.6	20	8.1
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.4
	THIRST	0	0.0	0	0.0	1	0.4
Nervous System	TOTAL	0	0.0	1	4.5	13	5.3
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	1	4.5	13	5.3
Skin and Appendages	TOTAL	0	0.0	3	13.6	14	5.7
	SWEATING	0	0.0	3	13.6	14	5.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: PAROXETINE

Body System	Preferred Term	Med taken N=13 Med < AE n	%	Med taken N=13 Med >= AE n	%	None taken N=169 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	67	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	9	100.0	9	100.0	102	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	2	15.4	15	8.9
Cardiovascular System	TOTAL	0	0.0	0	0.0	5	3.0
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	0	0.0	0	0.0	4	2.4
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	0	0.0	2	15.4	7	4.1
	DRY MOUTH	0	0.0	2	15.4	7	4.1
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	2	1.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	0	0.0	0	0.0	1	0.6
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: RANITIDINE HYDROCHLORIDE

Body System	Preferred Term	Med taken N=26 Med < AE n	%	Med taken N=26 Med >= AE n	%	None taken N=242 n	%
TOTAL	Total Male Subjects *	12	100.0	12	100.0	120	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	14	100.0	14	100.0	122	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	3	11.5	2	7.7	61	25.2
Cardiovascular System	TOTAL	1	3.8	1	3.8	23	9.5
	BRADYCARDIA	0	0.0	1	3.8	3	1.2
	HYPOTENSION	1	3.8	0	0.0	16	6.6
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.2
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	1	3.8	1	3.8	21	8.7
	DRY MOUTH	1	3.8	1	3.8	21	8.7
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.4
	THIRST	0	0.0	0	0.0	1	0.4
Nervous System	TOTAL	1	3.8	1	3.8	12	5.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	1	3.8	1	3.8	12	5.0
Skin and Appendages	TOTAL	0	0.0	0	0.0	17	7.0
	SWEATING	0	0.0	0	0.0	17	7.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: RANITIDINE HYDROCHLORIDE

Body System	Preferred Term	Med taken N=9 Med < AE n	%	Med taken N=9 Med >= AE n	%	None taken N=173 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	67	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	5	100.0	5	100.0	106	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	11.1	0	0.0	16	9.2
Cardiovascular System	TOTAL	0	0.0	0	0.0	5	2.9
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	0	0.0	0	0.0	4	2.3
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	0	0.0	0	0.0	9	5.2
	DRY MOUTH	0	0.0	0	0.0	9	5.2
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	1	11.1	0	0.0	1	0.6
	EXTRAPYRAMIDAL SYNDROME	1	11.1	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	1	0.6
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: LEVOTHYROXINE SODIUM

Body System	Preferred Term	Med taken N=19 Med < AE n	%	Med taken N=19 Med >= AE n	%	None taken N=249 n	%
TOTAL	Total Male Subjects *	4	100.0	4	100.0	128	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	15	100.0	15	100.0	121	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	11	57.9	0	0.0	55	22.1
Cardiovascular System	TOTAL	5	26.3	0	0.0	20	8.0
	BRADYCARDIA	1	5.3	0	0.0	3	1.2
	HYPOTENSION	4	21.1	0	0.0	13	5.2
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.2
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	3	15.8	0	0.0	20	8.0
	DRY MOUTH	3	15.8	0	0.0	20	8.0
Metabolic and Nutritional Disorders	TOTAL	1	5.3	0	0.0	0	0.0
	THIRST	1	5.3	0	0.0	0	0.0
Nervous System	TOTAL	1	5.3	0	0.0	13	5.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	1	5.3	0	0.0	13	5.2
Skin and Appendages	TOTAL	3	15.8	0	0.0	14	5.6
	SWEATING	3	15.8	0	0.0	14	5.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: LEVOTHYROXINE SODIUM

Body System	Preferred Term	Med taken N=15 Med < AE n	%	Med taken N=15 Med >= AE n	%	None taken N=167 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	15	100.0	15	100.0	96	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	4	26.7	0	0.0	13	7.8
Cardiovascular System	TOTAL	1	6.7	0	0.0	4	2.4
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	1	6.7	0	0.0	3	1.8
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	3	20.0	0	0.0	6	3.6
	DRY MOUTH	3	20.0	0	0.0	6	3.6
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	2	1.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	0	0.0	0	0.0	1	0.6
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: ESTROGENS CONJUGATED

Body System	Preferred Term	Med taken N=23 Med < AE n	%	Med taken N=23 Med >= AE n	%	None taken N=245 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	132	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	23	100.0	23	100.0	113	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	8	34.8	0	0.0	58	23.7
Cardiovascular System	TOTAL	3	13.0	0	0.0	22	9.0
	BRADYCARDIA	0	0.0	0	0.0	4	1.6
	HYPOTENSION	3	13.0	0	0.0	14	5.7
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.2
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	4	17.4	0	0.0	19	7.8
	DRY MOUTH	4	17.4	0	0.0	19	7.8
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.4
	THIRST	0	0.0	0	0.0	1	0.4
Nervous System	TOTAL	2	8.7	0	0.0	12	4.9
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	2	8.7	0	0.0	12	4.9
Skin and Appendages	TOTAL	2	8.7	0	0.0	15	6.1
	SWEATING	2	8.7	0	0.0	15	6.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: ESTROGENS CONJUGATED

Body System	Preferred Term	Med taken N=10 Med < AE n	%	Med taken N=10 Med >= AE n	%	None taken N=172 n	%
TOTAL	Total Male Subjects *	0	0.0	0	0.0	71	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	10	100.0	10	100.0	101	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	4	40.0	0	0.0	13	7.6
Cardiovascular System	TOTAL	1	10.0	0	0.0	4	2.3
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	1	10.0	0	0.0	3	1.7
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	2	20.0	0	0.0	7	4.1
	DRY MOUTH	2	20.0	0	0.0	7	4.1
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	2	1.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	0	0.0	0	0.0	1	0.6
Skin and Appendages	TOTAL	1	10.0	0	0.0	0	0.0
	SWEATING	1	10.0	0	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PAROXETINE Medication: ENALAPRIL MALEATE

Body System	Preferred Term	Med taken N=16 Med < AE n	%	Med taken N=16 Med >= AE n	%	None taken N=252 n	%
TOTAL	Total Male Subjects *	9	100.0	9	100.0	123	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	7	100.0	7	100.0	129	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	1	6.3	0	0.0	65	25.8
Cardiovascular System	TOTAL	1	6.3	0	0.0	24	9.5
	BRADYCARDIA	0	0.0	0	0.0	4	1.6
	HYPOTENSION	1	6.3	0	0.0	16	6.3
	POSTURAL HYPOTENSION	0	0.0	0	0.0	3	1.2
	VASODILATATION	0	0.0	0	0.0	1	0.4
Digestive System	TOTAL	0	0.0	0	0.0	23	9.1
	DRY MOUTH	0	0.0	0	0.0	23	9.1
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	1	0.4
	THIRST	0	0.0	0	0.0	1	0.4
Nervous System	TOTAL	0	0.0	0	0.0	14	5.6
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0
	TREMOR	0	0.0	0	0.0	14	5.6
Skin and Appendages	TOTAL	0	0.0	0	0.0	17	6.7
	SWEATING	0	0.0	0	0.0	17	6.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

EMEA LOQs Table 3.12
Number % of patients with Anti-Cholinergic Adverse Events by Body System, Preferred Term and Medication^
Patients over 65 years in Studies 487, 625, 637 and 646
On-Therapy plus 30 days post-therapy

Treatment Group: PLACEBO Medication: ENALAPRIL MALEATE

Body System	Preferred Term	Med taken N=16 Med < AE n	%	Med taken N=16 Med >= AE n	%	None taken N=166 n	%
TOTAL	Total Male Subjects *	5	100.0	5	100.0	66	100.0
	Total Male-Specific AEs *	0	0.0	0	0.0	0	0.0
	Total Female Subjects **	11	100.0	11	100.0	100	100.0
	Total Female-Specific AEs **	0	0.0	0	0.0	0	0.0
	Total Non Gender-Specific AEs	0	0.0	0	0.0	17	10.2
Cardiovascular System	TOTAL	0	0.0	0	0.0	5	3.0
	BRADYCARDIA	0	0.0	0	0.0	0	0.0
	HYPOTENSION	0	0.0	0	0.0	4	2.4
	POSTURAL HYPOTENSION	0	0.0	0	0.0	1	0.6
	VASODILATATION	0	0.0	0	0.0	1	0.6
Digestive System	TOTAL	0	0.0	0	0.0	9	5.4
	DRY MOUTH	0	0.0	0	0.0	9	5.4
Metabolic and Nutritional Disorders	TOTAL	0	0.0	0	0.0	0	0.0
	THIRST	0	0.0	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	2	1.2
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	1	0.6
	TREMOR	0	0.0	0	0.0	1	0.6
Skin and Appendages	TOTAL	0	0.0	0	0.0	1	0.6
	SWEATING	0	0.0	0	0.0	1	0.6

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females
^ The ten most frequently taken concomitant/follow-up medications across both treatment groups are examined

Paroxetine EMEA LOQs

EMEA LOQs Table 9.01

Incidence and Incidence Density for AEs with verbatim text containing AKATHIS by Treatment Group and Indication

Adult Placebo Controlled Trials

On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	17/8481 (0.2%)	3/5808 (0.1%)	3.89 (1.14, 13.27)	0.021
Depression	n/N (%)	3/3421 (0.1%)	3/2117 (0.1%)	0.62 (0.12, 3.07)	0.68
GAD	n/N (%)	1/1182 (0.1%)	0/985 (0.0%)		1.00
OCD	n/N (%)	5/542 (0.9%)	0/265 (0.0%)		0.18
PMDD	n/N (%)	1/760 (0.1%)	0/379 (0.0%)		1.00
PTSD	n/N (%)	2/786 (0.3%)	0/598 (0.0%)		0.51
Panic	n/N (%)	4/920 (0.4%)	0/780 (0.0%)		0.13
SAD	n/N (%)	1/870 (0.1%)	0/684 (0.0%)		1.00

Paroxetine EMEA LOQs

EMEA LOQs Table 9.02

Incidence and Incidence Density for AEs with verbatim text containing AKATHIS by Treatment Group and Indication

Adult Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	17/8481 (0.2%)	4/5808 (0.1%)	2.91 (0.98, 8.67)	0.047
Depression	n/N (%)	3/3421 (0.1%)	3/2117 (0.1%)	0.62 (0.12, 3.07)	0.68
GAD	n/N (%)	1/1182 (0.1%)	0/985 (0.0%)		1.00
OCD	n/N (%)	5/542 (0.9%)	1/265 (0.4%)	2.46 (0.29, 21.15)	0.67
PMDD	n/N (%)	1/760 (0.1%)	0/379 (0.0%)		1.00
PTSD	n/N (%)	2/786 (0.3%)	0/598 (0.0%)		0.51
Panic	n/N (%)	4/920 (0.4%)	0/780 (0.0%)		0.13
SAD	n/N (%)	1/870 (0.1%)	0/684 (0.0%)		1.00

Paroxetine EMEA LOQs

EMEA LOQs Table 9.03

Incidence and Incidence Density for AEs with verbatim text containing AKATHIS by Treatment Group and Indication

Adult Active Control Trials

On-Therapy

Indication		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	17/6522 (0.3%)	17/4969 (0.3%)	0.76 (0.39, 1.49)	0.49
Depression	n/N (%)	13/6040 (0.2%)	17/4589 (0.4%)	0.58 (0.28, 1.20)	0.14
OCD	n/N (%)	4/283 (1.4%)	0/181 (0.0%)		0.16
Panic	n/N (%)	0/199 (0.0%)	0/199 (0.0%)		

Paroxetine EMEA LOQs

EMEA LOQs Table 9.04
Incidence and Incidence Density for AEs with verbatim text containing AKATHIS by Treatment Group and Indication
Adult Active Control Trials
On-Therapy plus 30 days post-therapy

Indication		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	17/6522 (0.3%)	19/4969 (0.4%)	0.68 (0.35, 1.31)	0.31
Depression	n/N (%)	13/6040 (0.2%)	19/4589 (0.4%)	0.52 (0.26, 1.05)	0.074
OCD	n/N (%)	4/283 (1.4%)	0/181 (0.0%)		0.16
Panic	n/N (%)	0/199 (0.0%)	0/199 (0.0%)		

Paroxetine EMEA LOQs

EMEA LOQs Table 9.05

Incidence and Incidence Density for AEs with verbatim text containing AKATHIS by Treatment Group and Indication

Paediatric Placebo Controlled Trials

On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	4/738 (0.5%)	3/647 (0.5%)	1.17 (0.26, 5.25)	1.00
Depression	n/N (%)	2/378 (0.5%)	2/285 (0.7%)	0.75 (0.11, 5.38)	1.00
OCD	n/N (%)	2/195 (1.0%)	1/205 (0.5%)	2.11 (0.19, 23.50)	0.61
SAD	n/N (%)	0/165 (0.0%)	0/157 (0.0%)		

Paroxetine EMEA LOQs

EMEA LOQs Table 9.06

Incidence and Incidence Density for AEs with verbatim text containing AKATHIS by Treatment Group and Indication

Paediatric Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	4/738 (0.5%)	3/647 (0.5%)	1.17 (0.26, 5.25)	1.00
Depression	n/N (%)	2/378 (0.5%)	2/285 (0.7%)	0.75 (0.11, 5.38)	1.00
OCD	n/N (%)	2/195 (1.0%)	1/205 (0.5%)	2.11 (0.19, 23.50)	0.61
SAD	n/N (%)	0/165 (0.0%)	0/157 (0.0%)		

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
TOTAL	6753	79.6	3983	68.6
Total Male Subjects *	3245	100.0	2250	100.0
Total Male-Specific AEs *	751	23.1	62	2.8
Total Female Subjects **	5236	100.0	3558	100.0
Total Female-Specific AEs **	537	10.3	233	6.5
Total Non Gender-Specific AEs	6685	78.8	3961	68.2
HEADACHE	1885	22.2	1194	20.6
NAUSEA	1745	20.6	564	9.7
ABNORMAL EJACULATION *	579	17.8	35	1.6
SOMNOLENCE	1384	16.3	330	5.7
INSOMNIA	1209	14.3	539	9.3
ASTHENIA	1140	13.4	394	6.8
DRY MOUTH	959	11.3	335	5.8
DIARRHEA	922	10.9	396	6.8
DIZZINESS	894	10.5	394	6.8
RESPIRATORY DISORDER	732	8.6	519	8.9
CONSTIPATION	710	8.4	218	3.8
SWEATING	684	8.1	140	2.4
LIBIDO DECREASED	578	6.8	97	1.7
TREMOR	561	6.6	82	1.4
NERVOUSNESS	517	6.1	274	4.7
DECREASED APPETITE	467	5.5	115	2.0
IMPOTENCE *	175	5.4	23	1.0
INFECTION	434	5.1	282	4.9
DYSPEPSIA	410	4.8	257	4.4
FEMALE GENITAL DISORDERS **	252	4.8	16	0.4
ANXIETY	361	4.3	195	3.4
ABDOMINAL PAIN	355	4.2	224	3.9
SINUSITIS	344	4.1	215	3.7
TRAUMA	333	3.9	175	3.0
BACK PAIN	264	3.1	194	3.3
YAWN	242	2.9	10	0.2
MYALGIA	237	2.8	175	3.0
PHARYNGITIS	241	2.8	162	2.8
FLATULENCE	235	2.8	136	2.3
VOMITING	208	2.5	110	1.9
DYSMENORRHEA **	127	2.4	87	2.4
ABNORMAL VISION	202	2.4	51	0.9
ABNORMAL DREAMS	191	2.3	96	1.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
PARESTHESIA	189	2.2	106	1.8
VASODILATATION	185	2.2	63	1.1
AGITATION	178	2.1	124	2.1
WEIGHT GAIN	170	2.0	69	1.2
RHINITIS	158	1.9	116	2.0
INCREASED APPETITE	161	1.9	72	1.2
URINARY FREQUENCY	161	1.9	49	0.8
CONCENTRATION IMPAIRED	150	1.8	51	0.9
MYOCLONUS	153	1.8	35	0.6
DEPRESSION	137	1.6	138	2.4
ARTHRALGIA	134	1.6	107	1.8
PALPITATION	135	1.6	81	1.4
RASH	139	1.6	81	1.4
PAIN	130	1.5	111	1.9
CHEST PAIN	119	1.4	74	1.3
URINARY TRACT INFECTION	116	1.4	78	1.3
FLU SYNDROME	111	1.3	52	0.9
EMOTIONAL LABILITY	100	1.2	77	1.3
ALLERGIC REACTION	103	1.2	67	1.2
TOOTH DISORDER	101	1.2	67	1.2
MENSTRUAL DISORDER **	61	1.2	35	1.0
MIGRAINE	103	1.2	60	1.0
URINATION IMPAIRED	99	1.2	13	0.2
BRONCHITIS	95	1.1	65	1.1
COUGH INCREASED	96	1.1	64	1.1
HYPERTENSION	91	1.1	46	0.8
HYPERTONIA	94	1.1	47	0.8
TINNITUS	83	1.0	39	0.7
CONFUSION	89	1.0	32	0.6
TASTE PERVERSION	86	1.0	27	0.5
DEPERSONALIZATION	83	1.0	25	0.4
PRURITUS	78	0.9	56	1.0
FEVER	79	0.9	52	0.9
TACHYCARDIA	75	0.9	34	0.6
MALE GENITAL DISORDERS *	29	0.9	0	0.0
AMNESIA	65	0.8	36	0.6
CHILLS	69	0.8	30	0.5
HYPERKINESIA	65	0.8	24	0.4
BRUXISM	67	0.8	1	0.0
DYSPNEA	61	0.7	40	0.7

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
VERTIGO	62	0.7	42	0.7
LACK OF EMOTION	63	0.7	24	0.4
VAGINITIS **	37	0.7	15	0.4
WEIGHT LOSS	56	0.7	18	0.3
HYPOTENSION	49	0.6	28	0.5
HYPESTHESIA	48	0.6	25	0.4
THINKING ABNORMAL	48	0.6	22	0.4
MALAISE	51	0.6	17	0.3
PURPURA	49	0.6	20	0.3
SYNCOPE	53	0.6	16	0.3
THIRST	47	0.6	16	0.3
DYSPHAGIA	53	0.6	13	0.2
GINGIVITIS	46	0.5	38	0.7
ACNE	40	0.5	31	0.5
GASTROINTESTINAL DISORDER	46	0.5	28	0.5
OTITIS MEDIA	46	0.5	26	0.4
CONJUNCTIVITIS	33	0.4	33	0.6
CYSTITIS	31	0.4	34	0.6
PERIPHERAL EDEMA	32	0.4	35	0.6
VAGINAL MONILIASIS **	23	0.4	21	0.6
MENORRHAGIA **	20	0.4	19	0.5
EAR PAIN	30	0.4	19	0.3
POSTURAL HYPOTENSION	31	0.4	16	0.3
PROSTATE DISORDER *	14	0.4	6	0.3
ANEMIA	37	0.4	13	0.2
BLURRED VISION	38	0.4	11	0.2
DYSTONIA	37	0.4	11	0.2
MANIC REACTION	31	0.4	9	0.2
MYASTHENIA	33	0.4	10	0.2
GASTROENTERITIS	26	0.3	35	0.6
EPISTAXIS	25	0.3	21	0.4
ARTHRITIS	24	0.3	20	0.3
DYSURIA	27	0.3	17	0.3
EYE DISORDER	22	0.3	16	0.3
HERPES SIMPLEX	28	0.3	20	0.3
ARTHROSIS	23	0.3	14	0.2
BREAST PAIN **	16	0.3	8	0.2
EAR DISORDER	26	0.3	9	0.2
LIVER FUNCTION TESTS ABNORMAL	29	0.3	12	0.2
PNEUMONIA	28	0.3	11	0.2

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
SGPT INCREASED	25	0.3	11	0.2
ULCERATIVE STOMATITIS	23	0.3	12	0.2
UNINTENDED PREGNANCY **	17	0.3	8	0.2
URTICARIA	24	0.3	14	0.2
AMENORRHEA **	17	0.3	4	0.1
HYPOKINESIA	22	0.3	5	0.1
PARALYSIS	24	0.3	8	0.1
OROPHARYNX DISORDER	26	0.3	1	0.0
TESTES DISORDER *	9	0.3	1	0.0
CNS STIMULATION	20	0.2	28	0.5
ASTHMA	21	0.2	16	0.3
GASTRITIS	19	0.2	16	0.3
HAEMATURIA	19	0.2	15	0.3
INTENTIONAL OVERDOSE	13	0.2	15	0.3
TENDINOUS DISORDER	14	0.2	16	0.3
ABNORMAL LABORATORY VALUE	14	0.2	10	0.2
ALCOHOL ABUSE	20	0.2	11	0.2
ALOPECIA	14	0.2	10	0.2
ATAXIA	21	0.2	10	0.2
DRY SKIN	17	0.2	12	0.2
HOSTILITY	18	0.2	13	0.2
KERATOCONJUNCTIVITIS	21	0.2	14	0.2
LEUKOPENIA	13	0.2	9	0.2
LIBIDO INCREASED	13	0.2	9	0.2
LYMPHADENOPATHY	15	0.2	9	0.2
NEUROSIS	14	0.2	12	0.2
PHOTOSENSITIVITY	21	0.2	9	0.2
RECTAL DISORDER	16	0.2	10	0.2
ABNORMALITY OF ACCOMMODATION	20	0.2	5	0.1
DRUGGED FEELING	21	0.2	4	0.1
ECZEMA	19	0.2	5	0.1
EDEMA	15	0.2	4	0.1
ERUCTATION	21	0.2	7	0.1
EYE PAIN	15	0.2	4	0.1
FACE EDEMA	16	0.2	5	0.1
GENERALIZED EDEMA	17	0.2	8	0.1
HALLUCINATIONS	16	0.2	6	0.1
HYPERGLYCEMIA	13	0.2	7	0.1
INCOORDINATION	21	0.2	6	0.1
LEUKOCYTOSIS	13	0.2	8	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
MYOPATHY	16	0.2	7	0.1
NOCTURIA	16	0.2	6	0.1
SGOT INCREASED	16	0.2	6	0.1
SURGICAL PROCEDURE	13	0.2	8	0.1
URINARY RETENTION	20	0.2	6	0.1
VISION DISORDERS	13	0.2	6	0.1
MYDRIASIS	17	0.2	0	0.0
ALBUMINURIA	8	0.1	9	0.2
CONTACT DERMATITIS	11	0.1	9	0.2
HYPERCHOLESTEREMIA	11	0.1	10	0.2
LARYNX DISORDER	12	0.1	11	0.2
MACULOPAPULAR RASH	9	0.1	13	0.2
METRORRHAGIA **	7	0.1	6	0.2
NEURALGIA	5	0.1	9	0.2
OVARY DISORDER **	7	0.1	8	0.2
SPEECH DISORDER	9	0.1	10	0.2
ACCIDENTAL OVERDOSE	9	0.1	6	0.1
ANGINA PECTORIS	10	0.1	4	0.1
BILIRUBINEMIA	10	0.1	3	0.1
BONE DISORDER	6	0.1	5	0.1
BREAST ENLARGEMENT **	4	0.1	2	0.1
BURSITIS	7	0.1	6	0.1
CELLULITIS	8	0.1	3	0.1
COLITIS	12	0.1	8	0.1
DEAFNESS	6	0.1	3	0.1
DIABETES MELLITUS	9	0.1	4	0.1
ELECTROCARDIOGRAM ABNORMAL	10	0.1	8	0.1
ENDOMETRIAL DISORDER **	3	0.1	3	0.1
EYE APPENDAGE DISORDER	5	0.1	5	0.1
EYE HEMORRHAGE	5	0.1	3	0.1
FUNGAL DERMATITIS	8	0.1	6	0.1
FURUNCULOSIS	7	0.1	4	0.1
GLYCOSURIA	5	0.1	3	0.1
HAEMATOMA	11	0.1	3	0.1
HYPERTHYROIDISM	9	0.1	6	0.1
HYPERVENTILATION	8	0.1	4	0.1
HYPOTHYROIDISM	9	0.1	3	0.1
KIDNEY CALCULUS	9	0.1	6	0.1
MELENA	12	0.1	5	0.1
MONILIASIS	8	0.1	4	0.1

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
NAIL DISORDER	5	0.1	6	0.1
NAUSEA AND VOMITING	8	0.1	5	0.1
NEOPLASM	11	0.1	6	0.1
NEPHRITIS	6	0.1	3	0.1
NEUROPATHY	5	0.1	7	0.1
NYSTAGMUS	8	0.1	3	0.1
OTITIS EXTERNA	7	0.1	5	0.1
PARANOID REACTION	9	0.1	6	0.1
PERIPHERAL VASCULAR DISORDER	9	0.1	4	0.1
PHOTOPHOBIA	10	0.1	8	0.1
PLEURA DISORDER	5	0.1	5	0.1
PYURIA	9	0.1	3	0.1
RECTAL HEMORRHAGE	12	0.1	3	0.1
SKIN BENIGN NEOPLASM	7	0.1	5	0.1
SKIN DISORDER	12	0.1	3	0.1
SKIN HYPERTROPHY	6	0.1	7	0.1
STOMATITIS	9	0.1	4	0.1
THYROID DISORDER	6	0.1	3	0.1
TOOTH CARIES	12	0.1	7	0.1
URINARY INCONTINENCE	11	0.1	5	0.1
URINE ABNORMALITY	12	0.1	6	0.1
VAGINAL HEMORRHAGE **	5	0.1	3	0.1
VESTIBULAR DISORDER	7	0.1	4	0.1
WITHDRAWAL SYNDROME	10	0.1	4	0.1
ABDOMEN ENLARGED	5	0.1	1	0.0
ALKALINE PHOSPHATASE INCREASED	5	0.1	1	0.0
ARRHYTHMIA	8	0.1	2	0.0
BRADYCARDIA	11	0.1	1	0.0
BREAST NEOPLASM **	4	0.1	1	0.0
CONVULSION	7	0.1	2	0.0
DIPLOPIA	5	0.1	1	0.0
DRUG DEPENDENCE	5	0.1	2	0.0
DYSKINESIA	9	0.1	1	0.0
ESOPHAGITIS	9	0.1	2	0.0
EUPHORIA	7	0.1	2	0.0
EXTRASYSTOLES	6	0.1	0	0.0
GLOSSITIS	5	0.1	2	0.0
HERPES ZOSTER	8	0.1	2	0.0
HYPOCHROMIC ANEMIA	7	0.1	1	0.0
LEUKORRHEA	5	0.1	2	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
MASTITIS **	3	0.1	1	0.0
NECK PAIN	7	0.1	1	0.0
PHLEBITIS	5	0.1	0	0.0
POLYURIA	10	0.1	1	0.0
STUPOR	5	0.1	1	0.0
VESICULOBULLOUS RASH	5	0.1	1	0.0
VISUAL FIELD DEFECT	6	0.1	2	0.0
ABORTION **	1	0.0	2	0.1
AV BLOCK	1	0.0	3	0.1
BREAST CARCINOMA **	0	0.0	3	0.1
BUNDLE BRANCH BLOCK	1	0.0	4	0.1
CEREBROVASCULAR DISORDER	4	0.0	3	0.1
DEHYDRATION	3	0.0	4	0.1
DIGESTIVE SYSTEM DISORDER	2	0.0	3	0.1
EOSINOPHILIA	4	0.0	5	0.1
EXTRAPYRAMIDAL SYNDROME	1	0.0	4	0.1
GALL BLADDER DISORDER	0	0.0	4	0.1
GOUT	4	0.0	4	0.1
HAIR DISORDERS	4	0.0	5	0.1
HEMOPTYSIS	3	0.0	3	0.1
HYPERLIPEMIA	0	0.0	4	0.1
INCREASED SALIVATION	3	0.0	5	0.1
MENINGITIS	0	0.0	3	0.1
MONOCYTOSIS	3	0.0	3	0.1
MYOSITIS	4	0.0	3	0.1
NEUROVASCULAR COMPRESSION	3	0.0	4	0.1
NPN INCREASED	1	0.0	6	0.1
PAPANICOLAU SMEAR SUSPICIOUS **	1	0.0	4	0.1
PEPTIC ULCER	4	0.0	3	0.1
THROMBOCYTOPENIA	1	0.0	3	0.1
UTERINE FIBROIDS ENLARGED **	1	0.0	3	0.1
UTERINE HEMORRHAGE **	0	0.0	4	0.1
VASCULAR DISORDER	3	0.0	3	0.1
ABNORMAL GAIT	4	0.0	0	0.0
ABSCESS	3	0.0	1	0.0
AMBLYOPIA	1	0.0	0	0.0
ANAL DISORDER	1	0.0	0	0.0
ANAPHYLACTOID REACTION	2	0.0	0	0.0
ANISOCORIA	2	0.0	0	0.0
ANTICHOLINERGIC SYNDROME	1	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
ANTISOCIAL REACTION	2	0.0	0	0.0
APHASIA	1	0.0	0	0.0
APHTHOUS STOMATITIS	2	0.0	0	0.0
APNEA	1	0.0	0	0.0
ASPHYXIA	0	0.0	1	0.0
ASPIRATION PNEUMONIA	1	0.0	0	0.0
ATRIAL FIBRILLATION	1	0.0	0	0.0
AVITAMINOSIS	1	0.0	0	0.0
BLEEDING TIME INCREASED	1	0.0	0	0.0
BLEPHARITIS	3	0.0	2	0.0
BLINDNESS	0	0.0	1	0.0
BLOODY DIARRHEA	1	0.0	0	0.0
BONE PAIN	1	0.0	0	0.0
BRAIN EDEMA	1	0.0	0	0.0
BUCCAL CAVITY DISORDERS	2	0.0	0	0.0
BULIMIA	1	0.0	1	0.0
BUN INCREASED	2	0.0	1	0.0
CACHEXIA	1	0.0	0	0.0
CARCINOMA OF LARYNX	1	0.0	0	0.0
CARDIAC DISORDERS	1	0.0	2	0.0
CARDIOSPASM	1	0.0	0	0.0
CARDIOVASCULAR DISORDER	2	0.0	2	0.0
CATARACT SPECIFIED	1	0.0	2	0.0
CENTRAL NERVOUS SYSTEM DISORDER	1	0.0	0	0.0
CERVICITIS **	1	0.0	1	0.0
CERVIX DISORDER	2	0.0	1	0.0
CHEILITIS	1	0.0	0	0.0
CHEST PAIN SUBSTERNAL	1	0.0	1	0.0
CHILLS AND FEVER	2	0.0	0	0.0
CHOLECYSTITIS	1	0.0	0	0.0
CHOLELITHIASIS	0	0.0	1	0.0
CHOREOATHETOSIS	1	0.0	0	0.0
CHRONIC LYMPHOCYTIC LEUKEMIA	1	0.0	0	0.0
COAGULATION DISORDER	0	0.0	1	0.0
COMA	1	0.0	0	0.0
CONGENITAL ANOMALY	1	0.0	1	0.0
CORNEAL LESION	0	0.0	1	0.0
CORNEAL ULCER	1	0.0	0	0.0
CORONARY ARTERY DISORDER	1	0.0	1	0.0
CORONARY THROMBOSIS	1	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
CREATINE PHOSPHOKINASE INCREASED	0	0.0	1	0.0
CYANOSIS	1	0.0	0	0.0
DELIRIUM	1	0.0	0	0.0
DELUSIONS	1	0.0	0	0.0
DERMATOSES, GENERAL	1	0.0	1	0.0
DUODENAL ULCER HEMORRHAGE	1	0.0	0	0.0
DUODENITIS	1	0.0	0	0.0
DYSARTHRIA	1	0.0	2	0.0
DYSPARUNIA **	1	0.0	0	0.0
ECCHYMOSIS	1	0.0	0	0.0
EMPHYSEMA	1	0.0	0	0.0
ENZYMATIC ABNORMALITY	1	0.0	0	0.0
EPIDIDYMITIS	2	0.0	0	0.0
ERYTHEMA MULTIFORME	1	0.0	0	0.0
ERYTHROCYTES ABNORMAL	0	0.0	1	0.0
EXFOLIATIVE DERMATITIS	4	0.0	1	0.0
FECAL INCONTINENCE	3	0.0	1	0.0
FEMALE BREAST DISORDERS **	1	0.0	0	0.0
FEMALE LACTATION **	1	0.0	0	0.0
FERTILITY DECREASED FEMALE **	2	0.0	0	0.0
FIBROCYSTIC BREAST **	1	0.0	1	0.0
GASTROINTESTINAL FLU	4	0.0	1	0.0
GASTROINTESTINAL HEMORRHAGE	1	0.0	1	0.0
GENERALIZED SPASM	3	0.0	0	0.0
GLAUCOMA	2	0.0	1	0.0
GLOMERULITIS	0	0.0	1	0.0
GOITER	2	0.0	2	0.0
GUM HEMORRHAGE	1	0.0	0	0.0
GUM HYPERPLASIA	1	0.0	0	0.0
HEARING DISORDERS	1	0.0	0	0.0
HEART FAILURE	4	0.0	0	0.0
HEMATEMESIS	2	0.0	2	0.0
HEMORRHAGE	1	0.0	0	0.0
HEPATITIS	2	0.0	0	0.0
HEPATOSPLENOMEGALY	1	0.0	0	0.0
HERNIA	2	0.0	0	0.0
HICCUP	4	0.0	1	0.0
HIRSUTISM	1	0.0	1	0.0
HYPALGESIA	1	0.0	0	0.0
HYPERACUSIS	2	0.0	0	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
HYPERALGESIA	1	0.0	0	0.0
HYPERKALEMIA	4	0.0	0	0.0
HYPERNATREMIA	1	0.0	1	0.0
HYPERPHOSPHATEMIA	1	0.0	0	0.0
HYPERURICEMIA	1	0.0	0	0.0
HYPOGLYCEMIA	3	0.0	2	0.0
HYPOKALEMIA	2	0.0	2	0.0
HYPONATREMIA	1	0.0	1	0.0
HYPOTHERMIA	1	0.0	0	0.0
HYPOTONIA	0	0.0	1	0.0
HYSTERIA	3	0.0	2	0.0
ILEITIS	1	0.0	0	0.0
INTESTINAL OBSTRUCTION	1	0.0	0	0.0
INTRACRANIAL HYPERTENSION	0	0.0	1	0.0
IRON DISORDERS	1	0.0	0	0.0
JAUNDICE	1	0.0	1	0.0
JOINT DISORDER	1	0.0	0	0.0
KETOSIS	1	0.0	0	0.0
KIDNEY FUNCTION ABNORMAL	1	0.0	0	0.0
KIDNEY PAIN	4	0.0	1	0.0
LACTIC DEHYDROGENASE INCREASED	1	0.0	0	0.0
LEUKOPLAKIA OF MOUTH	1	0.0	0	0.0
LYMPHOCYTOSIS	1	0.0	2	0.0
LYMPHOMA LIKE REACTION	1	0.0	0	0.0
MANIC DEPRESSIVE REACTION	1	0.0	0	0.0
MELANOSIS	0	0.0	1	0.0
MOUTH HAEMORRHAGE	0	0.0	1	0.0
MOUTH ULCERATION	2	0.0	1	0.0
MYOCARDIAL INFARCT	0	0.0	1	0.0
MYOCARDIAL ISCHEMIA	4	0.0	0	0.0
NAUSEA VOMITING AND DIARRHEA	2	0.0	1	0.0
NECK RIGIDITY	1	0.0	2	0.0
NERVOUS SYSTEM DISORDER	1	0.0	0	0.0
NIGHT BLINDNESS	1	0.0	1	0.0
OBESITY	2	0.0	1	0.0
OLIGURIA	2	0.0	0	0.0
OSTEOPOROSIS	1	0.0	0	0.0
OVERDOSE	1	0.0	1	0.0
PALLOR	1	0.0	1	0.0
PANCREATITIS	2	0.0	2	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
PAROSMIA	4	0.0	1	0.0
PELVIC PAIN	0	0.0	1	0.0
PELVIC PAIN *	1	0.0	0	0.0
PENIS DISORDER *	1	0.0	1	0.0
PEPTIC ULCER HEMORRHAGE	1	0.0	0	0.0
PERIODONTAL ABSCESS	0	0.0	2	0.0
PERIPHERAL NEURITIS	2	0.0	0	0.0
PERSONALITY DISORDER	2	0.0	2	0.0
PNEUMOTHORAX	1	0.0	1	0.0
POLYCYTHEMIA	0	0.0	2	0.0
PREGNANCY AND PUERPERAL DISORDERS **	1	0.0	1	0.0
PRIAPISM *	0	0.0	1	0.0
PSYCHOSIS	4	0.0	0	0.0
PSYCHOTIC DEPRESSION	1	0.0	0	0.0
PULMONARY EDEMA	1	0.0	0	0.0
PULMONARY EMBOLUS	0	0.0	1	0.0
PUNCTURE SITE REACTION	1	0.0	0	0.0
PUPILLARY DISORDER	3	0.0	0	0.0
PUSTULAR RASH	4	0.0	0	0.0
REFLEXES DECREASED	1	0.0	1	0.0
REFLEXES INCREASED	2	0.0	0	0.0
RESPIRATORY ALKALOSIS	0	0.0	1	0.0
RESPIRATORY FLU	1	0.0	1	0.0
RETINAL DETACHMENT	0	0.0	1	0.0
RETINAL DISORDER	2	0.0	0	0.0
RHEUMATOID ARTHRITIS	1	0.0	1	0.0
SALIVARY GLAND ENLARGEMENT	1	0.0	0	0.0
SALPINGITIS	3	0.0	1	0.0
SEBORRHEA	2	0.0	1	0.0
SEPSIS	1	0.0	0	0.0
SIALADENITIS	1	0.0	0	0.0
SINUS DISORDER	0	0.0	1	0.0
SKIN CARCINOMA	2	0.0	1	0.0
SKIN DISCOLORATION	4	0.0	2	0.0
SKIN MELANOMA	0	0.0	1	0.0
SKIN ULCER	1	0.0	1	0.0
SPERMATOGENESIS ARREST *	1	0.0	0	0.0
SPUTUM INCREASED	2	0.0	2	0.0
STOMACH ULCER	3	0.0	2	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

EMEA LOQs Table 9.07
Number (%) of Patients with Adverse Events On Therapy by Preferred Term and by Descending Order of Paroxetine Frequency
Adult Placebo Controlled Trials
Randomised Phase

Preferred Term	Paroxetine (N=8481) n	%	Placebo (N=5808) n	%
STRIDOR	2	0.0	0	0.0
SUPRAVENTRICULAR EXTRASYSTOLES	0	0.0	1	0.0
SUPRAVENTRICULAR TACHYCARDIA	2	0.0	0	0.0
SWEAT GLAND DISORDER	2	0.0	0	0.0
SWEATING DECREASED	1	0.0	2	0.0
TASTE LOSS	2	0.0	2	0.0
TENOSYNOVITIS	1	0.0	0	0.0
TETANY	2	0.0	2	0.0
THROMBOCYTHEMIA	1	0.0	1	0.0
THROMBOPHLEBITIS	1	0.0	1	0.0
THROMBOSIS	0	0.0	1	0.0
TONGUE DISCOLORATION	2	0.0	0	0.0
TOOTH MALFORMATION	1	0.0	0	0.0
TORTICOLLIS	3	0.0	0	0.0
TRACHEA DISORDER	1	0.0	2	0.0
TRAUMATIC FRACTURE	3	0.0	2	0.0
TRISMUS	1	0.0	0	0.0
URINARY CASTS	1	0.0	1	0.0
URINARY TRACT DISORDER	2	0.0	1	0.0
URINARY URGENCY	2	0.0	0	0.0
UTERINE NEOPLASM	2	0.0	0	0.0
UTERINE SPASM **	1	0.0	0	0.0
UTERUS DISORDERS **	2	0.0	0	0.0
VAGINA DISORDERS **	1	0.0	1	0.0
VARICOSE VEIN	1	0.0	1	0.0
VASCULAR ANOMALY	1	0.0	2	0.0
VASCULAR HEADACHE	1	0.0	0	0.0
VASOSPASM	0	0.0	1	0.0
VENTRICULAR EXTRASYSTOLES	1	0.0	2	0.0
VITREOUS HUMOR DISORDERS	0	0.0	1	0.0
VOICE ALTERATION	3	0.0	1	0.0

* Percentage calculated from the total number of males
** Percentage calculated from the total number of females

Paroxetine EMEA LOQs

EMEA LOQs Table 9.08
Incidence of Possibly Suicide-Related AEs by Treatment Group, Prior Exposure to Paroxetine and Age Group
Adult Placebo Control Trials
On-Therapy

Pre rand. Paroxetine use	Age Group		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	66/8481 (0.8%)	55/5808 (0.9%)	0.82 (0.57, 1.18)	0.31
	<18 years	n/N (%)	0/5 (0.0%)	0/1 (0.0%)		
	18-29 years	n/N (%)	31/1727 (1.8%)	17/1204 (1.4%)	1.28 (0.7, 2.32)	0.46
	30-39 years	n/N (%)	18/2550 (0.7%)	18/1728 (1.0%)	0.68 (0.35, 1.3)	0.24
	40-49 years	n/N (%)	12/2270 (0.5%)	11/1515 (0.7%)	0.73 (0.32, 1.65)	0.52
	50-59 years	n/N (%)	3/1152 (0.3%)	9/807 (1.1%)	0.23 (0.06, 0.86)	0.03
	60-69 years	n/N (%)	0/530 (0.0%)	0/381 (0.0%)		
	70+ years	n/N (%)	2/247 (0.8%)	0/172 (0.0%)		0.51
No/Unknown	Overall	n/N (%)	66/7694 (0.9%)	51/5057 (1.0%)	0.85 (0.59, 1.23)	0.39
	<18 years	n/N (%)	0/5 (0.0%)	0/1 (0.0%)		
	18-29 years	n/N (%)	31/1591 (1.9%)	17/1080 (1.6%)	1.24 (0.68, 2.26)	0.55
	30-39 years	n/N (%)	18/2358 (0.8%)	17/1532 (1.1%)	0.69 (0.35, 1.33)	0.30
	40-49 years	n/N (%)	12/2046 (0.6%)	11/1300 (0.8%)	0.69 (0.3, 1.57)	0.40
	50-59 years	n/N (%)	3/996 (0.3%)	6/669 (0.9%)	0.33 (0.08, 1.34)	0.17
	60-69 years	n/N (%)	0/472 (0.0%)	0/318 (0.0%)		
	70+ years	n/N (%)	2/226 (0.9%)	0/157 (0.0%)		0.51
Yes	Overall	n/N (%)	0/787 (0.0%)	4/751 (0.5%)		0.06
	18-29 years	n/N (%)	0/136 (0.0%)	0/124 (0.0%)		
	30-39 years	n/N (%)	0/192 (0.0%)	1/196 (0.5%)		1.00
	40-49 years	n/N (%)	0/224 (0.0%)	0/215 (0.0%)		
	50-59 years	n/N (%)	0/156 (0.0%)	3/138 (2.2%)		0.10
	60-69 years	n/N (%)	0/58 (0.0%)	0/63 (0.0%)		
	70+ years	n/N (%)	0/21 (0.0%)	0/15 (0.0%)		

Includes paroxetine and placebo data from multiple arm trials with active controls

EMEA LOQs Table 9.09
Incidence of Possibly Suicide-Related AEs by Treatment Group, Prior Exposure to Paroxetine and Age Group
Adult Active Control Trials
On-Therapy

Pre rand. Paroxetine use	Age Group		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	55/6522 (0.8%)	63/4969 (1.3%)	0.66 (0.46, 0.95)	0.03
	<18 years	n/N (%)	0/4 (0.0%)	0/6 (0.0%)		
	18-29 years	n/N (%)	10/969 (1.0%)	20/779 (2.6%)	0.4 (0.18, 0.85)	0.02
	30-39 years	n/N (%)	13/1544 (0.8%)	10/1146 (0.9%)	0.96 (0.42, 2.21)	1.00
	40-49 years	n/N (%)	12/1647 (0.7%)	13/1182 (1.1%)	0.66 (0.3, 1.45)	0.31
	50-59 years	n/N (%)	9/1038 (0.9%)	14/835 (1.7%)	0.51 (0.22, 1.19)	0.14
	60-69 years	n/N (%)	7/831 (0.8%)	5/626 (0.8%)	1.06 (0.33, 3.34)	1.00
	70+ years	n/N (%)	4/457 (0.9%)	1/390 (0.3%)	3.43 (0.38, 30.83)	0.38
	Unknown	n/N (%)	0/32 (0.0%)	0/5 (0.0%)		
No/Unknown	Overall	n/N (%)	55/6510 (0.8%)	63/4958 (1.3%)	0.66 (0.46, 0.95)	0.03
	<18 years	n/N (%)	0/4 (0.0%)	0/6 (0.0%)		
	18-29 years	n/N (%)	10/969 (1.0%)	20/775 (2.6%)	0.39 (0.18, 0.85)	0.02
	30-39 years	n/N (%)	13/1542 (0.8%)	10/1144 (0.9%)	0.96 (0.42, 2.21)	1.00
	40-49 years	n/N (%)	12/1646 (0.7%)	13/1179 (1.1%)	0.66 (0.3, 1.45)	0.31
	50-59 years	n/N (%)	9/1031 (0.9%)	14/834 (1.7%)	0.52 (0.22, 1.2)	0.14
	60-69 years	n/N (%)	7/829 (0.8%)	5/625 (0.8%)	1.06 (0.33, 3.34)	1.00
	70+ years	n/N (%)	4/457 (0.9%)	1/390 (0.3%)	3.43 (0.38, 30.83)	0.38
	Unknown	n/N (%)	0/32 (0.0%)	0/5 (0.0%)		
Yes	Overall	n/N (%)	0/12 (0.0%)	0/11 (0.0%)		
	18-29 years	n/N (%)		0/4 (0.0%)		
	30-39 years	n/N (%)	0/2 (0.0%)	0/2 (0.0%)		
	40-49 years	n/N (%)	0/1 (0.0%)	0/3 (0.0%)		
	50-59 years	n/N (%)	0/7 (0.0%)	0/1 (0.0%)		
	60-69 years	n/N (%)	0/2 (0.0%)	0/1 (0.0%)		

Includes paroxetine and active control data from multiple arm trials with placebo

Paroxetine EMEA LOQs

EMEA LOQs Table 9.10
Incidence of Possibly Suicide-Related AEs by Treatment Group, Prior Exposure to SSRIs and Age Group
Adult Placebo Control Trials
On-Therapy

Pre rand. SSRI use	Age Group		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	66/8481 (0.8%)	55/5808 (0.9%)	0.82 (0.57, 1.18)	0.31
	<18 years	n/N (%)	0/5 (0.0%)	0/1 (0.0%)		
	18-29 years	n/N (%)	31/1727 (1.8%)	17/1204 (1.4%)	1.28 (0.7, 2.32)	0.46
	30-39 years	n/N (%)	18/2550 (0.7%)	18/1728 (1.0%)	0.68 (0.35, 1.3)	0.24
	40-49 years	n/N (%)	12/2270 (0.5%)	11/1515 (0.7%)	0.73 (0.32, 1.65)	0.52
	50-59 years	n/N (%)	3/1152 (0.3%)	9/807 (1.1%)	0.23 (0.06, 0.86)	0.03
	60-69 years	n/N (%)	0/530 (0.0%)	0/381 (0.0%)		
	70+ years	n/N (%)	2/247 (0.8%)	0/172 (0.0%)		0.51
No/Unknown	Overall	n/N (%)	60/7134 (0.8%)	50/4652 (1.1%)	0.78 (0.54, 1.14)	0.20
	<18 years	n/N (%)	0/5 (0.0%)	0/1 (0.0%)		
	18-29 years	n/N (%)	26/1494 (1.7%)	17/1010 (1.7%)	1.03 (0.56, 1.92)	1.00
	30-39 years	n/N (%)	18/2214 (0.8%)	16/1423 (1.1%)	0.72 (0.37, 1.42)	0.38
	40-49 years	n/N (%)	12/1895 (0.6%)	11/1190 (0.9%)	0.68 (0.3, 1.55)	0.39
	50-59 years	n/N (%)	3/906 (0.3%)	6/598 (1.0%)	0.33 (0.08, 1.32)	0.17
	60-69 years	n/N (%)	0/428 (0.0%)	0/289 (0.0%)		
	70+ years	n/N (%)	1/192 (0.5%)	0/141 (0.0%)		1.00
Yes	Overall	n/N (%)	6/1347 (0.4%)	5/1156 (0.4%)	1.03 (0.31, 3.38)	1.00
	18-29 years	n/N (%)	5/233 (2.1%)	0/194 (0.0%)		0.07
	30-39 years	n/N (%)	0/336 (0.0%)	2/305 (0.7%)		0.23
	40-49 years	n/N (%)	0/375 (0.0%)	0/325 (0.0%)		
	50-59 years	n/N (%)	0/246 (0.0%)	3/209 (1.4%)		0.10
	60-69 years	n/N (%)	0/102 (0.0%)	0/92 (0.0%)		
	70+ years	n/N (%)	1/55 (1.8%)	0/31 (0.0%)		1.00

Includes paroxetine and placebo data from multiple arm trials with active controls

Paroxetine EMEA LOQs

EMEA LOQs Table 9.11
Incidence of Possibly Suicide-Related AEs by Treatment Group, Prior Exposure to SSRIs and Age Group
Adult Active Control Trials
On-Therapy

Pre rand. SSRI use	Age Group		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	Overall	n/N (%)	55/6522 (0.8%)	63/4969 (1.3%)	0.66 (0.46, 0.95)	0.03
	<18 years	n/N (%)	0/4 (0.0%)	0/6 (0.0%)		
	18-29 years	n/N (%)	10/969 (1.0%)	20/779 (2.6%)	0.4 (0.18, 0.85)	0.02
	30-39 years	n/N (%)	13/1544 (0.8%)	10/1146 (0.9%)	0.96 (0.42, 2.21)	1.00
	40-49 years	n/N (%)	12/1647 (0.7%)	13/1182 (1.1%)	0.66 (0.3, 1.45)	0.31
	50-59 years	n/N (%)	9/1038 (0.9%)	14/835 (1.7%)	0.51 (0.22, 1.19)	0.14
	60-69 years	n/N (%)	7/831 (0.8%)	5/626 (0.8%)	1.06 (0.33, 3.34)	1.00
	70+ years	n/N (%)	4/457 (0.9%)	1/390 (0.3%)	3.43 (0.38, 30.83)	0.38
	Unknown	n/N (%)	0/32 (0.0%)	0/5 (0.0%)		
No/Unknown	Overall	n/N (%)	55/6438 (0.9%)	63/4898 (1.3%)	0.66 (0.46, 0.95)	0.03
	<18 years	n/N (%)	0/4 (0.0%)	0/6 (0.0%)		
	18-29 years	n/N (%)	10/955 (1.0%)	20/768 (2.6%)	0.4 (0.18, 0.85)	0.02
	30-39 years	n/N (%)	13/1528 (0.9%)	10/1129 (0.9%)	0.96 (0.42, 2.2)	1.00
	40-49 years	n/N (%)	12/1622 (0.7%)	13/1157 (1.1%)	0.66 (0.3, 1.44)	0.31
	50-59 years	n/N (%)	9/1020 (0.9%)	14/825 (1.7%)	0.52 (0.22, 1.2)	0.14
	60-69 years	n/N (%)	7/823 (0.9%)	5/622 (0.8%)	1.06 (0.33, 3.35)	1.00
	70+ years	n/N (%)	4/454 (0.9%)	1/386 (0.3%)	3.42 (0.38, 30.72)	0.38
	Unknown	n/N (%)	0/32 (0.0%)	0/5 (0.0%)		
Yes	Overall	n/N (%)	0/84 (0.0%)	0/71 (0.0%)		
	18-29 years	n/N (%)	0/14 (0.0%)	0/11 (0.0%)		
	30-39 years	n/N (%)	0/16 (0.0%)	0/17 (0.0%)		
	40-49 years	n/N (%)	0/25 (0.0%)	0/25 (0.0%)		
	50-59 years	n/N (%)	0/18 (0.0%)	0/10 (0.0%)		
	60-69 years	n/N (%)	0/8 (0.0%)	0/4 (0.0%)		
	70+ years	n/N (%)	0/3 (0.0%)	0/4 (0.0%)		

Includes paroxetine and active control data from multiple arm trials with placebo

Appendix 1: Analysis of risk factors for possibly suicide related events, self-harm and hostility

14:55 Monday, January 12, 2004 52

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.03	0.01	0.08	<0.001
Age		1	0.97	0.95	0.99	0.008
Treatment	Paroxetine	1	1.71	0.50	5.80	0.391
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.98	0.95	1.01	0.219
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 53

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Gender	Female		1	1.11	0.64	1.92	0.716
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.90	0.50	1.62	0.726
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.86	0.41	1.81	0.691
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 54

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Race	Other		1	0.15	0.02	1.09	0.061
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.76	0.53	1.10	0.149
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	5.27	0.61	45.31	0.130
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 55

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Disease Severity	Mild to Moderate		1	0.64	0.36	1.15	0.139
	Normal/Missing		1	1.09	0.50	2.37	0.835
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.80	0.45	1.42	0.452
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	1.13	0.52	2.46	0.753
		Normal/Missing	1	0.82	0.25	2.67	0.739
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 56

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Indication	Depression		1	5.19	2.82	9.54	<0.001
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.42	0.17	0.99	0.048
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	2.10	0.80	5.48	0.129
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 57

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
CR vs IR	CR/CRIR		1	0.09	0.02	0.36	<0.001
	IR		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.74	0.50	1.07	0.112
	Placebo		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Paroxetine	CR/CRIR	1	4.45	0.93	21.27	0.062
		IR	0	1.00	1.00	1.00	.
	Placebo	CR/CRIR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 58

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Medical History

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.06	0.02	0.27	<0.001
Medical History	No		1	0.14	0.03	0.62	0.009
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.94	0.12	7.08	0.952
	Placebo		0	1.00	1.00	1.00	.
Treatment x Medical History	Paroxetine	No	1	0.88	0.11	6.84	0.901
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 59

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.03	<0.001
Prior Psychotropic Medication	No		1	0.29	0.17	0.49	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.73	0.44	1.23	0.239
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	1.36	0.66	2.81	0.406
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 60

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.08	0.05	0.12	<0.001
Baseline Suicidal Ideation	No		1	0.08	0.05	0.14	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.45	0.23	0.89	0.021
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	2.29	1.02	5.14	0.044
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 61

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Baseline Agitation	No		1	0.85	0.36	1.98	0.700
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.58	0.19	1.81	0.349
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Paroxetine	No	1	1.47	0.44	4.86	0.531
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 62

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.06	<0.001
On-therapy AE of Agitation	No		1	1.07	0.15	7.82	0.945
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.42	0.13	15.83	0.777
	Placebo		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of Agitation	Paroxetine	No	1	0.57	0.05	6.55	0.653
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 63

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.10	<0.001
On-therapy AE of Hyperkinesia	No	1	0.73	0.10	5.28	0.754
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.82	0.57	1.17	0.277
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 64

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
Treatment	Paroxetine	1	0.82	0.57	1.18	0.280
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 65

Possibly Suicide Related Events, Adult Placebo Controlled Studies, Covariate = Early Emergent Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Early Emergent Agitation	No	1	2.54	0.63	10.32	0.191
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.82	0.57	1.17	0.276
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 123

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Age		1	1.00	0.98	1.01	0.705
Treatment	Comparator	1	3.83	1.22	12.01	0.021
	Paroxetine	0	1.00	1.00	1.00	.
Treatment x Age	Comparator	1	0.98	0.95	1.00	0.091
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 124

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Gender	Female		1	1.63	0.87	3.04	0.127
	Male/Missing		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.83	1.46	5.48	0.002
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Gender	Comparator	Female	1	0.39	0.17	0.87	0.021
		Male/Missing	0	1.00	1.00	1.00	.
	Paroxetine	Female	0	1.00	1.00	1.00	.
		Male/Missing	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 125

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Race	Other		1	1.24	0.72	2.12	0.436
	White		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.61	1.03	2.51	0.038
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Race	Comparator	Other	1	0.90	0.40	2.00	0.790
		White	0	1.00	1.00	1.00	.
	Paroxetine	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 126

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Disease Severity	Mild to Moderate		1	0.36	0.16	0.77	0.009
	Normal/Missing		1	0.74	0.41	1.33	0.313
	Severe		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.45	0.84	2.50	0.178
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Comparator	Mild to Moderate	1	1.58	0.60	4.11	0.352
		Normal/Missing	1	0.78	0.32	1.90	0.584
		Severe	0	1.00	1.00	1.00	.
	Paroxetine	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 127

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Indication	Depression		1	4.34	0.60	31.43	0.146
	Other		0	1.00	1.00	1.00	.
Treatment	Comparator		1	5.12	0.57	45.97	0.145
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Indication	Comparator	Depression	1	0.28	0.03	2.62	0.265
		Other	0	1.00	1.00	1.00	.
	Paroxetine	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 128

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
CR vs IR	CR		1	0.59	0.08	4.30	0.605
	IR		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.48	1.02	2.14	0.037
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Comparator	CR	1	1.96	0.20	19.53	0.568
		IR	0	1.00	1.00	1.00	.
	Paroxetine	CR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 129

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Medical History
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
Treatment	Comparator	1	1.51	1.05	2.17	0.026
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 130

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Prior Psychotropic Medication	No		1	0.65	0.36	1.15	0.140
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.69	0.91	3.14	0.098
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Comparator	No	1	0.82	0.38	1.76	0.602
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 131

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Control Medication Class

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Control Medication Class	Other/Benzodiazepine		1	0.80	0.41	1.56	0.513
	SSRI		1	1.33	0.69	2.55	0.394
	Tetracyclic		1	0.43	0.10	1.81	0.250
	Tricyclic		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.32	0.79	2.23	0.291
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Control Medication Class	Comparator	Other/Benzodiazepine	1	0.67	0.17	2.62	0.565
		SSRI	1	1.29	0.55	2.99	0.558
		Tetracyclic	1	1.54	0.26	9.15	0.633
		Tricyclic	0	1.00	1.00	1.00	.
	Paroxetine	Other/Benzodiazepine	0	1.00	1.00	1.00	.
		SSRI	0	1.00	1.00	1.00	.
		Tetracyclic	0	1.00	1.00	1.00	.
		Tricyclic	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 132

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.03	<0.001
Baseline Suicidal Ideation	No		1	0.37	0.20	0.68	0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.36	0.65	2.85	0.411
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Comparator	No	1	1.14	0.49	2.66	0.765
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 133

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Baseline Agitation	No		1	0.77	0.44	1.34	0.351
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.16	0.60	2.24	0.654
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Comparator	No	1	1.46	0.66	3.21	0.350
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 134

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.04	0.02	0.08	<0.001
On-therapy AE of Agitation	No		1	0.21	0.09	0.49	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.76	0.21	2.75	0.677
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of Agitation	Comparator	No	1	2.09	0.55	8.00	0.280
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 135

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hyperkinesia

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.19	<0.001
On-therapy AE of Hyperkinesia	No		1	0.32	0.04	2.37	0.264
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.81	0.24	32.64	0.408
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of hyperkinesia	Comparator	No	1	0.53	0.04	6.30	0.614
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 136

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hostility
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
Treatment	Comparator	1	1.51	1.05	2.17	0.026
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 137

Possibly Suicide Related Events, Adult Active Controlled Studies, Covariate = Early Emergent Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Early Emergent Agitation	No		1	0.93	0.29	2.99	0.902
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.69	0.11	4.17	0.688
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Early emergent agitation	Comparator	No	1	2.27	0.36	14.19	0.382
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 189

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.07	0.001
Age		1	1.19	0.89	1.58	0.237
Treatment	Paroxetine	1	0.23	0.00	54.62	0.596
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	1.17	0.81	1.68	0.408
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 190

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.02	<0.001
Gender	Female		1	6.43	0.77	53.69	0.086
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	3.13	0.32	30.27	0.324
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.61	0.05	7.18	0.696
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 191

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Race	Other		1	3.61	0.80	16.37	0.096
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	3.19	1.04	9.74	0.042
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	0.33	0.05	2.20	0.253
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 192

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.05	<0.001
Disease Severity	Mild to Moderate		1	0.46	0.08	2.77	0.397
	Normal/Missing		1	0.97	0.16	5.89	0.975
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	2.90	0.77	10.87	0.114
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	0.41	0.04	3.82	0.435
		Normal/Missing	1	1.06	0.13	8.53	0.959
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 193

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Indication
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Indication	Depression	1	5.61	1.91	16.45	0.002
	Other	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.07	0.86	5.01	0.106
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 194

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Medical History
Note that the covariate and the interaction term have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.02	<0.001
Treatment	Paroxetine	1	2.29	0.95	5.51	0.065
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 195

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Prior Psychotropic Medication
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Prior Psychotropic Medication	No	1	4.80	0.64	35.69	0.126
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.19	0.91	5.28	0.081
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 196

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.10	0.03	0.34	<0.001
Baseline Suicidal Ideation	No		1	0.06	0.01	0.30	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.12	0.26	4.80	0.883
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	2.46	0.39	15.63	0.340
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 197

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.00	0.16	<0.001
Baseline Agitation	No		1	0.44	0.05	3.76	0.456
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	3.52	0.38	32.69	0.268
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Paroxetine	No	1	0.59	0.05	6.68	0.670
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 198

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.02	0.00	0.17	<0.001
On-therapy AE of Agitation	No	1	0.53	0.07	4.11	0.544
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.25	0.93	5.44	0.071
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 199

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.02	<0.001
Treatment	Paroxetine	1	2.29	0.95	5.51	0.065
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 200

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.02	0.00	0.14	<0.001
On-therapy AE of Hostility	No	1	0.67	0.09	5.20	0.704
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.25	0.93	5.45	0.072
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

14:55 Monday, January 12, 2004 201

Possibly Suicide Related Events, Paediatric Placebo Controlled Studies, Covariate = Early Emergent Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.18	<0.001
Early Emergent Agitation	No		1	0.40	0.05	3.40	0.402
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.11	0.07	18.42	0.941
	Placebo		0	1.00	1.00	1.00	.
Treatment x Early emergent agitation	Paroxetine	No	1	2.24	0.12	43.19	0.594
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 53

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.03	0.01	0.10	<0.001
Age		1	0.96	0.93	0.99	0.004
Treatment	Paroxetine	1	2.08	0.49	8.90	0.323
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.98	0.94	1.02	0.249
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 54

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Gender	Female		1	0.97	0.50	1.86	0.926
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.02	0.53	1.96	0.960
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.84	0.36	1.98	0.693
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 55

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.01	<0.001
Race	Other		1	0.22	0.03	1.61	0.136
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.87	0.57	1.34	0.535
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	3.06	0.33	28.65	0.327
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 56

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.01	0.02	<0.001
Disease Severity	Mild to Moderate		1	0.49	0.25	0.98	0.043
	Normal/Missing		1	0.74	0.27	1.99	0.544
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.72	0.38	1.37	0.314
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	1.61	0.65	3.99	0.300
		Normal/Missing	1	1.38	0.34	5.61	0.653
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 57

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Indication	Depression		1	11.67	4.55	29.95	<0.001
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.88	0.27	2.87	0.826
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	0.96	0.27	3.43	0.952
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 58

Self Harm Events, Adult Placebo Controlled Studies, Covariate = CR vs IR
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.01	0.01	<0.001
CR vs IR	CR/CRIR	1	0.22	0.11	0.46	<0.001
	IR	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.93	0.61	1.42	0.745
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 59

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Medical History

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.23	<0.001
Medical History	No		1	0.21	0.03	1.55	0.125
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.94	0.17	22.46	0.596
	Placebo		0	1.00	1.00	1.00	.
Treatment x Medical History	Paroxetine	No	1	0.47	0.04	5.61	0.548
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 60

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.03	<0.001
Prior Psychotropic Medication	No		1	0.18	0.09	0.35	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.72	0.41	1.28	0.263
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	1.96	0.82	4.68	0.131
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 61

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.07	0.04	0.11	<0.001
Baseline Suicidal Ideation	No		1	0.06	0.03	0.11	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.39	0.18	0.83	0.015
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	3.57	1.40	9.09	0.008
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 62

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Baseline Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Baseline Agitation	No	1	10.21	1.42	73.35	0.021
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.93	0.61	1.42	0.749
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 63

Self Harm Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.03	<0.001
On-therapy AE of Agitation	No	1	0.85	0.21	3.46	0.817
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.92	0.60	1.40	0.693
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 64

Self Harm Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.09	<0.001
On-therapy AE of Hyperkinesia	No	1	0.54	0.07	3.94	0.545
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.92	0.60	1.40	0.683
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 65

Self Harm Events, Adult Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.01	<0.001
Treatment	Paroxetine	1	0.92	0.60	1.40	0.693
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 66

Self Harm Events, Adult Placebo Controlled Studies, Covariate = Early Emergent Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Early Emergent Agitation	No	1	1.85	0.45	7.54	0.390
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	0.92	0.60	1.40	0.688
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 126

Self Harm Events, Adult Active Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Age		1	1.00	0.98	1.02	0.984
Treatment	Comparator	1	5.08	1.04	24.81	0.045
	Paroxetine	0	1.00	1.00	1.00	.
Treatment x Age	Comparator	1	0.97	0.94	1.01	0.102
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 127

Self Harm Events, Adult Active Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Gender	Female		1	4.37	1.32	14.44	0.016
	Male/Missing		0	1.00	1.00	1.00	.
Treatment	Comparator		1	5.66	1.61	19.91	0.007
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Gender	Comparator	Female	1	0.17	0.04	0.68	0.013
		Male/Missing	0	1.00	1.00	1.00	.
	Paroxetine	Female	0	1.00	1.00	1.00	.
		Male/Missing	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 128

Self Harm Events, Adult Active Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Race	Other		1	0.65	0.29	1.48	0.308
	White		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.14	0.63	2.07	0.657
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Race	Comparator	Other	1	2.33	0.76	7.17	0.141
		White	0	1.00	1.00	1.00	.
	Paroxetine	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 129

Self Harm Events, Adult Active Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Disease Severity	Mild to Moderate		1	0.18	0.05	0.63	0.007
	Normal/Missing		1	0.54	0.25	1.19	0.126
	Severe		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.29	0.65	2.57	0.470
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Comparator	Mild to Moderate	1	1.59	0.34	7.49	0.556
		Normal/Missing	1	1.23	0.39	3.85	0.725
		Severe	0	1.00	1.00	1.00	.
	Paroxetine	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 130

Self Harm Events, Adult Active Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Indication	Depression		1	2.24	0.30	16.50	0.429
	Other		0	1.00	1.00	1.00	.
Treatment	Comparator		1	3.83	0.40	36.95	0.246
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Indication	Comparator	Depression	1	0.36	0.03	3.65	0.385
		Other	0	1.00	1.00	1.00	.
	Paroxetine	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 131

Self Harm Events, Adult Active Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
CR vs IR	CR		1	1.15	0.16	8.48	0.893
	IR		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.43	0.85	2.39	0.178
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Comparator	CR	1	1.35	0.11	15.83	0.812
		IR	0	1.00	1.00	1.00	.
	Paroxetine	CR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 132

Self Harm Events, Adult Active Controlled Studies, Covariate = Medical History
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Treatment	Comparator	1	1.45	0.88	2.40	0.147
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 133

Self Harm Events, Adult Active Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Prior Psychotropic Medication	No		1	0.76	0.34	1.73	0.517
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.44	1.05	5.67	0.038
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Comparator	No	1	0.40	0.14	1.18	0.096
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 134

Self Harm Events, Adult Active Controlled Studies, Covariate = Control Medication Class

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Control Medication Class	Other/Benzodiazepine		1	0.38	0.13	1.12	0.079
	SSRI		1	0.87	0.34	2.21	0.766
	Tetracyclic		1	0.66	0.15	2.86	0.576
	Tricyclic		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.39	0.74	2.62	0.309
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Control Medication Class	Comparator	Other/Benzodiazepine	1	1.39	0.23	8.51	0.725
		SSRI	1	0.71	0.19	2.60	0.603
		Tetracyclic	1	0.73	0.09	5.76	0.767
		Tricyclic	0	1.00	1.00	1.00	.
	Paroxetine	Other/Benzodiazepine	0	1.00	1.00	1.00	.
		SSRI	0	1.00	1.00	1.00	.
		Tetracyclic	0	1.00	1.00	1.00	.
		Tricyclic	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 135

Self Harm Events, Adult Active Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Baseline Suicidal Ideation	No		1	0.40	0.17	0.93	0.034
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.63	0.60	4.41	0.333
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Comparator	No	1	0.85	0.27	2.68	0.775
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 136

Self Harm Events, Adult Active Controlled Studies, Covariate = Baseline Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.01	<0.001
Baseline Agitation	No		1	0.57	0.27	1.20	0.141
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.65	0.24	1.73	0.385
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Baseline Agitation	Comparator	No	1	3.13	0.98	9.96	0.053
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 137

Self Harm Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.02	0.01	0.07	<0.001
On-therapy AE of Agitation	No		1	0.16	0.06	0.47	<0.001
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.28	0.03	2.56	0.261
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x On-therapy AE of Agitation	Comparator	No	1	5.79	0.60	55.75	0.129
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 138

Self Harm Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.09	<0.001
On-therapy AE of Hyperkinesia	No	1	0.35	0.05	2.58	0.305
	Yes	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.45	0.88	2.40	0.147
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 139

Self Harm Events, Adult Active Controlled Studies, Covariate = On-therapy AE of Hostility
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Treatment	Comparator	1	1.45	0.88	2.40	0.147
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 140

Self Harm Events, Adult Active Controlled Studies, Covariate = Early Emergent Agitation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Early Emergent Agitation	No		1	0.46	0.14	1.54	0.208
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	0.34	0.04	3.33	0.358
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Early Emergent Agitation	Comparator	No	1	4.61	0.45	47.32	0.198
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 192

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.15	0.006
Age		1	1.13	0.82	1.55	0.463
Treatment	Paroxetine	1	0.03	0.00	17.69	0.284
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	1.34	0.88	2.05	0.170
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 193

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Gender
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Gender	Female	1	7.70	1.78	33.39	0.006
	Male	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.38	0.86	6.61	0.096
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 194

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.02	<0.001
Race	Other		1	1.18	0.13	10.69	0.881
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	2.49	0.79	7.87	0.120
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	1.30	0.11	15.68	0.835
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 195

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.05	<0.001
Disease Severity	Mild to Moderate/Normal/ Missing		1	0.31	0.05	1.87	0.202
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.91	0.47	7.72	0.366
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate/Normal/ Missing	1	2.03	0.25	16.24	0.504
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate/Normal/ Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 196

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Indication
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Indication	Depression	1	20.19	2.69	151.42	0.003
	Other	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.35	0.84	6.52	0.103
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 197

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Medical History
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 198

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Prior Psychotropic Medication
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Prior Psychotropic Medication	No	1	3.74	0.50	28.14	0.200
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.56	0.93	7.10	0.070
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 199

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.07	0.02	0.28	<0.001
Baseline Suicidal Ideation	No		1	0.07	0.01	0.46	0.005
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.73	0.33	9.12	0.518
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	1.58	0.19	13.13	0.672
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 200

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.02	0.01	0.08	<0.001
Baseline Agitation	No	1	0.30	0.10	0.92	0.036
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.65	0.96	7.35	0.061
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 201

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Agitation
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 202

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hyperkinesia
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:05 Monday, January 12, 2004 203

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = On-therapy AE of Hostility
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.13	<0.001
On-therapy AE of Hostility	No	1	0.55	0.07	4.29	0.566
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.60	0.93	7.23	0.068
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

Self Harm Events, Paediatric Placebo Controlled Studies, Covariate = Early Emergent Agitation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.06	<0.001
Early Emergent Agitation	No	1	1.07	0.14	8.16	0.945
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	2.66	0.96	7.37	0.059
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 33

Hostility Events, Adult Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.03	<0.001
Age		1	0.98	0.94	1.02	0.386
Treatment	Paroxetine	1	2.21	0.26	18.56	0.465
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.98	0.93	1.03	0.457
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 34

Hostility Events, Adult Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Gender	Female		1	1.39	0.48	4.01	0.540
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.67	0.59	4.74	0.338
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	0.44	0.12	1.68	0.231
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 35

Hostility Events, Adult Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Race	Other		1	1.17	0.27	5.16	0.835
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.93	0.47	1.86	0.843
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	1.79	0.30	10.64	0.522
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 36

Hostility Events, Adult Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Disease Severity	Mild to Moderate		1	0.95	0.31	2.91	0.928
	Normal/Missing		1	1.59	0.38	6.69	0.524
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.82	0.25	2.68	0.739
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate	1	1.57	0.37	6.79	0.543
		Normal/Missing	1	0.81	0.09	6.92	0.844
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 37

Hostility Events, Adult Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Indication	Depression		1	1.36	0.50	3.65	0.545
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.05	0.45	2.47	0.904
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	0.92	0.26	3.30	0.902
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 38

Hostility Events, Adult Placebo Controlled Studies, Covariate = CR vs IR

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
CR vs IR	CR/CRIR		1	0.16	0.02	1.18	0.072
	IR		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.89	0.45	1.74	0.725
	Placebo		0	1.00	1.00	1.00	.
Treatment x CR vs IR	Paroxetine	CR/CRIR	1	3.69	0.39	35.12	0.256
		IR	0	1.00	1.00	1.00	.
	Placebo	CR/CRIR	0	1.00	1.00	1.00	.
		IR	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 39

Hostility Events, Adult Placebo Controlled Studies, Covariate = Medical History
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
Treatment	Paroxetine	1	1.03	0.55	1.94	0.934
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 40

Hostility Events, Adult Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Prior Psychotropic Medication	No		1	2.44	0.55	10.76	0.238
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	1.18	0.20	7.09	0.854
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	0.83	0.12	5.63	0.849
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 41

Hostility Events, Adult Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Baseline Suicidal Ideation	No	1	0.49	0.17	1.37	0.173
	Yes	0	1.00	1.00	1.00	.
Treatment	Paroxetine	1	1.03	0.54	1.93	0.939
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 81

Hostility Events, Adult Active Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.02	<0.001
Age		1	0.99	0.96	1.02	0.424
Treatment	Comparator	1	1.76	0.24	12.89	0.580
	Paroxetine	0	1.00	1.00	1.00	.
Treatment x Age	Comparator	1	1.00	0.95	1.04	0.848
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 82

Hostility Events, Adult Active Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Gender	Female		1	0.50	0.20	1.26	0.142
	Male/Missing		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.16	0.44	3.00	0.767
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Gender	Comparator	Female	1	1.53	0.42	5.53	0.521
		Male/Missing	0	1.00	1.00	1.00	.
	Paroxetine	Female	0	1.00	1.00	1.00	.
		Male/Missing	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 83

Hostility Events, Adult Active Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Race	Other		1	1.09	0.42	2.83	0.852
	White		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.62	0.76	3.45	0.216
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Race	Comparator	Other	1	0.62	0.13	2.95	0.553
		White	0	1.00	1.00	1.00	.
	Paroxetine	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 84

Hostility Events, Adult Active Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Disease Severity	Mild to Moderate		1	2.07	0.64	6.72	0.228
	Normal/Missing		1	0.93	0.25	3.47	0.913
	Severe		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.07	0.27	4.29	0.922
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Comparator	Mild to Moderate	1	1.38	0.27	7.05	0.696
		Normal/Missing	1	1.22	0.17	8.93	0.848
		Severe	0	1.00	1.00	1.00	.
	Paroxetine	Mild to Moderate	0	1.00	1.00	1.00	.
		Normal/Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 85

Hostility Events, Adult Active Controlled Studies, Covariate = Indication
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.01	<0.001
Indication	Depression	1	0.69	0.24	1.95	0.485
	Other	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.46	0.77	2.76	0.246
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 86

Hostility Events, Adult Active Controlled Studies, Covariate = CR vs IR
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
CR vs IR	CR	1	0.72	0.10	5.27	0.746
	IR	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.46	0.77	2.77	0.241
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 87

Hostility Events, Adult Active Controlled Studies, Covariate = Medical History
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
Treatment	Comparator	1	1.46	0.77	2.76	0.245
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 88

Hostility Events, Adult Active Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.01	<0.001
Prior Psychotropic Medication	No		1	2.33	0.54	10.16	0.259
	Yes		0	1.00	1.00	1.00	.
Treatment	Comparator		1	2.86	0.55	14.74	0.210
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Comparator	No	1	0.45	0.08	2.69	0.383
		Yes	0	1.00	1.00	1.00	.
	Paroxetine	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 89

Hostility Events, Adult Active Controlled Studies, Covariate = Control Medication Class

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.00	<0.001
Control Medication Class	Other/Benzodiazepine		1	1.60	0.46	5.55	0.455
	SSRI		1	3.46	1.10	10.92	0.034
	Tetracyclic		1	1.12	0.13	9.61	0.917
	Tricyclic		0	1.00	1.00	1.00	.
Treatment	Comparator		1	1.07	0.31	3.71	0.912
	Paroxetine		0	1.00	1.00	1.00	.
Treatment x Control Medication Class	Comparator	Other/Benzodiazepine	1	2.16	0.32	14.39	0.426
		SSRI	1	1.05	0.21	5.23	0.952
		Tetracyclic	1	3.82	0.31	47.49	0.298
		Tricyclic	0	1.00	1.00	1.00	.
	Paroxetine	Other/Benzodiazepine	0	1.00	1.00	1.00	.
		SSRI	0	1.00	1.00	1.00	.
		Tetracyclic	0	1.00	1.00	1.00	.
		Tricyclic	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

Hostility Events, Adult Active Controlled Studies, Covariate = Baseline Suicidal Ideation
Note that the interaction term has not been included as it did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.00	0.00	0.00	<0.001
Baseline Suicidal Ideation	No	1	4.82	0.66	35.19	0.121
	Yes	0	1.00	1.00	1.00	.
Treatment	Comparator	1	1.47	0.77	2.77	0.240
	Paroxetine	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 122

Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Age

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.78	0.038
Age		1	0.95	0.69	1.31	0.763
Treatment	Paroxetine	1	58.97	0.68	5089.0	0.073
	Placebo	0	1.00	1.00	1.00	.
Treatment x Age	Paroxetine	1	0.83	0.59	1.17	0.287
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 123

Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Gender

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Gender	Female		1	0.35	0.04	3.38	0.363
	Male		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	5.77	1.67	20.00	0.006
	Placebo		0	1.00	1.00	1.00	.
Treatment x Gender	Paroxetine	Female	1	1.47	0.13	16.20	0.753
		Male	0	1.00	1.00	1.00	.
	Placebo	Female	0	1.00	1.00	1.00	.
		Male	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 124

Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Race

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.00	0.00	0.02	<0.001
Race	Other		1	4.79	0.67	34.39	0.119
	White		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	11.16	2.62	47.45	0.001
	Placebo		0	1.00	1.00	1.00	.
Treatment x Race	Paroxetine	Other	1	0.11	0.01	1.09	0.059
		White	0	1.00	1.00	1.00	.
	Placebo	Other	0	1.00	1.00	1.00	.
		White	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 125

Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Disease Severity

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.05	<0.001
Disease Severity	Mild to Moderate/Normal/ Missing		1	0.15	0.02	1.50	0.107
	Severe		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	2.90	0.77	10.87	0.114
	Placebo		0	1.00	1.00	1.00	.
Treatment x Disease Severity	Paroxetine	Mild to Moderate/Normal/ Missing	1	5.45	0.49	60.76	0.168
		Severe	0	1.00	1.00	1.00	.
	Placebo	Mild to Moderate/Normal/ Missing	0	1.00	1.00	1.00	.
		Severe	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 126

Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Indication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.03	<0.001
Indication	Depression		1	0.42	0.04	4.07	0.455
	Other		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	7.04	2.07	23.90	0.002
	Placebo		0	1.00	1.00	1.00	.
Treatment x Indication	Paroxetine	Depression	1	0.76	0.07	8.65	0.826
		Other	0	1.00	1.00	1.00	.
	Placebo	Depression	0	1.00	1.00	1.00	.
		Other	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 127

Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Medical History
Note that the covariate and the interaction terms have not been included as they did not converge

Parameter	Level 1	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept		1	0.01	0.00	0.02	<0.001
Treatment	Paroxetine	1	6.10	2.12	17.54	<0.001
	Placebo	0	1.00	1.00	1.00	.
Scale		0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 128

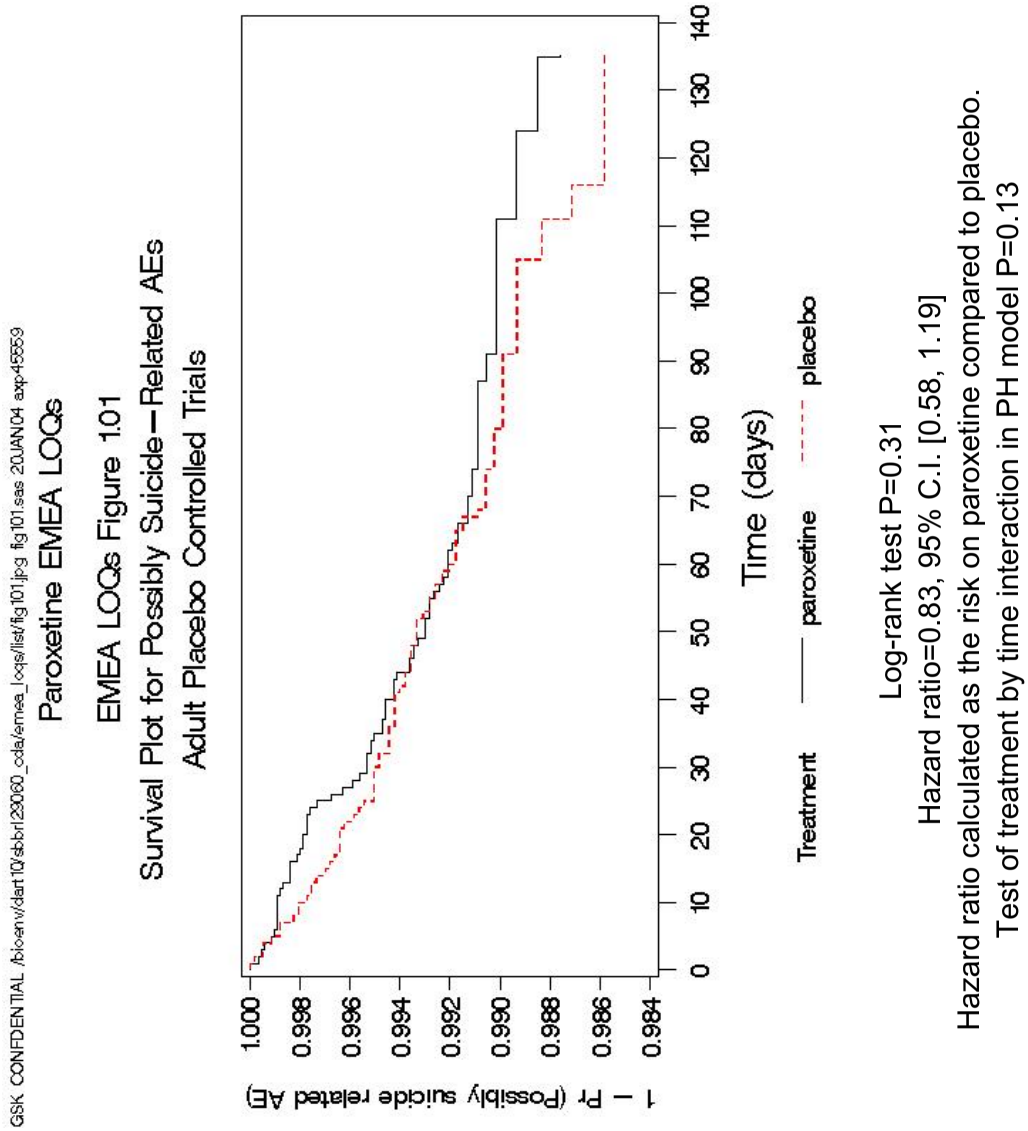
Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Prior Psychotropic Medication

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.01	0.00	0.06	<0.001
Prior Psychotropic Medication	No		1	0.74	0.08	7.16	0.794
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	4.75	0.52	43.12	0.166
	Placebo		0	1.00	1.00	1.00	.
Treatment x Prior Psychotropic Medication	Paroxetine	No	1	1.38	0.11	17.07	0.802
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_

16:42 Monday, January 12, 2004 129

Hostility Events, Paediatric Placebo Controlled Studies, Covariate = Baseline Suicidal Ideation

Parameter	Level 1	Level 2	Degrees of Freedom	Odds Ratio	Lower CI	Upper CI	P-value
Intercept			1	0.03	0.00	0.24	<0.001
Baseline Suicidal Ideation	No		1	0.15	0.02	1.50	0.107
	Yes		0	1.00	1.00	1.00	.
Treatment	Paroxetine		1	0.54	0.03	9.00	0.671
	Placebo		0	1.00	1.00	1.00	.
Treatment x Baseline Suicidal Ideation	Paroxetine	No	1	14.91	0.70	315.51	0.083
		Yes	0	1.00	1.00	1.00	.
	Placebo	No	0	1.00	1.00	1.00	.
		Yes	0	1.00	1.00	1.00	.
Scale			0	2.72	2.72	2.72	_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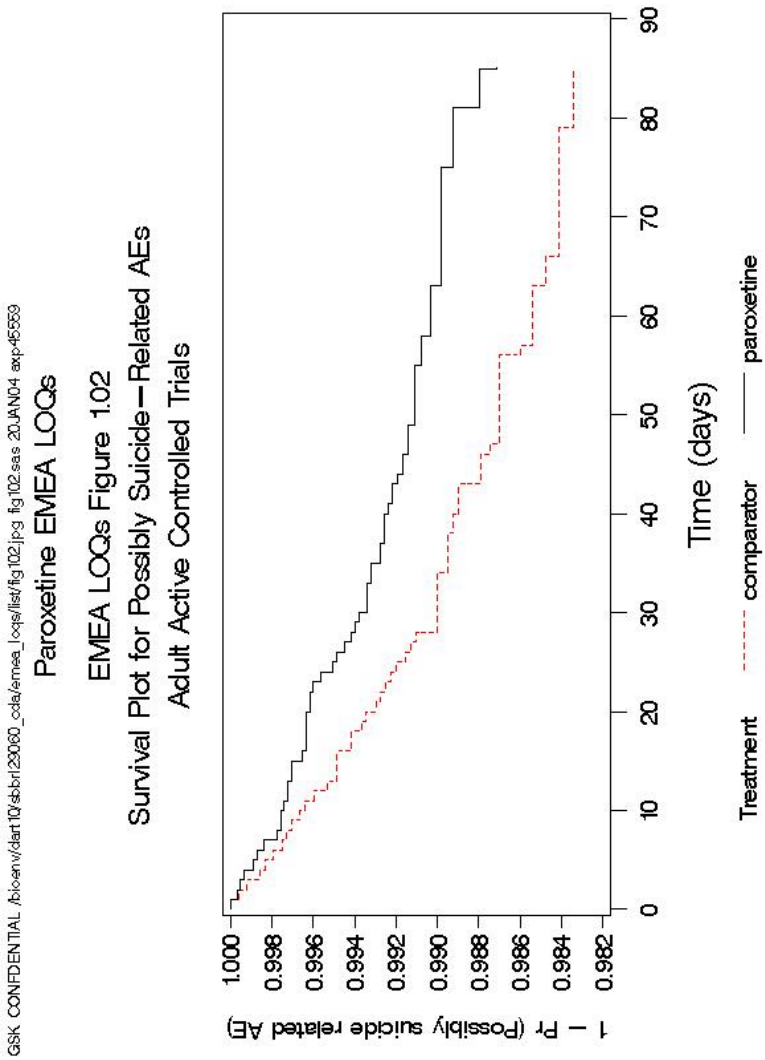
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.01
Survival Plot for Possibly Suicide−Related AEs
Adult Placebo Controlled Trials
1 − Pr (Possibly suicide related AE)
1.000
0.998
0.996
0.994
0.992
0.990
0.988
0.986
0.984
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
Time (days)
Treatment
paroxetine
placebo
Log-rank test P=0.31
Hazard ratio=0.83, 95% C.I. [0.58, 1.19]
Hazard ratio calculated as the risk on paroxetine compared to placebo.
Test of treatment by time interaction in PH model P=0.13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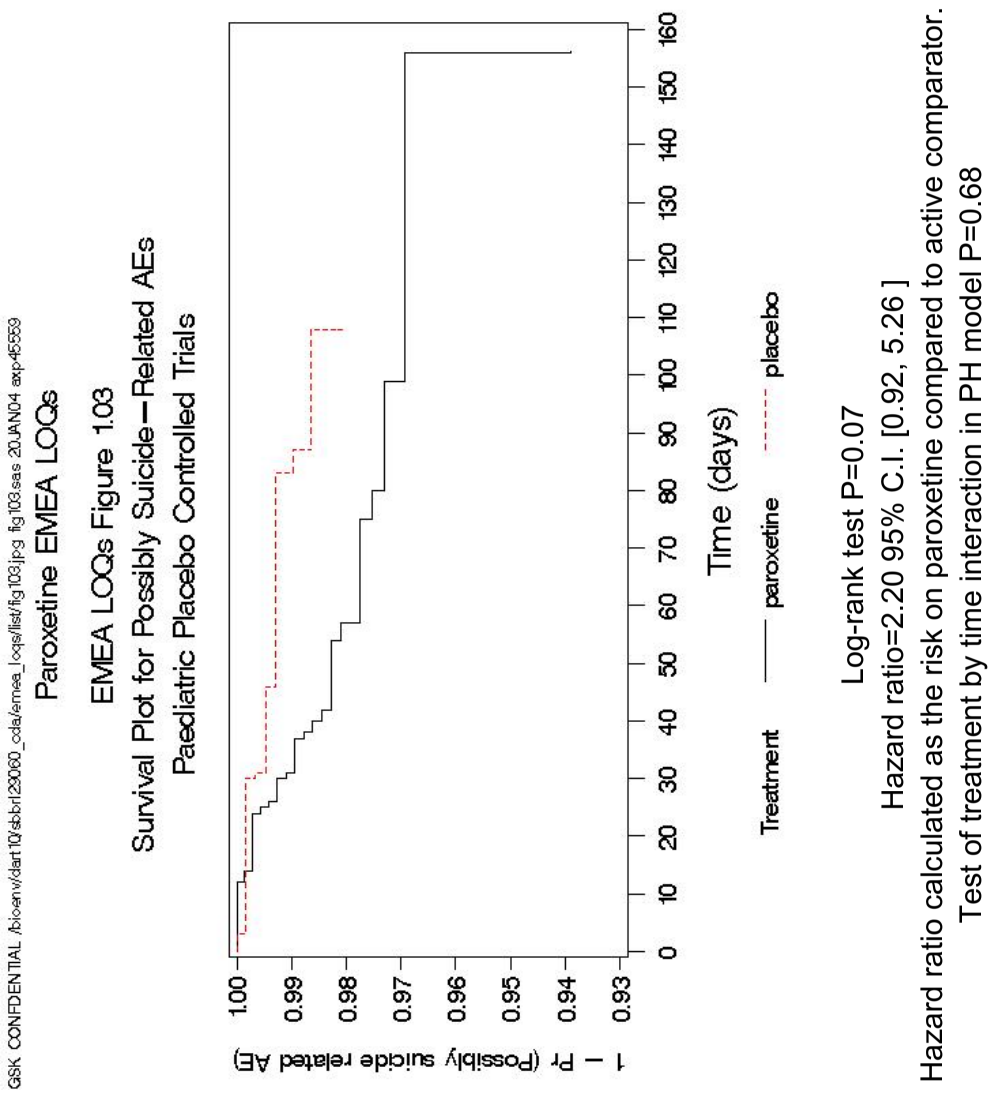
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.02
Survival Plot for Possibly Suicide–Related AEs
Adult Active Controlled Trials
1 – Pr (Possibly suicide related AE)
1.000
0.998
0.996
0.994
0.992
0.990
0.988
0.986
0.984
0.982
0
10
20
30
40
50
60
70
80
90
Time (days)
Treatment
comparator
paroxetine
Log-rank test P=0.022
Hazard ratio=0.66 95% C.I. [0.46, 0.94]
Hazard ratio calculated as the risk on paroxetine compared to active comparator.
Test of treatment by time interaction in PH model P=0.33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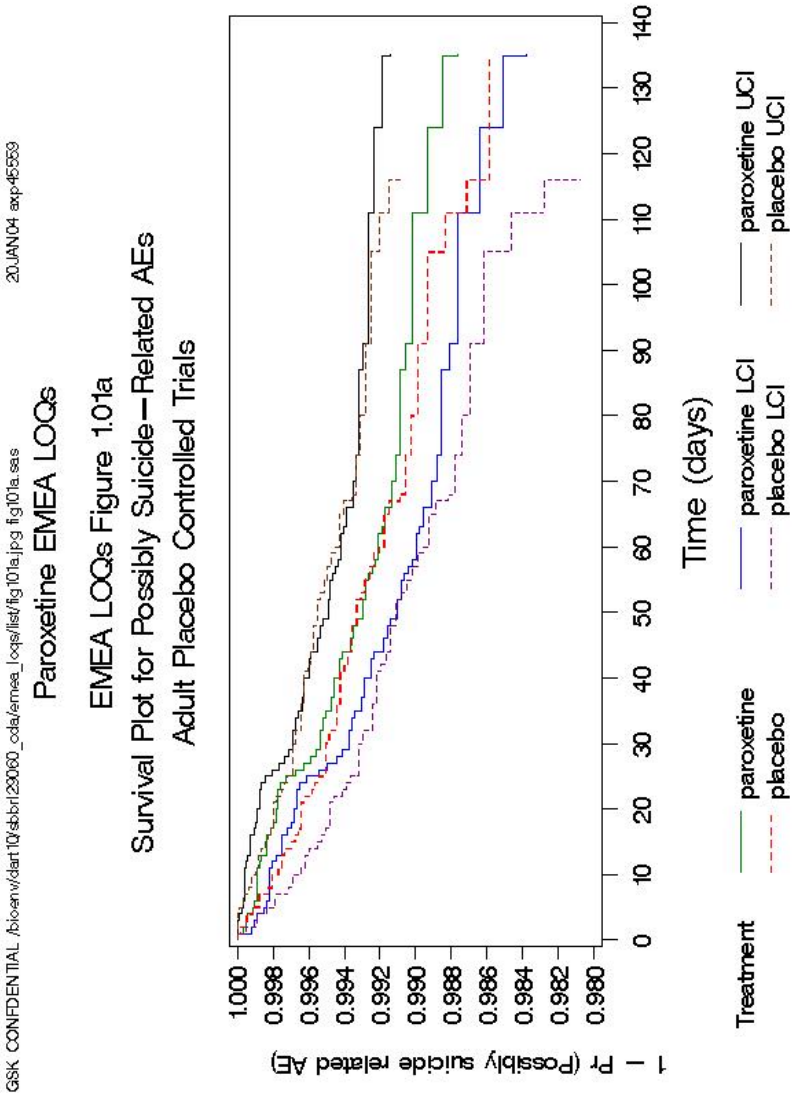
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.03
Survival Plot for Possibly Suicide–Related AEs
Paediatric Placebo Controlled Trials
1 – Pr (Possibly suicide related AE)
1.00
0.99
0.98
0.97
0.96
0.95
0.94
0.93
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
150
160
Time (days)
Treatment
paroxetine
placebo
Log-rank test P=0.07
Hazard ratio=2.20 95% C.I. [0.92, 5.26]
Hazard ratio calculated as the risk on paroxetine compared to active comparator.
Test of treatment by time interaction in PH model P=0.68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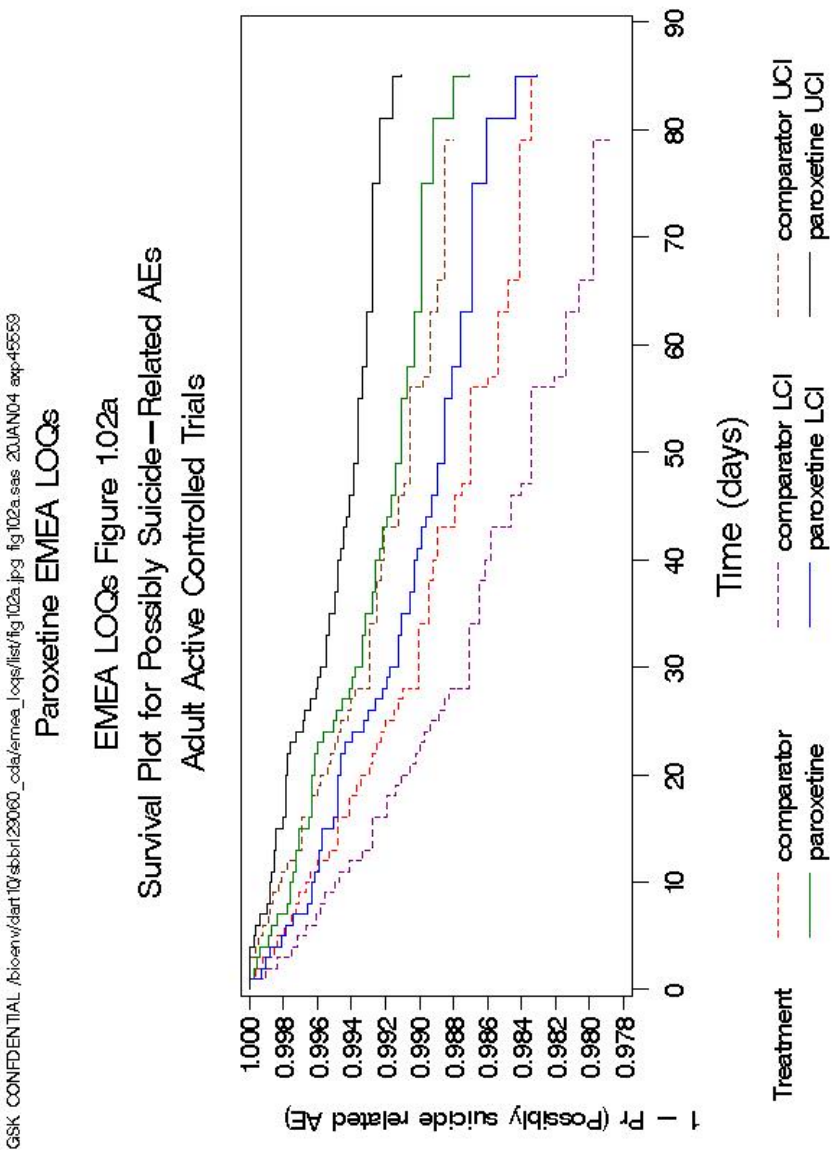
20JAN04 axp45559
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.01a
Survival Plot for Possibly Suicide–Related AEs
Adult Placebo Controlled Trials
1 – Pr (Possibly suicide related AE)
1.000
0.998
0.996
0.994
0.992
0.990
0.988
0.986
0.984
0.982
0.980
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
Time (days)
Treatment
paroxetine
placebo
paroxetine LCI
placebo LCI
paroxetine UCI
placebo UCI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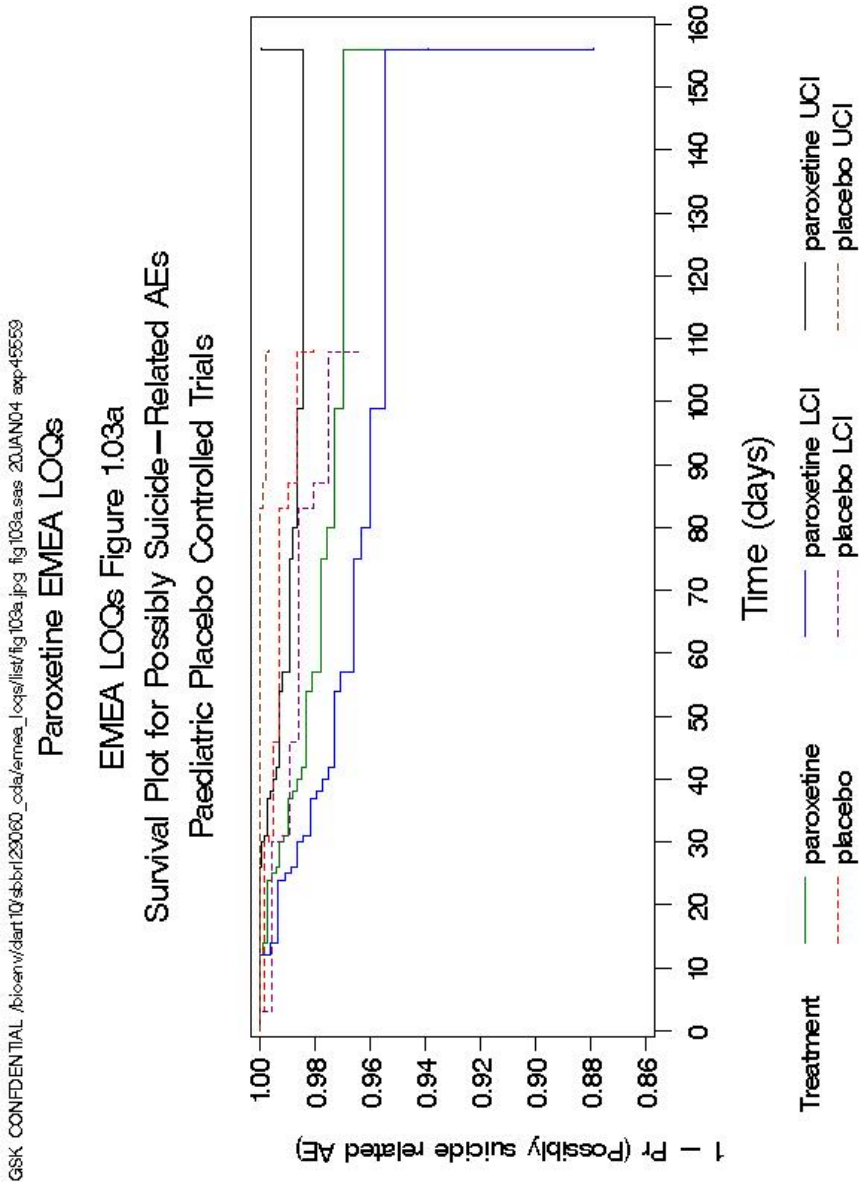
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.02a
Survival Plot for Possibly Suicide–Related AEs
Adult Active Controlled Trials
1 – Pr (Possibly suicide related AE)
1.000
0.998
0.996
0.994
0.992
0.990
0.988
0.986
0.984
0.982
0.980
0.978
0
10
20
30
40
50
60
70
80
90
Time (days)
Treatment
comparator
paroxetine
comparator LCI
paroxetine LCI
comparator UCI
paroxetine UCI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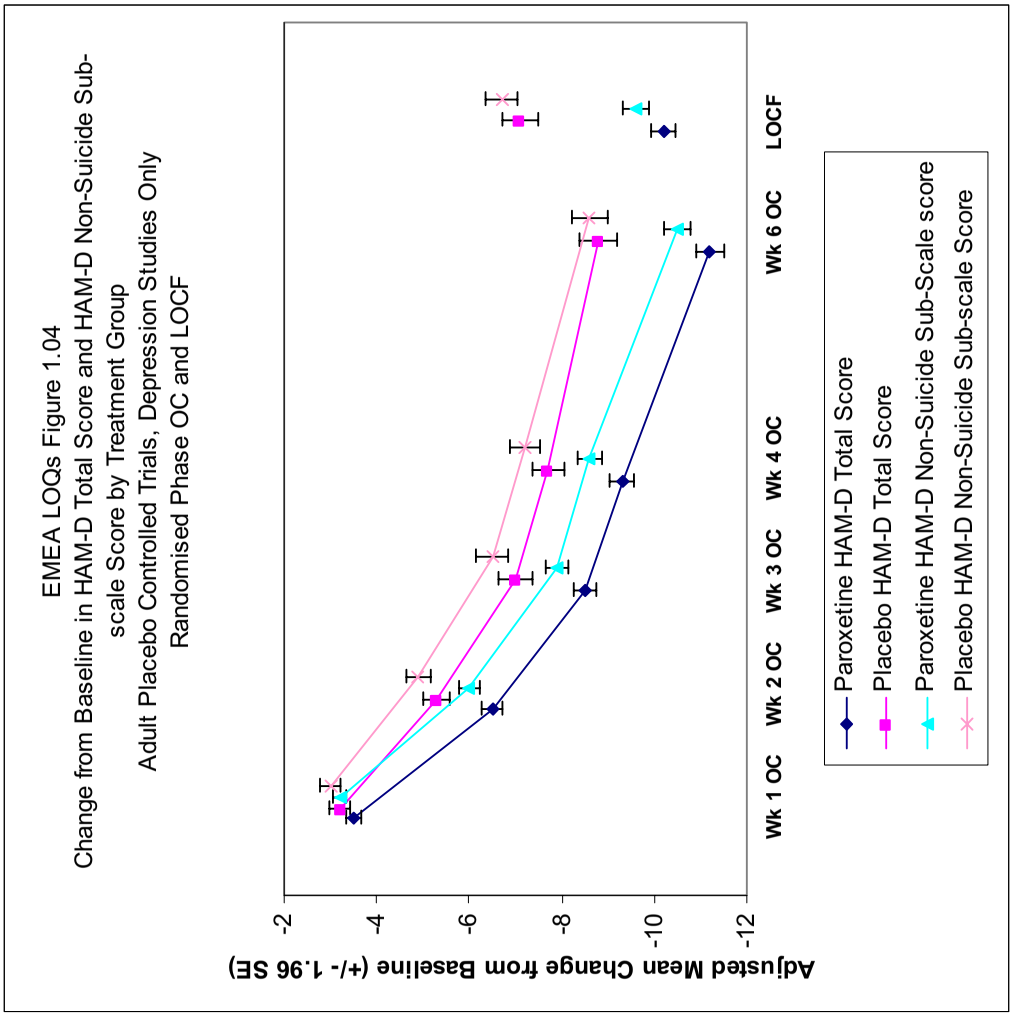
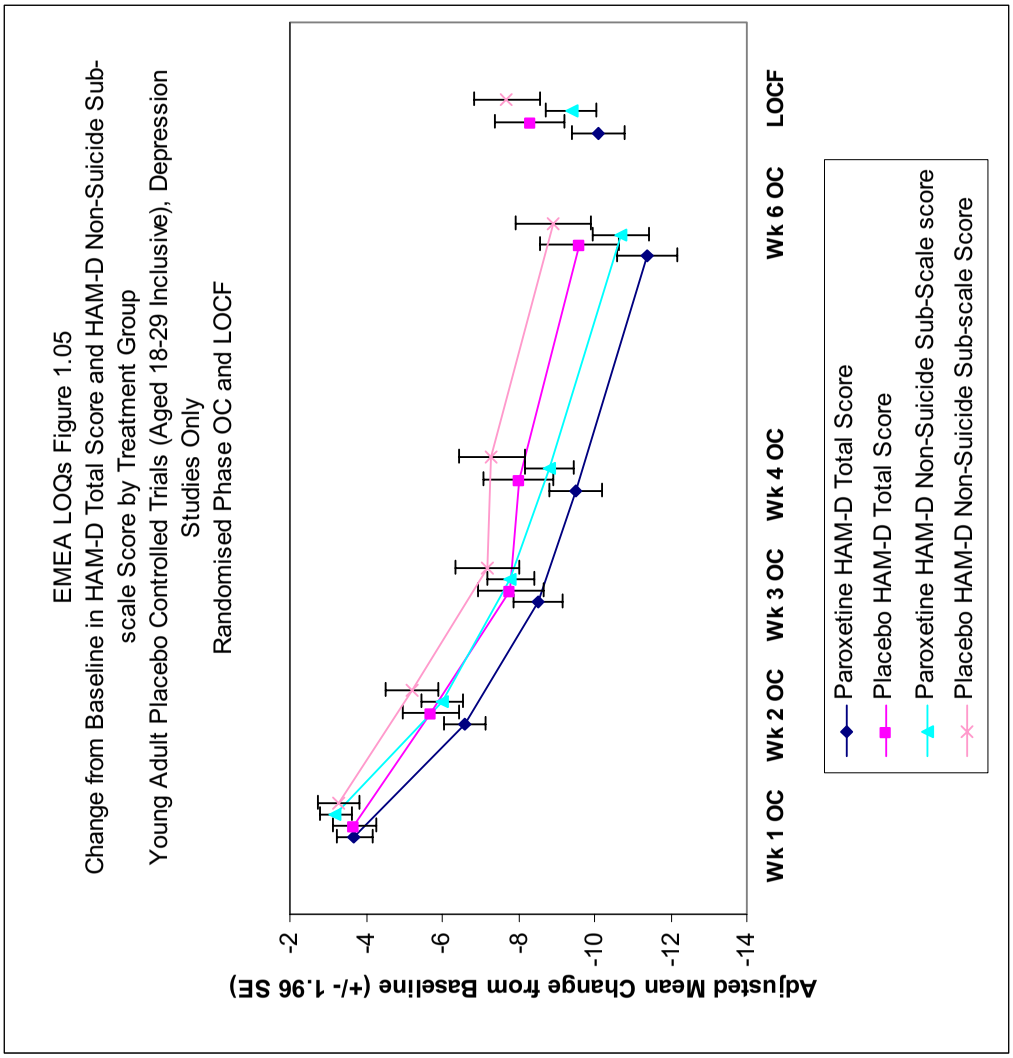
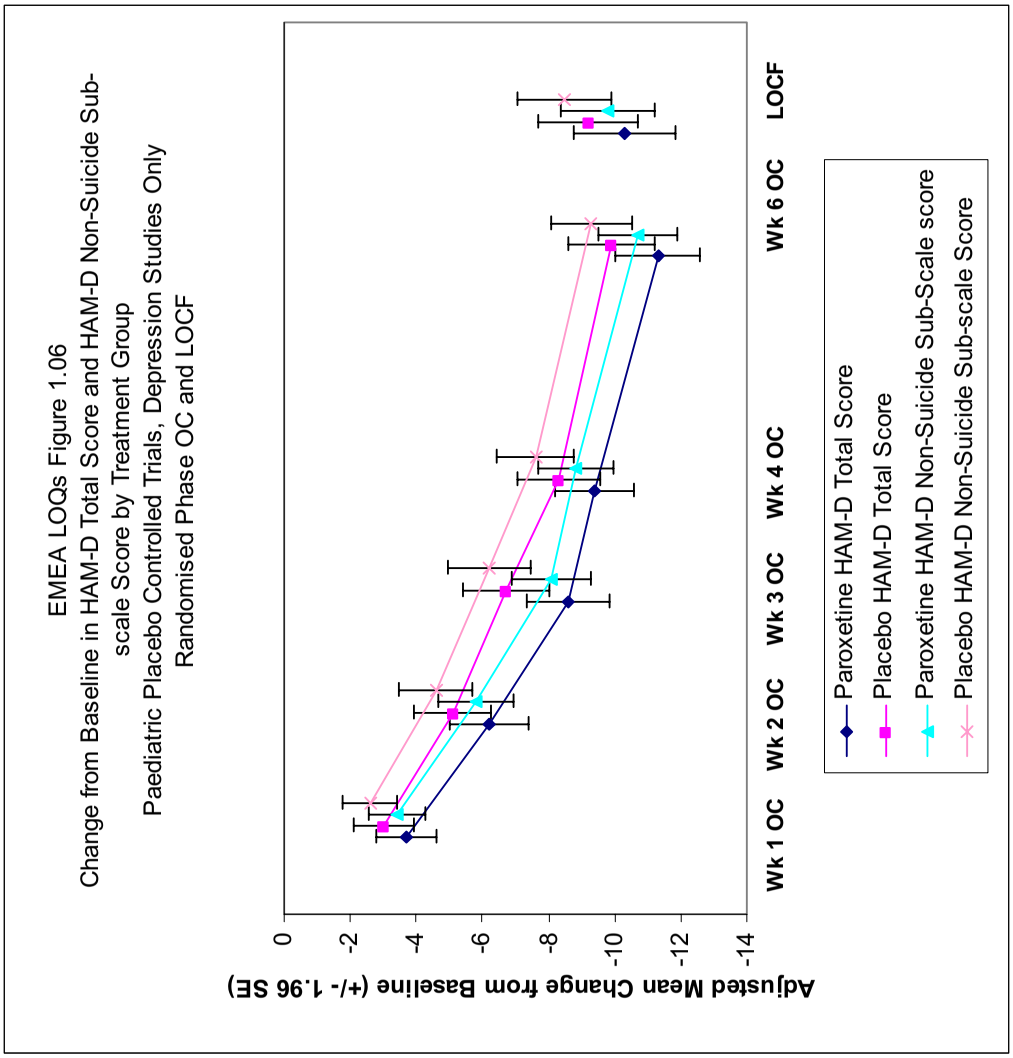
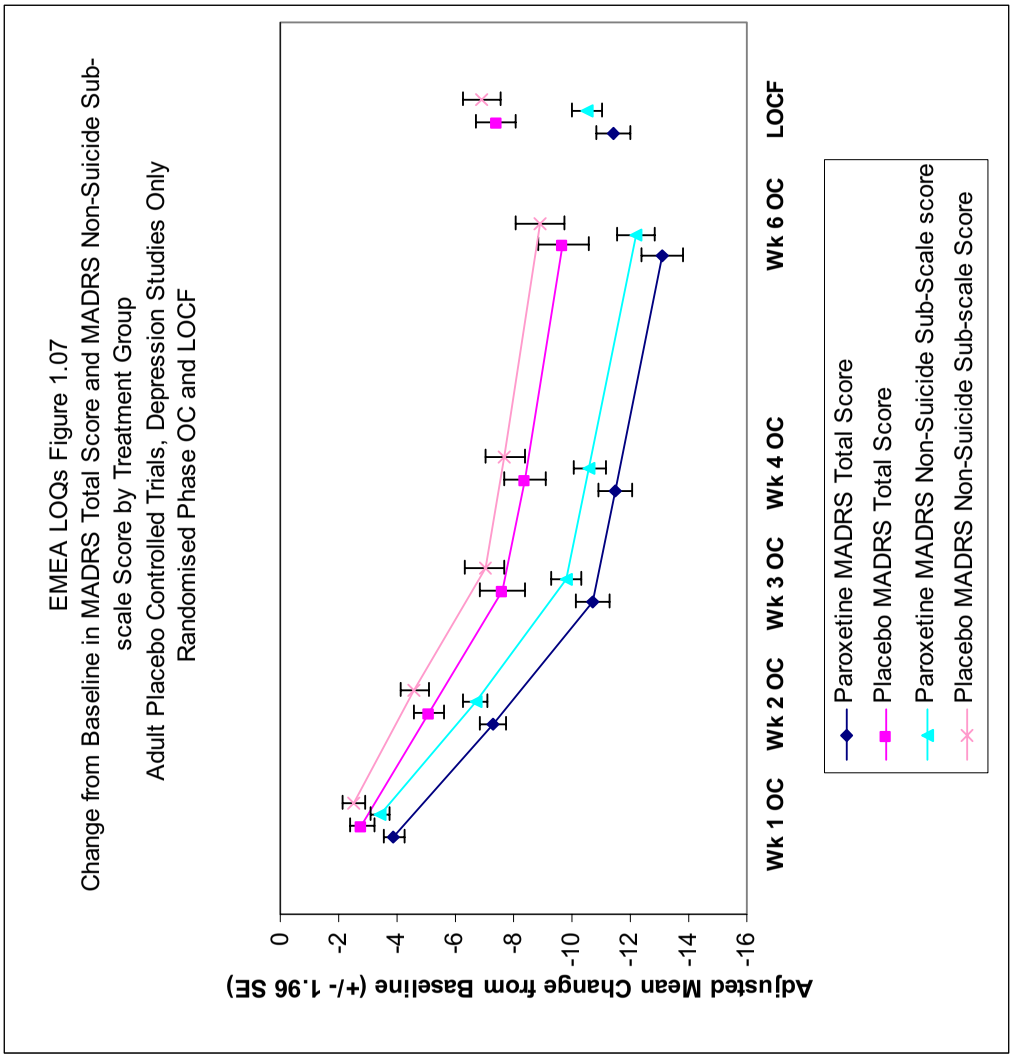
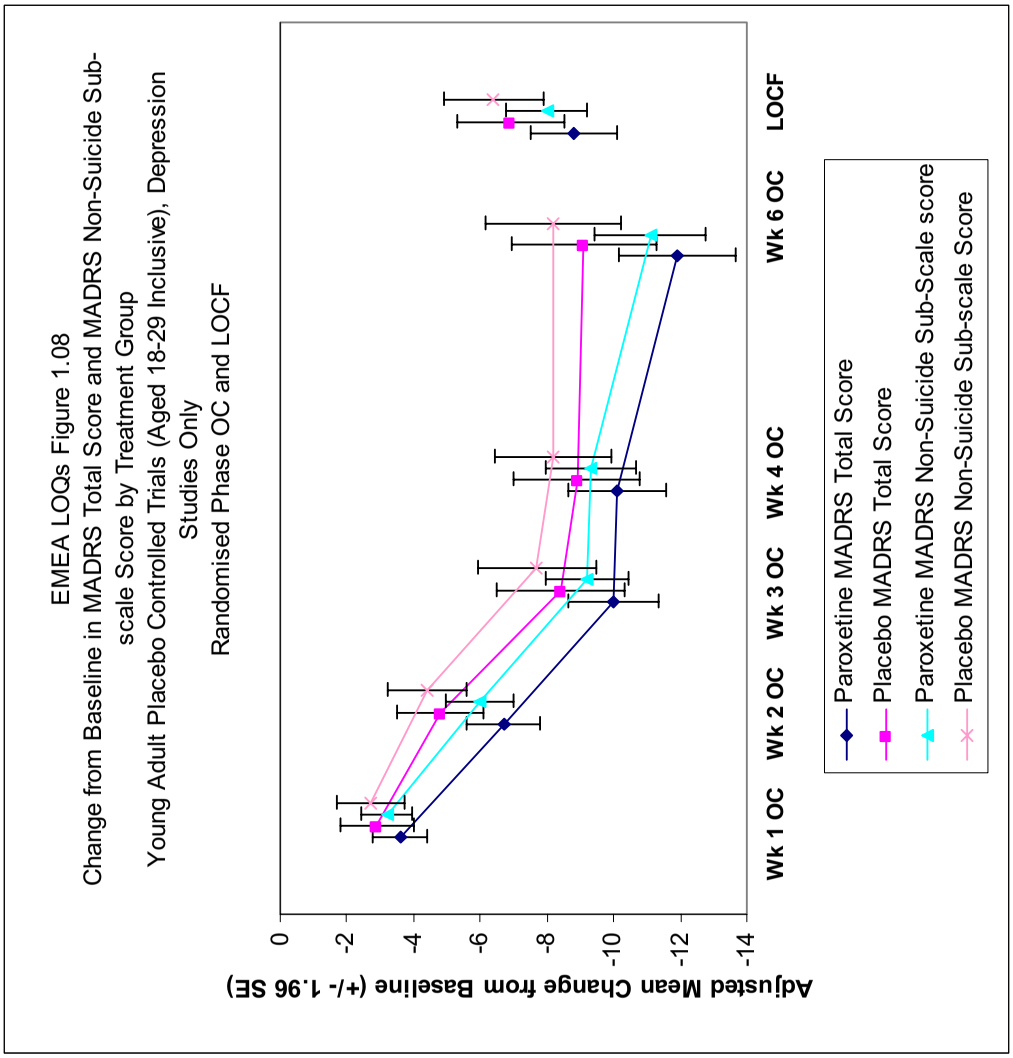
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.03a
Survival Plot for Possibly Suicide–Related AEs
Paediatric Placebo Controlled Trials
1 – Pr (Possibly suicide related AE)
1.00
0.98
0.96
0.94
0.92
0.90
0.88
0.86
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
150
160
Time (days)
Treatment
paroxetine
placebo
paroxetine LCI
placebo LCI
paroxetine UCI
placebo UCI

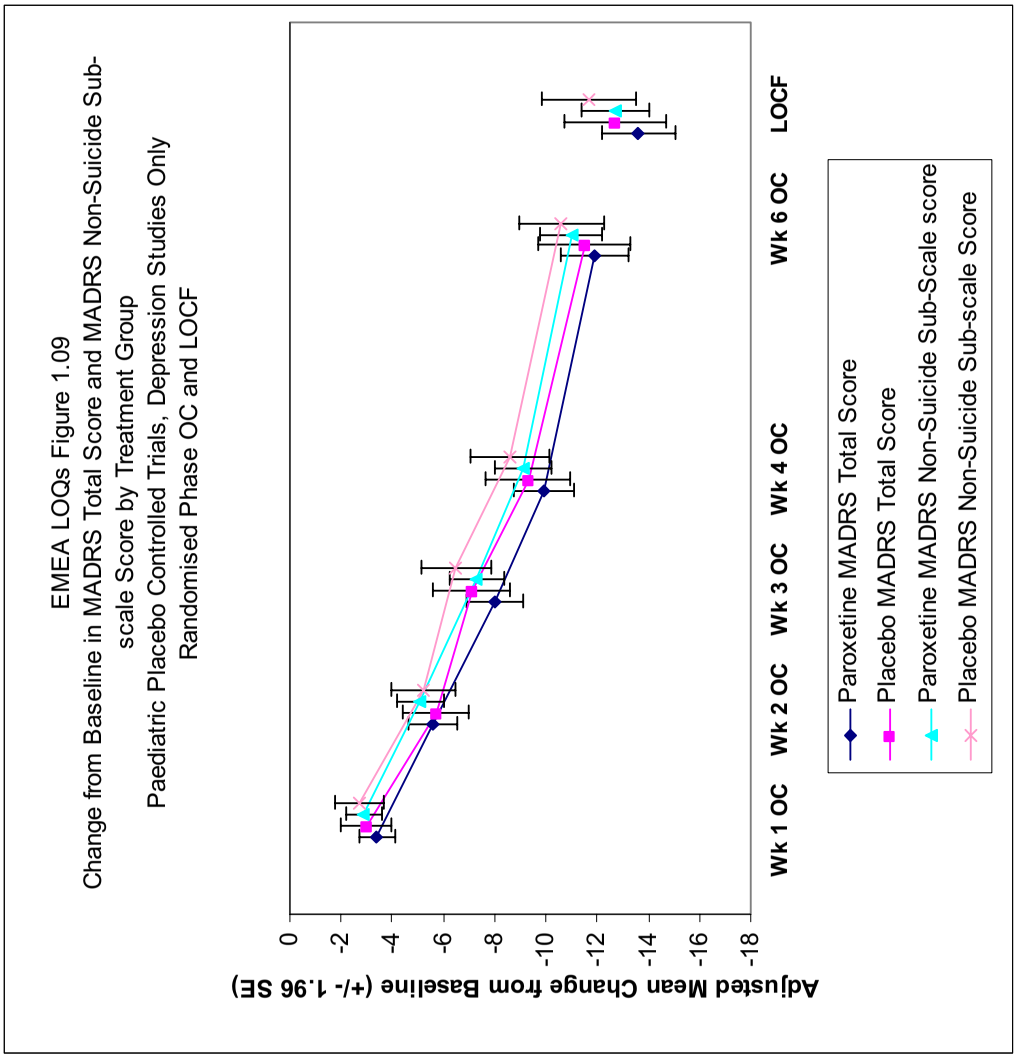

EMEA LOQs Figure 1.04
Change from Baseline in HAM-D Total Score and HAM-D Non-Suicide Sub-scale Score by Treatment Group
Adult Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF
Adjusted Mean Change from Baseline (+/- 1.96 SE)
-2
-4
-6
-8
-10
-12
Wk 1 OC
Wk 2 OC
Wk 3 OC
Wk 4 OC
Wk 6 OC
LOCF
Paroxetine HAM-D Total Score
Placebo HAM-D Total Score
Paroxetine HAM-D Non-Suicide Sub-Scale score
Placebo HAM-D Non-Suicide Sub-scale Score

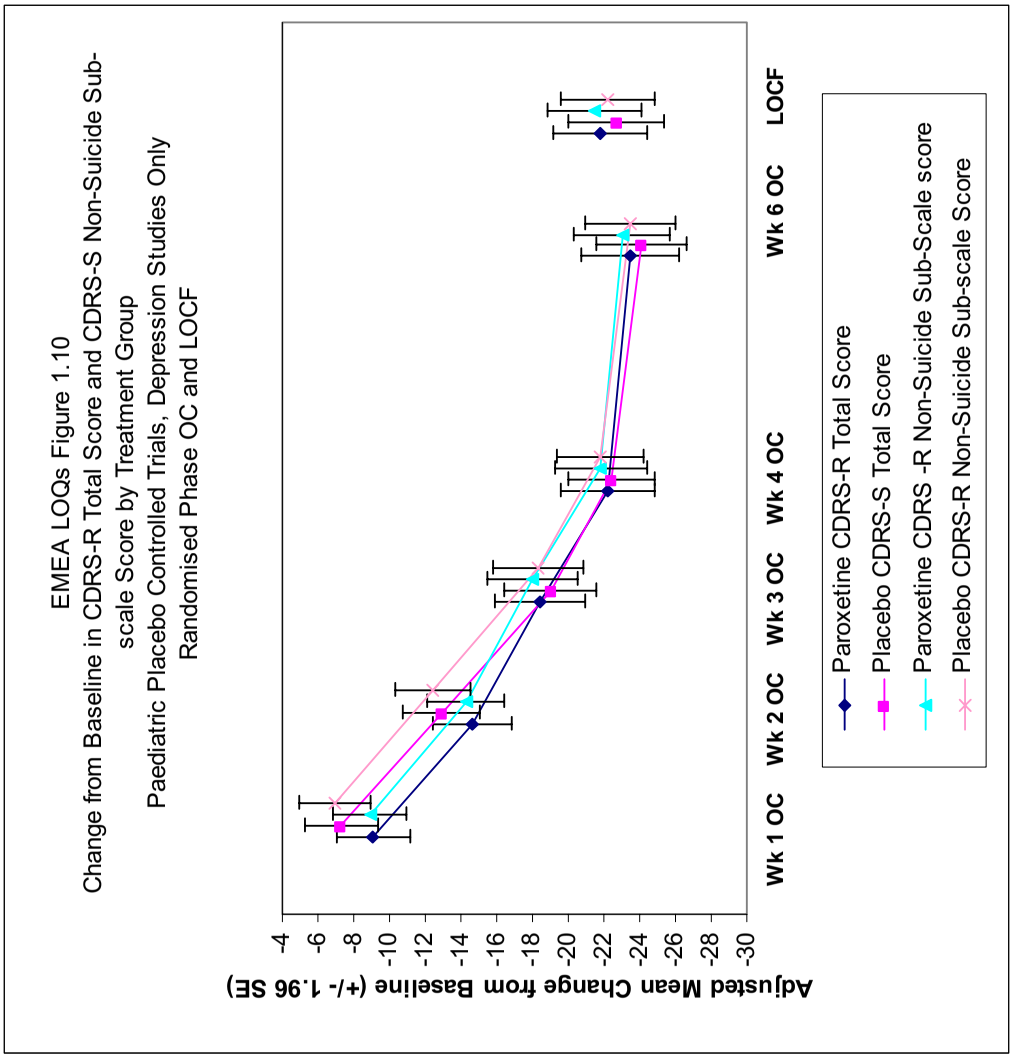

EMEA LOQs Figure 1.05
Change from Baseline in HAM-D Total Score and HAM-D Non-Suicide Sub-scale Score by Treatment Group
Young Adult Placebo Controlled Trials (Aged 18-29 Inclusive), Depression Studies Only
Randomised Phase OC and LOCF
Adjusted Mean Change from Baseline (+/- 1.96 SE)
-2
-4
-6
-8
-10
-12
-14
Wk 1 OC
Wk 2 OC
Wk 3 OC
Wk 4 OC
Wk 6 OC
LOCF
Paroxetine HAM-D Total Score
Placebo HAM-D Total Score
Paroxetine HAM-D Non-Suicide Sub-Scale score
Placebo HAM-D Non-Suicide Sub-scale Score

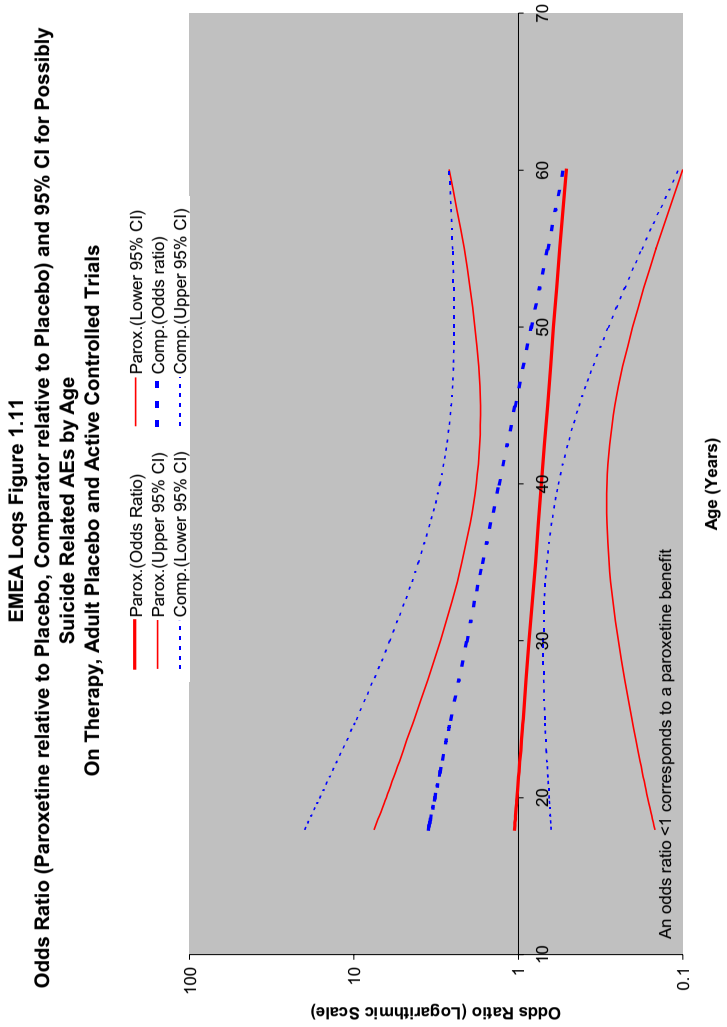

EMEA LOQs Figure 1.06
Change from Baseline in HAM-D Total Score and HAM-D Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF
Adjusted Mean Change from Baseline (+/- 1.96 SE)
0
-2
-4
-6
-8
-10
-12
-14
Wk 1 OC
Wk 2 OC
Wk 3 OC
Wk 4 OC
Wk 6 OC
LOCF
Paroxetine HAM-D Total Score
Placebo HAM-D Total Score
Paroxetine HAM-D Non-Suicide Sub-Scale score
Placebo HAM-D Non-Suicide Sub-scale Score

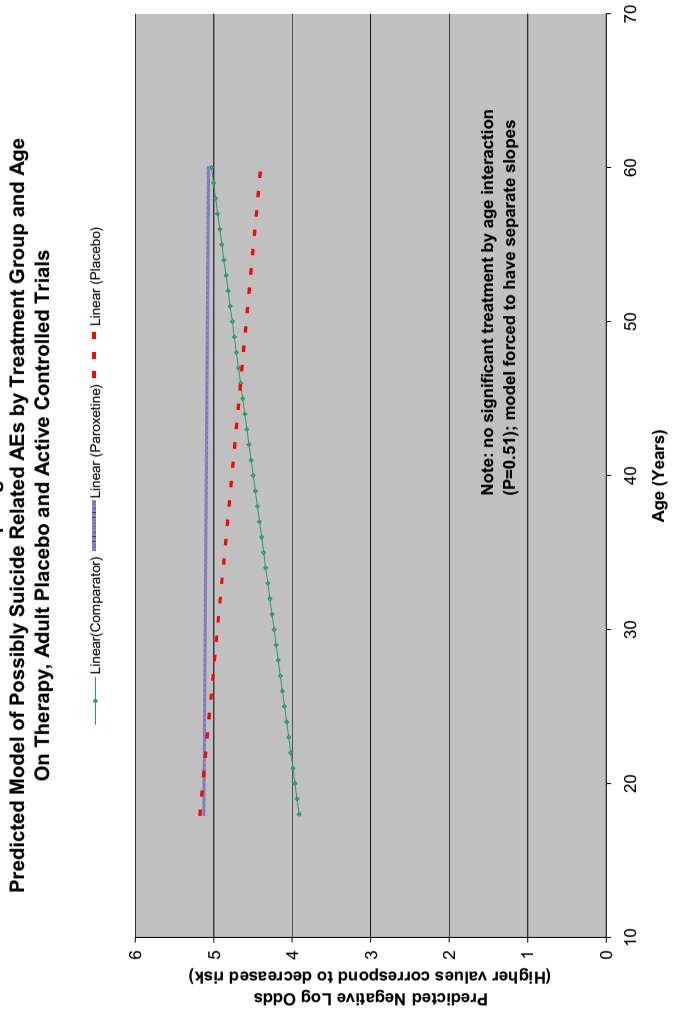

EMEA LOQs Figure 1.07
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Adult Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF
Adjusted Mean Change from Baseline (+/- 1.96 SE)
0
-2
-4
-6
-8
-10
-12
-14
-16
Wk 1 OC
Wk 2 OC
Wk 3 OC
Wk 4 OC
Wk 6 OC
LOCF
Paroxetine MADRS Total Score
Placebo MADRS Total Score
Paroxetine MADRS Non-Suicide Sub-Scale score
Placebo MADRS Non-Suicide Sub-scale Score

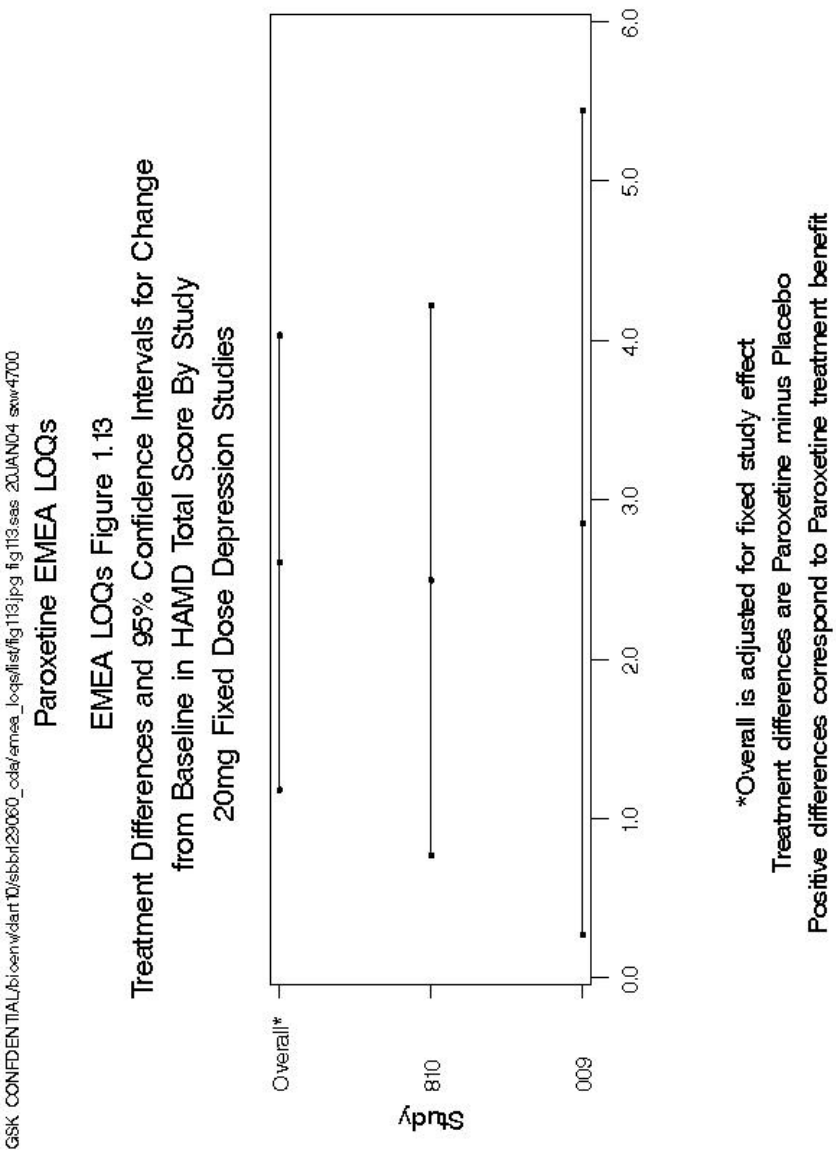

EMEA LOQs Figure 1.08
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Young Adult Placebo Controlled Trials (Aged 18-29 Inclusive), Depression Studies Only
Randomised Phase OC and LOCF
Adjusted Mean Change from Baseline (+/- 1.96 SE)
0
-2
-4
-6
-8
-10
-12
-14
Wk 1 OC
Wk 2 OC
Wk 3 OC
Wk 4 OC
Wk 6 OC
LOCF
Paroxetine MADRS Total Score
Placebo MADRS Total Score
Paroxetine MADRS Non-Suicide Sub-Scale score
Placebo MADRS Non-Suicide Sub-scale Score

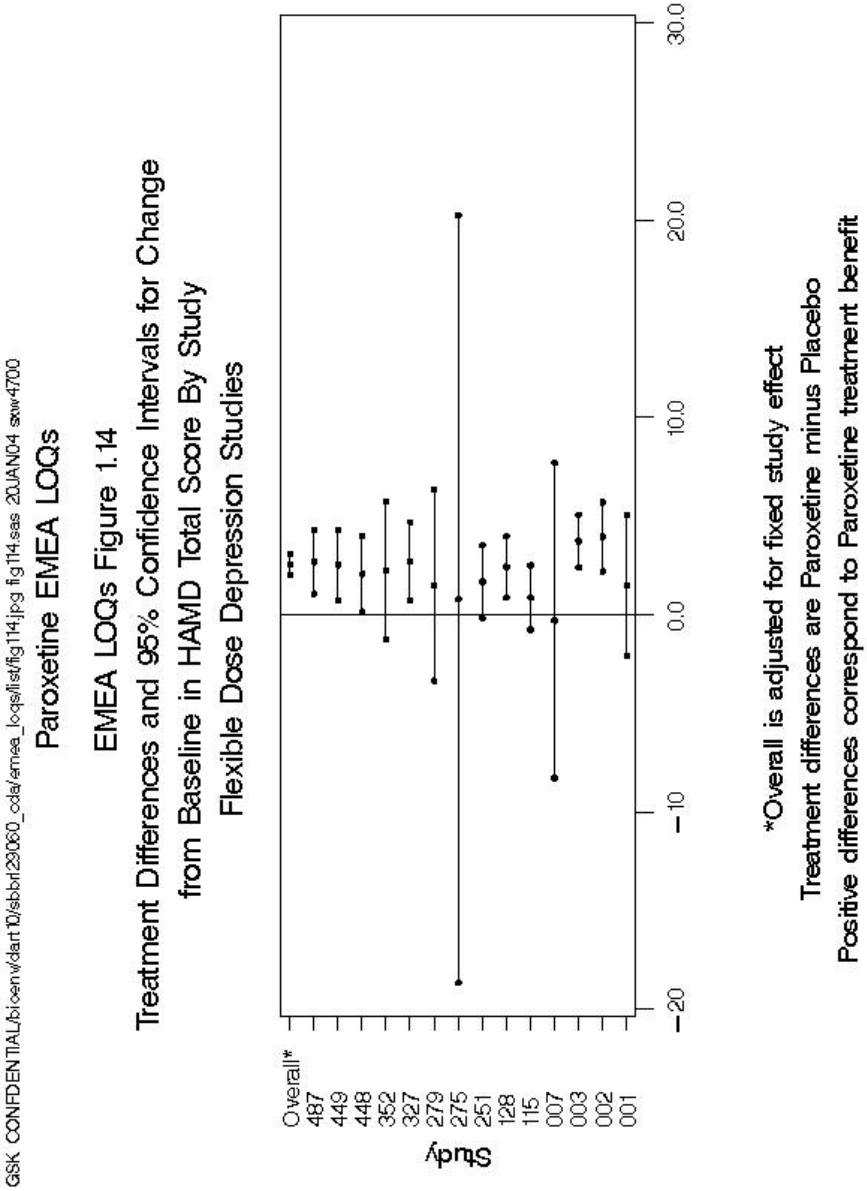

EMEA LOQs Figure 1.09
Change from Baseline in MADRS Total Score and MADRS Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF
Adjusted Mean Change from Baseline (+/- 1.96 SE)
0
-2
-4
-6
-8
-10
-12
-14
-16
-18
Wk 1 OC
Wk 2 OC
Wk 3 OC
Wk 4 OC
Wk 6 OC
LOCF
Paroxetine MADRS Total Score
Placebo MADRS Total Score
Paroxetine MADRS Non-Suicide Sub-Scale score
Placebo MADRS Non-Suicide Sub-scale Score


EMEA LOQs Figure 1.10
Change from Baseline in CDRS-R Total Score and CDRS-S Non-Suicide Sub-scale Score by Treatment Group
Paediatric Placebo Controlled Trials, Depression Studies Only
Randomised Phase OC and LOCF
Adjusted Mean Change from Baseline (+/- 1.96 SE)
-4
-6
-8
-10
-12
-14
-16
-18
-20
-22
-24
-26
-28
-30
Wk 1 OC
Wk 2 OC
Wk 3 OC
Wk 4 OC
Wk 6 OC
LOCF
Paroxetine CDRS-R Total Score
Placebo CDRS-S Total Score
Paroxetine CDRS -R Non-Suicide Sub-Scale score
Placebo CDRS-R Non-Suicide Sub-scale Score

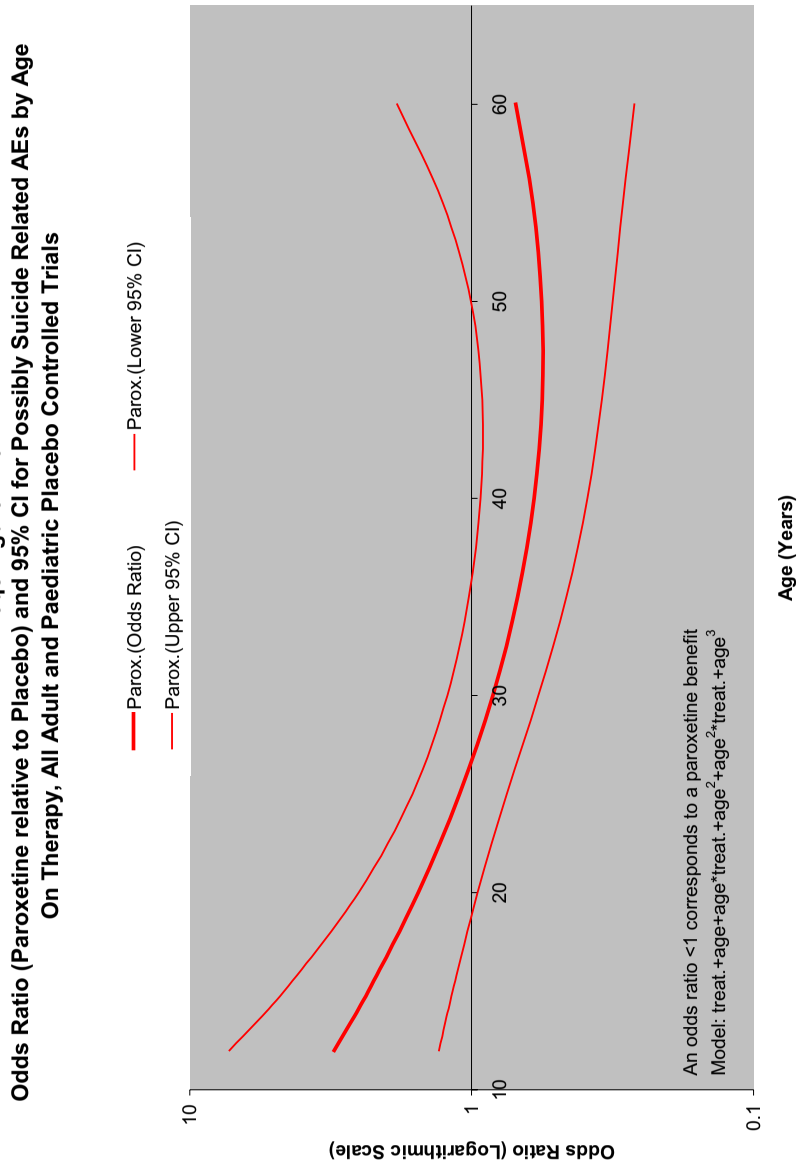

EMEA Logs Figure 1.11
Odds Ratio (Paroxetine relative to Placebo, Comparator relative to Placebo) and 95% CI for Possibly Suicide Related AEs by Age
On Therapy, Adult Placebo and Active Controlled Trials
Parox.(Odds Ratio)
Parox.(Upper 95% CI)
Comp.(Lower 95% CI)
Parox.(Lower 95% CI)
Comp.(Odds ratio)
Comp.(Upper 95% CI)
Odds Ratio (Logarithmic Scale)
100
10
1
0.1
10
20
30
40
50
60
70
Age (Years)
An odds ratio <1 corresponds to a paroxetine benefit


EMEA Logs Figure 1.12
Predicted Model of Possibly Suicide Related AEs by Treatment Group and Age
On Therapy, Adult Placebo and Active Controlled Trials
Linear(Comparator)
Linear (Paroxetine)
Linear (Placebo)
Predicted Negative Log Odds
(Higher values correspond to decreased risk)
6
5
4
3
2
1
0
10
20
30
40
50
60
70
Age (Years)
Note: no significant treatment by age interaction
(P=0.51); model forced to have separate slopes

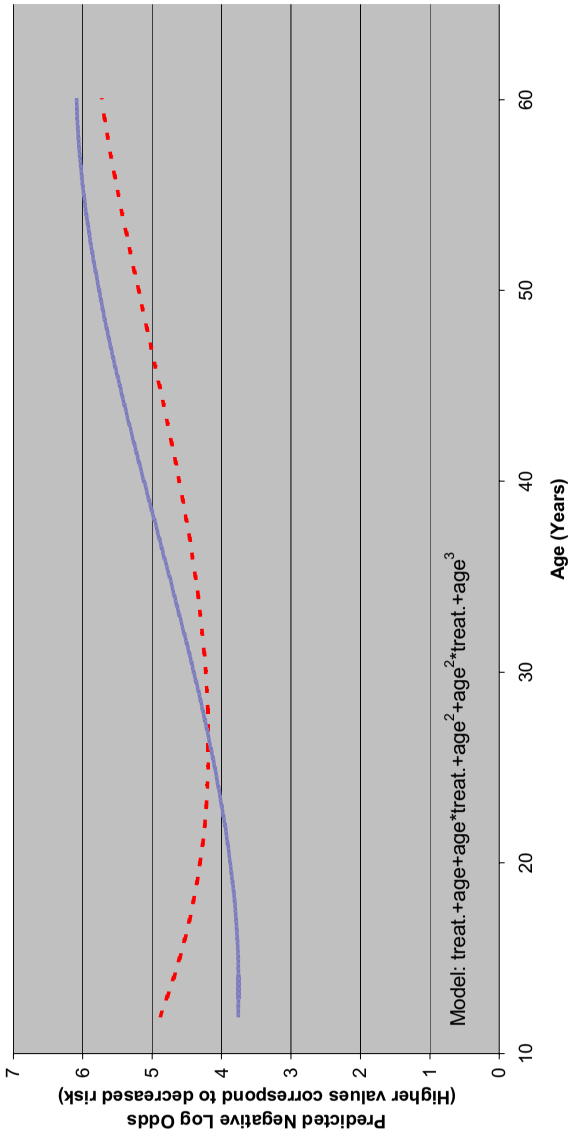

GSK CONFIDENTIAL/b\cen\v\dart10/sbb/t29060_cda/emea_loqs/list/fig113.jpg fig113.sas 20JAN04 snw4700
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.13
Treatment Differences and 95% Confidence Intervals for Change
from Baseline in HAMD Total Score By Study
20mg Fixed Dose Depression Studies
Study
Overall*
810
009
0.0
1.0
2.0
3.0
4.0
5.0
6.0
*Overall is adjusted for fixed study effect
Treatment differences are Paroxetine minus Placebo
Positive differences correspond to Paroxetine treatment benefit


GSK CONFIDENTIAL/bi-cen w/dart10/sbbrl29060_cda/emea_loqs/list/fig114.jpg fig114.sas 20JAN04 sxw4700
Paroxetine EMEA LOQs
EMEA LOQs Figure 1.14
Treatment Differences and 95% Confidence Intervals for Change
from Baseline in HAMD Total Score By Study
Flexible Dose Depression Studies
Study
Overall*
487
449
448
352
327
279
275
251
128
115
007
003
002
001
-20
-10
0.0
10.0
20.0
30.0
*Overall is adjusted for fixed study effect
Treatment differences are Paroxetine minus Placebo
Positive differences correspond to Paroxetine treatment benefit

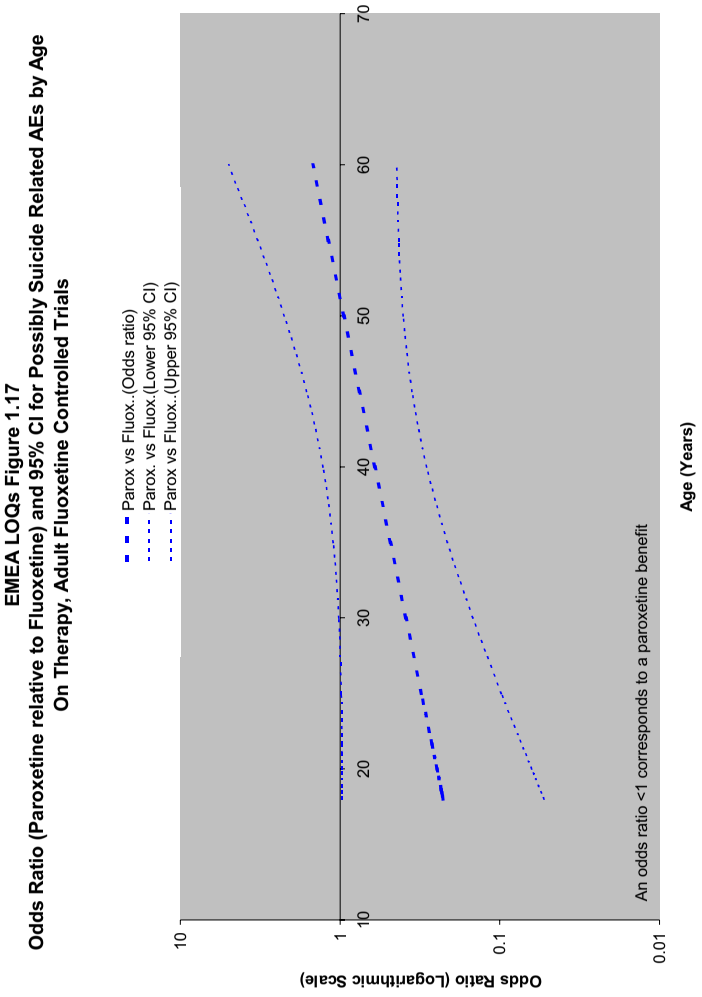
EMEA Loqs Figure 1.15
Odds Ratio (Paroxetine relative to Placebo) and 95% CI for Possibly Suicide Related AEs by Age On Therapy, All Adult and Paediatric Placebo Controlled Trials



EMEA Loqs Figure 1.16
Predicted Model of Possibly Suicide Related AEs by Treatment Group and Age
On Therapy, All Adult and Paediatric Placebo Controlled Trials



EMEA LOQs Figure 1.17
Odds Ratio (Paroxetine relative to Fluoxetine) and 95% CI for Possibly Suicide Related AEs by Age
On Therapy, Adult Fluoxetine Controlled Trials



Study	Adult Placebo Controlled	Adult Active Controlled	Paediatric Placebo Controlled	Indication	Comparator	Duration (wk)	Paroxetine Dose (mg/day)	n
001	Yes	No	No	Depression	Placebo	6	10 to 50	50
002	Yes	No	No	Depression	Placebo	6	10 to 50	341
003	Yes	Yes	No	Depression	Placebo; Imipramine	6	10 to 50	726
006 and 011	No	Yes	No	Depression	Doxepin	6	10 to 40	272
007	Yes	Yes	No	MDD with melancholia	Placebo; Amitriptyline	6	10 to 60	38
009	Yes	No	No	MDD	Placebo	12	10 to 40	460
019	No	Yes	No	Depression	Amitriptyline	6	30	66
020	No	Yes	No	Depression	Mianserin	6	30	33
022	No	Yes	No	Depression	Mianserin	6	30	36
025	No	Yes	No	Depression	Clomipramine	6	30	8
026	No	Yes	No	Depression	Mianserin	6	30	46
027	No	Yes	No	Depression	Imipramine	6	15 to 30	27
028	No	Yes	No	Depression	Amitriptyline	6	30	5
029	No	Yes	No	Depression	Amitriptyline	6	15 to 30	9
030	No	Yes	No	Depression	Mianserin	6	30	33
032	No	Yes	No	Depression	Amitriptyline	6	20 to 30	59
035	No	Yes	No	Depression	Amitriptyline	6	30	7
038	No	Yes	No	Depression	Mianserin	6	15 to 30	59
043	No	Yes	No	Depression	Amitriptyline	6	30	24
046	No	Yes	No	Depression	Amitriptyline	6	30	9
047	No	Yes	No	Depression	Dothiepin	6	20 to 30	
049	No	Yes	No	Depression	Amitriptyline	6	20 to 30	15
057	Yes	No	No	Suicidal behaviour	Placebo	52	40	267
059	No	Yes	No	Depression	Amitriptyline	6		143
060	No	Yes	No	Depression	Amitriptyline	6		91
061	No	Yes	No	Depression	Fluoxetine	6	20 to 40	106
063	No	Yes	No	Depression	Amitriptyline	5	30	50

Study	Adult Placebo Controlled	Adult Active Controlled	Paediatric Placebo Controlled	Indication	Comparator	Duration (wk)	Paroxetine Dose (mg/day)	n
064	No	Yes	No	Depression	Fluoxetine	6	20 to 40	99
065	No	Yes	No	Depression	Maprotiline	6	20 to 40	60
069	No	Yes	No	Depression	Clomipramine	6	20 to 30	92
070	No	Yes	No	Depression	Clomipramine	5	20 to 30	59
071	No	Yes	No	Depression				16
073	No	Yes	No	Depression	Amitriptyline	6		10
074	No	Yes	No	Depression	Amitriptyline	6		40
076	Yes	Yes	No	Depression	Placebo; Maprotiline	4	30	12
077	No	Yes	No	Depression	Amitriptyline	6		93
078	No	Yes	No	Depression	Amitriptyline	6	20 to 30	309
079	No	Yes	No	Depression	Fluoxetine	6	20 to 40	90
080	No	Yes	No	Depression	Clomipramine		30	24
082	No	Yes	No	Depression	Maprotiline	6	20 to 40	71
083	Yes	No	No	Depression	Placebo	52	20 to 40	135
084	No	Yes	No	Depression	Clomipramine			11
086	No	Yes	No	Depression	Maprotiline	6	20 to 40	544
088	No	Yes	No	Depression	Imipramine	12	30	13
089	No	Yes	No	Depression	Imipramine	8 to 12	20 to 40	14
090	No	Yes	No	Depression	Imipramine	6	30 to 50	151
095	No	Yes	No	Depression	Imipramine	6 to 12	20 or 40	202
106	Yes	No	No	Intermittent Brief Depression	Placebo	24	20	36
108	Yes	No	No	Panic Disorder	Placebo	12	20 to 60	120
109	No	Yes	No	Depression	Amitriptyline	12, to 12 months	20 to 50	132
112	No	Yes	No	Depression	Fluvoxamine	6	20 to 30	120
115	Yes	Yes	No	Depression	Placebo; Fluoxetine	12	20 to 50	691
116	Yes	No	No	OCD	Placebo	12	20 to 60	348

Study	Adult Placebo Controlled	Adult Active Controlled	Paediatric Placebo Controlled	Indication	Comparator	Duration (wk)	Paroxetine Dose (mg/day)	n
126 (Ext. of 116)	Yes	No	No	OCD	Placebo	12 months	20 to 60	263
118	Yes	Yes	No	OCD	Placebo; Clomipramine	12	20 to 60	241
127 (Ext. of 118)	Yes	Yes	No	OCD	Placebo	12 months	20 to 60	144
120	Yes	No	No	Panic Disorder	Placebo	10	10 to 40	278
222 (Ext. of 120)	Yes	No	No	Panic Disorder	Placebo	28	10 to 40	138
128	Yes	Yes	No	Depression	Placebo; Fluoxetine	12	20 to 50	848
131	No	Yes	No	Depression	Fluoxetine	12	20 to 50	203
135	No	Yes	No	Depression	Fluoxetine	6	20	121
136	Yes	Yes	No	OCD	Placebo; Clomipramine	12	10 to 60	437
241 (Ext. of 136)	Yes	Yes	No	OCD	Placebo; Clomipramine	52	20 to 60	83
184	No	Yes	No	Depression	Amitriptyline	6	30	9
187	Yes	Yes	No	Panic Disorder	Placebo; Clomipramine	12	10 to 60	368
228 (Ext. of 187)	Yes	Yes	No	Panic Disorder	Placebo; Clomipramine	9 months	20 to 60	180
190	Yes	No	No	Depression	Placebo	up to 18 months	20 to 50	125
197	No	Yes	No	Depression	Imipramine	8	20 to 40	198

Study	Adult Placebo Controlled	Adult Active Controlled	Paediatric Placebo Controlled	Indication	Comparator	Duration (wk)	Paroxetine Dose (mg/day)	n
201	Yes	No	No	Alcohol dependence	Placebo	12	30	117
223	Yes	Yes	No	Panic Disorder	Placebo; Alprazolam	10	10 to 60	226
239	No	Yes	No	Depression	Fluoxetine; Nortriptyline	8 (plus 4 months)	20 to 30	1602
245	No	Yes	No	Depression with anxiety	Clomipramine	12	20 to 40	1019
251	Yes	No	No	Depression with anxiety	Placebo	8	20 to 50	254
256	No	Yes	No	Depression	Mianserin	6	30	73
260	No	Yes	No	Depression	Amitriptyline	6	30	44
261	No	Yes	No	Depression	Clomipramine	6	30	120
272	No	Yes	No	Depression	Amitriptyline	6	30	8
274	Yes	No	No	Depression	Placebo	4	30	47
275	Yes	Yes	No	Depression	Placebo; maprotiline	4	30	11
276	Yes	No	No	Depression	Placebo	6	30	41
279	Yes	Yes	No	Depression	Placebo; mianserin	6	30	45
281	No	Yes	No	Depression	Amitriptyline	6	30	162
289	No	Yes	No	Depression	Clomipramine	6	30	85
290	No	Yes	No	Depression	Clomipramine	6	30	79
291	No	Yes	No	Depression	Clomipramine	5	20	83
292	No	Yes	No	Depression	Amitriptyline	6	30	90
308	No	Yes	No	Depression	Amitriptyline	6	30	22
309	No	Yes	No	Depression	Amitriptyline	6	30	21
310	No	Yes	No	Depression	Amitriptyline	8	30	23
312	No	Yes	No	Depression	Amitriptyline	7		0
314	No	Yes	No	Depression	Amitriptyline	6	30	18
316	No	Yes	No	Depression	Amitriptyline	7	30	17
318	No	Yes	No	Depression	Amitriptyline	7	30	21
319	No	Yes	No	Depression	Amitriptyline	8	30	2

Study	Adult Placebo Controlled	Adult Active Controlled	Paediatric Placebo Controlled	Indication	Comparator	Duration (wk)	Paroxetine Dose (mg/day)	n
327	Yes	No	No	Dysthymia	Placebo	12	20 to 50	166
329	No	No	Yes	Unipolar Major Depression	Placebo; Imipramine	8 + 6 months	20 to 40	275
331	No	Yes	No	Depression with IHD	Nortriptyline	6	20 to 30	81
352	Yes	Yes	No	Bipolar Depression	Placebo; Imipramine	10	20 to 50	117
377	No	No	Yes	Unipolar Major Depression	Placebo	12	20 to 40	286
382	Yes	No	No	Social Phobia	Placebo	12	20 to 50	187
470 (Ext. of 382)	Yes	No	No	Social Phobia	Placebo	40	20 to 50	98
400	Yes	No	No	Premenstrual Dysphoric Disorder	Placebo	4 menstrual cycles	20	48
427	Yes	No	No	Premenstrual Dysphoric Disorder	Placebo	4 menstrual cycles	5 to 20	38
448	Yes	No	No	MDD	Placebo; Paroxetine CR	12	20 to 50 (IR); 25 to 62.5 (CR)	310
449	Yes	No	No	MDD	Placebo; Paroxetine CR	12	20 to 50 (IR); 25 to 62.5 (CR)	330
453	No	No	Yes	OCD	Placebo	38	10 to 60	339
454	Yes	No	No	Social Phobia	Placebo	12	20 to 60	384
487	Yes	No	No	MDD	Placebo; Paroxetine CR	12	10 to 40 (IR); 12.5 to 50 (CR)	319
494	Yes	No	No	Panic Disorder	Placebo	10	12.5 to 75 (CR)	283

Study	Adult Placebo Controlled	Adult Active Controlled	Paediatric Placebo Controlled	Indication	Comparator	Duration (wk)	Paroxetine Dose (mg/day)	n
495	Yes	No	No	Panic Disorder	Placebo	10	12.5 to 75 (CR)	321
497	Yes	No	No	Panic Disorder	Placebo	10	12.5 to 75 (CR)	293
502	Yes	No	No	Social Phobia	Placebo	12	20 to 50	290
595	Yes	No	No	Social Phobia	Placebo	36	20 to 50	437
625	Yes	No	No	Depression following a stroke	Placebo	8	20 to 50	229
627	Yes	No	No	PTSD	Placebo	12	20 to 50	322
637	Yes	No	No	GAD	Placebo	8	20 to 50	374
641	Yes	No	No	GAD	Placebo	8	20 to 40	566
642	Yes	No	No	GAD	Placebo	8	20 to 50	331
646	Yes	No	No	GAD	Placebo	32	20 to 50	652
648	Yes	No	No	PTSD	Placebo	12	20 to 50	323
650	Yes	No	No	PTSD	Placebo	36	20 to 50	265
651	Yes	No	No	PTSD	Placebo	12	20 to 40	551
676	No	No	Yes	Social Anxiety Disorder	Placebo	16	10 to 50	322
677	Yes	No	No	Premenstrual Dysphoric Disorder	Placebo	3 menstrual cycles	12.5 to 25 (CR)	327
688	Yes	No	No	Premenstrual Dysphoric Disorder	Placebo	3 menstrual cycles	12.5 to 25 (CR)	361
689	Yes	No	No	Premenstrual Dysphoric Disorder	Placebo	3 menstrual cycles	12.5 to 25 (CR)	371
711 (Ext. of 677, 688 & 689)	Yes	No	No	Premenstrual Dysphoric Disorder	Placebo	6 menstrual cycles	12.5 to 25 (CR)	1059

Study	Adult Placebo Controlled	Adult Active Controlled	Paediatric Placebo Controlled	Indication	Comparator	Duration (wk)	Paroxetine Dose (mg/day)	n
701	No	No	Yes	Depression	Placebo	8	10 to 50	203
704	No	No	Yes	OCD	Placebo	10	10 to 50	207
785	Yes	Yes	No	Depression	Placebo; Citalopram	6	12.5 to 25 (CR)	511
790	Yes	No	No	Social Anxiety Disorder	Placebo	12	12.5 to 37.5 (CR)	375
791	Yes	No	No	GAD	Placebo	8	12.5 to 37.5 (CR)	335
810	Yes	No	No	Depression	Placebo	8	12.5, 25 (CR)	459

Study	Exclusion criteria in relation to suicide	Suicidality Classification	
001	Patients with known suicidal tendencies	4	Known, established or current risk excluded
002	Patients with known suicide gestures	4	Known, established or current risk excluded
003	Patients who were serious suicidal risks	3b	Severe or serious risks excluded (Investigator's opinion)
006 and 011	Patients who were serious suicidal risks	3b	Severe or serious risks excluded (Investigator's opinion)
007	Patients who were serious suicidal risks	3b	Severe or serious risks excluded (Investigator's opinion)
009	Patients who were serious suicidal risks	3b	Severe or serious risks excluded (Investigator's opinion)
019	None	2	No specific criteria (or unknown)
020	None	2	No specific criteria (or unknown)
022	None	2	No specific criteria (or unknown)
025	None	2	No specific criteria (or unknown)
026	None	2	No specific criteria (or unknown)
027	None	2	No specific criteria (or unknown)
028	Had exhibited established suicidal tendencies	4	Known, established or current risk excluded
029	Exhibited suicidal tendencies at the time of the study	4	Known, established or current risk excluded
030	None	2	No specific criteria (or unknown)
032	None	2	No specific criteria (or unknown)
035	None	2	No specific criteria (or unknown)
038	Scored 4 on the suicide item of the HAM-D scale	3a	Severe or serious risks excluded (HAMD item 3 = 4)
043	Had a score of 4 on the suicide item of the HAM-D	3a	Severe or serious risks excluded (HAMD item 3 = 4)
046	Exhibited suicidal tendencies at the time of the study	4	Known, established or current risk excluded
047	Patients who have exhibited established suicidal tendencies	4	Known, established or current risk excluded
049	Exhibited suicidal tendencies at the time of the study	4	Known, established or current risk excluded
057	Inclusion: Episode of suicidal behaviour within the last 10 days (index episode). History of at least one episode of suicidal behaviour in addition to the index episode. Exclusion: Genuine suicidal ideation.	1	Suicidal behaviour required
059	Patients at Severe Risk of Suicide	3b	Severe or serious risks excluded (Investigator's opinion)
060	Patients at Severe Risk of Suicide	3b	Severe or serious risks excluded (Investigator's opinion)
061	Patients at severe risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
063	None	2	No specific criteria (or unknown)

Study	Exclusion criteria in relation to suicide	Suicidality Classification	
064	Patients at severe risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
065	None	2	No specific criteria (or unknown)
069	None	2	No specific criteria (or unknown)
070	Patients at severe risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
071	Patients who have shown marked suicidal tendencies	3b	Severe or serious risks excluded (Investigator's opinion)
073	Patients at Severe Risk of Suicide	3b	Severe or serious risks excluded (Investigator's opinion)
074	Patients with acute suicide endangerment	3b	Severe or serious risks excluded (Investigator's opinion)
076	Severe risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
077	Patients with acute suicide endangerment	3b	Severe or serious risks excluded (Investigator's opinion)
078	None	2	No specific criteria (or unknown)
079	Severe risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
080	Patients at Severe Risk of Suicide	3b	Severe or serious risks excluded (Investigator's opinion)
082	None	2	No specific criteria (or unknown)
083	Patients known to be at high risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
084	Serious risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
086	Patients with an acute risk of suicide	4	
088	Exhibited established suicidal tendencies or were severely inhibited patients (ECT treatment required)	4	Known, established or current risk excluded
089	Exhibited suicidal tendencies	4	Known, established or current risk excluded
090	Serious suicidal risk (score of > 3 on HAM-D item 3)	3a	Severe or serious risks excluded (HAMD item 3 = 4)
095	Patients with a high risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
106	Serious immediate risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
108	Immediate suicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
109	Inclusion:Score of 1 or more on HAM-D item 3. Exclusion: Patients with a high risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
112	None	2	No specific criteria (or unknown)
115	Patients who, in the investigator's judgment, posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
116	Patients who, in the investigator's judgment, posed a serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)

Study	Exclusion criteria in relation to suicide	Suicidality Classification	
126 (Ext. of 116)	Patients who, in the investigator's judgment, posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
118	Patients who, in the investigator's judgment, posed a serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
127 (Ext. of 118)	Patients who, in the investigator's judgment, posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
120	High risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
222 (Ext. of 120)	High risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
128	Patients who, in the investigator's judgment, pose a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
131	Patients at serious risk of suicide including those who are acutely suicidal to such a degree that precautions against suicide must be taken	3b	Severe or serious risks excluded (Investigator's opinion)
135	Patients at severe risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
136	Patients who, in the investigator's opinion, were at serious risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
241 (Ext. of 136)	Patients who, in the investigator's opinion, were at serious risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
184	Exhibited established suicidal tendencies	4	Known, established or current risk excluded
187	Patients with a high risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
228 (Ext. of 187)	Patients with a high risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
190	Patients who, in the investigator's judgment, pose a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
197	Patients who, in the investigator's opinion, posed a suicidal risk	4	Known, established or current risk excluded

Study	Exclusion criteria in relation to suicide	Suicidality Classification	
201	Patients with a significant risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
223	Patients who, in the investigator's judgment, pose a high risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
239	Patients who, in the investigator's judgment, posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
245	Patients who, in the investigator's judgment, posed a current suicidal risk	4	Known, established or current risk excluded
251	Patients who, in the investigator's judgment, posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
256	None	2	No specific criteria (or unknown)
260	None	2	No specific criteria (or unknown)
261	Suicidal risk of severely retarded patients (ECT-treatment required)	4	Known, established or current risk excluded
272	None	2	No specific criteria (or unknown)
274	Patients who were at particular risk from suicidal attempts or gestures	3b	Severe or serious risks excluded (Investigator's opinion)
275	Exhibited suicidal tendencies at the time of the study	4	Known, established or current risk excluded
276	Patients who had shown suicidal tendencies	4	Known, established or current risk excluded
279	None	2	No specific criteria (or unknown)
281	None	2	No specific criteria (or unknown)
289	Patients who had shown marked suicidal tendencies	3b	Severe or serious risks excluded (Investigator's opinion)
290	Patients who have shown marked suicidal tendencies	3b	Severe or serious risks excluded (Investigator's opinion)
291	None	2	No specific criteria (or unknown)
292	None	2	No specific criteria (or unknown)
308	None	2	No specific criteria (or unknown)
309	None	2	No specific criteria (or unknown)
310	None	2	No specific criteria (or unknown)
312	None	2	No specific criteria (or unknown)
314	None	2	No specific criteria (or unknown)
316	None	2	No specific criteria (or unknown)
318	None	2	No specific criteria (or unknown)
319	None	2	No specific criteria (or unknown)

Study	Exclusion criteria in relation to suicide	Suicidality Classification	
327	Patients who posed a current, serious risk of suicide or homicide	3b	Severe or serious risks excluded (Investigator's opinion)
329	Presence of suicidal ideation with a definite plan or of a suicide attempt within the current episode, or any past history of attempting suicide by medication overdose	3b	Severe or serious risks excluded (Investigator's opinion)
331	Patients who, in the investigator's judgment, posed a current serious suicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
352	Patients who, in the investigator's judgment, posed a current,serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
377	Serious suicidal ideation. Patients with a history of suicide attempt but who were not considered a significant risk now, could be included	3b	Severe or serious risks excluded (Investigator's opinion)
382	Patients who, in the investigator's judgment, posed serious suicidal or homicidal risks	3b	Severe or serious risks excluded (Investigator's opinion)
470 (Ext. of 382)	Patients who, in the investigator's judgment, posed serious suicidal or homicidal risks	3b	Severe or serious risks excluded (Investigator's opinion)
400	Current severe psychiatric disorder (with or without delusions/hallucinations or significant suicide risk)	3b	Severe or serious risks excluded (Investigator's opinion)
427	Patients for whom there was a significant risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
448	Patients who, in the investigator's judgment posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
449	Patients who, in the investigator's judgment posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
453	Patients who, in the investigator's judgement pose a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
454	Patients who, in the investigator's judgment pose a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
487	Patients who, in the investigator's judgment posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
494	A current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)

Study	Exclusion criteria in relation to suicide	Suicidality Classification	
495	A current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
497	A current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
502	Posed a current, serious suicidal or homicidal risk in the investigator's judgment	3b	Severe or serious risks excluded (Investigator's opinion)
595	Patients who, in the investigator's judgment posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
625	Patients who in the investigator's judgement posed a current suicidal risk	4	Known, established or current risk excluded
627	Posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
637	Posed a current, serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
641	Patients who posed a current suicidal or homicidal risk in the investigator's judgment	4	Known, established or current risk excluded
642	Patients who posed a current suicidal or homicidal risk in the investigator's judgment	4	Known, established or current risk excluded
646	Posed a current suicidal or homicidal risk	4	Known, established or current risk excluded
648	Patients who, in the investigator's judgement, posed a current homicidal or suicidal risk	4	Known, established or current risk excluded
650	Posed a current suicidal risk	4	Known, established or current risk excluded
651	Patients who, in the investigator's judgement, posed a current homicidal or suicidal risk	4	Known, established or current risk excluded
676	Patients who were a serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
677	Subjects with a significant risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
688	Subjects with a significant risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
689	Subjects with a significant risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)
711 (Ext. of 677, 688 & 689)	Subjects with a significant risk of suicide	3b	Severe or serious risks excluded (Investigator's opinion)

Study	Exclusion criteria in relation to suicide	Suicidality Classification	
701	Patients who, in the investigator's judgment, posed a suicidal or homicidal risk	4	Known, established or current risk excluded
704	Patients who, in the investigator's judgment, posed a current suicidal or homicidal risk	4	Known, established or current risk excluded
785	Patients who, in the investigator's judgment, posed a current suicidal or homicidal risk	4	Known, established or current risk excluded
790	Subjects who, in the investigator's judgment, posed a current serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)
791	Posed a current suicidal or homicidal risk in the investigator's judgement	4	Known, established or current risk excluded
810	Subjects who, in the investigator's judgment, posed a current serious suicidal or homicidal risk	3b	Severe or serious risks excluded (Investigator's opinion)

Study	Age, Mean	Age, SD	Age, Median	Age, Mode	Age, Min	Age, Max
001	43.4	12.33	42.5	31	20	65
002	41.5	12.17	40	30	18	77
003	40.4	11.6	39	34	18	74
006 and 011	67.1, 68.4	5.45, 5.71	66, 67	65, 67	60, 60	82, 85
007	42.4	10.06	41	36	24	68
009	41	12.88	38	32	18	85
019	35	11.01	35	40	17	65
020	51.4	13.39	53	40	23	78
022	42.2	14.29	42	25	17	66
025	48	11.6	47.5		28	61
026	74.8	5.68	75	72	65	87
027	46.6	16	46	67	20	67
028	69.2	4.37	69	69	62	78
029	46.6	13.43	49	49	26	64
030	45.8	11.83	45	38	25	70
032	44.6	11.72	42.5	42	21	72
035	51.3	8.79	52	60	36	60
038	41.8	11.34	40	36	19	69
043	36.2	10.91	35	38	18	61
046	73.7	5.4	73	80	65	83
047	43.1	13.24	42	38	19	65
049	71.9	7.19	72	66	43	93
057	34.4	11.41	32	32	18	74
059	47.1	11.43	49	47	20	65
060	71.2	5.69	69	65	63	84
061	74	6.13	75	78	61	85
063	42.1	11.13	42.5	42	21	62

Study	Age, Mean	Age, SD	Age, Median	Age, Mode	Age, Min	Age, Max
064	44.3	12.17	44	34	18	66
065	40.4	12.14	39.5	57	19	63
069	71.3	6.94	73	73	60	85
070	72.6	10.06	73.5	60	50	90
071	66.5	4.31	66	61	61	75
073	47	12.97	50	50	20	66
074	45.6	11.15	48.5	55	23	62
076	47.9	13.61	49.5	56	26	65
077	44.1	11.52	42.5	36	20	68
078	49	12.8	49	43	20	77
079	38.7	12.21	39	20	19	65
080	48.8	8.46	49	38	30	64
082	44.5	11.71	44	39	19	65
083	47.1	8.78	48	52	23	65
084	81.5	6.67	84	88	68	88
086	44.4	12.21	45	53	18	71
088	51.3	10	52	62	29	65
089	52	10.89	49.5	44	28	69
090	43.8	11.65	43	48	18	69
095	43.5	8.7	43.5	39	22	65
106	29.7	7.37	29	29	18	48
108	37.3	9.75	36	34	21	69
109	49.5	12.44	52	62	20	70
112	43.5	10.63	43	28	20	65
115	41.7	12.27	41	43	18	86
116	41.4	13.49	40	40	16	78

Study	Age, Mean	Age, SD	Age, Median	Age, Mode	Age, Min	Age, Max
126 (Ext. of 116)						
118	38.9	11.48	37	36	16	77
127 (Ext. of 118)						
120	36.4	10.06	35	29	18	65
222 (Ext. of 120)						
128	42.1	12.55	40	36	18	82
131	40.5	10.74	40	45	18	65
135	40.8	11.04	41	41	19	68
136	37.8	12.16	36	26	16	74
241 (Ext. of 136)						
184	37.8	10.97	36.5	36	19	62
187	34.8	9.05	34	27	18	66
228 (Ext. of 187)						
190	44.1	11.43	44	39	20	74
197	76.6	9.2	77	83	59	98

Study	Age, Mean	Age, SD	Age, Median	Age, Mode	Age, Min	Age, Max
201	40.7	9.03	38	33	23	62
223	39.1	11.45	38	36	18	74
239	41.5	12.5	40	37	18	91
245	42.6	12.82	43	29	18	70
251	41.3	10.84	41	46	18	71
256	51.3	11.66	52	42	26	74
260	61.6	13.18	63	70	25	85
261	48.5	11.38	49	45	22	69
272	55.3	5.26	55	55	47	63
274	42.5	12.41	42	58	18	64
275	55.6	6.6	57	60	42	63
276	44.2	12.58	44	27	22	64
279	44.3	18.42	42	20	17	75
281	40.3	13.43	39	46	18	67
289	45.4	11.39	47	58	21	65
290	68.7	5.67	69	74	60	83
291	70.6	8.42	69	65	57	96
292	46.8	12.85	48	49	18	72
308	44.4	11.8	46	47	27	66
309	39.3	11.01	37	31	20	56
310	40.5	10.24	43	28	25	61
312	41.8	10.21	37	36	36	57
314	45	12.65	50	54	23	62
316	44.3	13.04	42	35	24	70
318	49	8.89	45.5	43	36	65
319	51.5	0.71	51.5		51	52

Study	Age, Mean	Age, SD	Age, Median	Age, Mode	Age, Min	Age, Max
327	41.7	11.11	41	41	22	77
329	15	1.66	15	16	11	18
331	57.9	11.77	59	67	34	84
352	41.3	10.42	41	37	21	71
377	15.6	1.62	16	17	12	19
382	36.3	11.71	34	26	18	76
470 (Ext. of 382)						
400	35.6	5.87	35	35	23	45
427	35.2	6.51	36.5	37	19	46
448	39	10.46	39	43	18	64
449	41.1	11.57	42	45	18	71
453	11.8	2.75	12	12	6	18
454	37	10.15	37	38	18	70
487	69.9	6.03	70	71	60	88
494	37.4	10.17	37	25	19	63

Study	Age, Mean	Age, SD	Age, Median	Age, Mode	Age, Min	Age, Max
495	36.5	10.38	35	33	18	72
497	39	10.56	39	26	19	65
502	36.1	11.55	34.5	27	18	85
595	38.2	11.39	38	43	18	71
625	64.9	10.95	67	68	22	85
627	39.2	11.62	38	38	18	75
637	46	14.96	44	33	18	78
641	40.5	12.65	40	26	18	74
642	40.3	12.15	40	42	19	80
646	43.4	12.97	42	37	18	83
648	40.6	11.66	41	49	18	78
650	42.7	12.95	42	37	18	82
651	41.6	11.64	42	33	18	77
676	13.2	2.77	14	14	7	17
677	35.4	5.87	36	40	19	45
688	36.9	4.94	38	41	20	46
689	36.2	5.6	37	39	19	45
711 (Ext. of 677, 688 & 689)						

Study	Age, Mean	Age, SD	Age, Median	Age, Mode	Age, Min	Age, Max
701	12.1	2.97	12	10	7	17
704	11.3	3	11	11	6	17
785	41	11.9	41	50	18	65
790	38.8	11.01	39	45	18	69
791	39.1	13.65	37	26	18	81
810	38.8	11.6	38	37	18	74

Study	Baseline level of suicidal risk by HAM-D item 3 (H) or MADRS item 10 (M): Number of patients included in the analyses "N" by treatment group paroxetine/active comparator/placebo	Mean score - HAM-D Item 3 (H) by treatment group	SD (H)	Min (H)	Max (H)
001	25/0/25 (H); 25/0/25 (M)	1.16/0/1.24	0.62/0/0.78	0/0/0	2/0/2
002	170/0/171 (H); 170/0/171 (M)	1.48/0/1.42	0.90/0/0.81	0/0/0	4/0/3
003	241/241/244 (H); 241/241/244 (M)	0.97/1.02/1.00	0.81/0.79/0.81	0/0/0	3/4/3/
006 and 011	33/33/0, 103/103/0 (H); 33/33/0, 101/101/0 (M)	1.18/1.33/0, 0.83/0.81/0	0.81/0.89/0, 0.77/0.78/0	0/0/0, 0/0/0	3/3/0, 3/3/0
007	13/13/12 (H); 13/13/11 (M)	2.00/2.46/2.25	0.82/0.52/0.75	0/2/1	03/03/2003
009	421/0/53 (H); 421/0/53 (M)	1.11/0/1.06	0.83/0/0.74	0/0/0	3/0/2
019	31/35/0 (H)	1.52/1.60/0	1.12/1.12/0	0/0/0	3/4/0/
020	24/24/0 (H)	1.17/0.96/0	0.76/0.69/0	0/0/0	2/2/0/
022	16/17/0 (H)	1.25/1.29/0	1.18/1.10/0	0/0/0	3/3/0/
025	4/4/0/ (H)	2.00/1.25/0	1.15/1.50/0	1/0/0	3/3/0/
026	30/30/0 (H)	1.23/1.17/0	0.68/0.70/0	0/0/0	3/2/0/
027	17/15/0 (H)	1.06/1.27/0	0.83/1.22/0	0/0/0	2/3/0/
028	8/6/0/ (H)	0.88/1.00/0	0.64/0.89/0	0/0/0	2/2/0/
029	4/5/0/ (H)	1.00/1.00/0	0.82/0.71/0	0/0/0	2/2/0/
030	21/19/0 (H)	0.90/0.79/0	0.94/0.85/0	0/0/0	3/3/0/
032	30/30/0 (H)	1.00/1.20/0	1.02/1.13/0	0/0/0	3/3/0/
035	3/4/0/ (H)	1.00/1.00/0	1.00/1.41/0	0/0/0	2/3/0/
038	32/29/0 (H)	1.75/1.76/0	0.76/0.64/0	0/0/0	3/3/0/
043	15/18/0 (H)	0.20/0.50/0	0.56/0.79/0	0/0/0	2/3/0/
046	21/22/0 (H)	0.33/0.50/0	0.73/0.74/0	0/0/0	2/2/0/
047	46/48/0 (H)	0.43/0.25/0	0.83/0.64/0	0/0/0	3/3/0/
049	62/32/0 (H)	0.24/0.31/0	0.50/0.78/0	0/0/0	2/4/0/
057	128/0/127 (M)				
059	72/71/0 (H); 72/71/0 (M)	1.07/1.13/0	0.84/0.89/0	0/0/0	4/4/0/
060	43/47/0 (H); 43/47/0 (M)	1.07/0.89/0	0.91/0.91/0	0/0/0	4/4/0/
061	54/52/0 (H); 54/52/0 (M)	1.20/1.23/0	0.74/0.88/0	0/0/0	3/4/0/
063	21/19/0 (H); 21/19/0 (M)	0.90/0.74/0	0.83/0.81/0	0/0/0	3/2/0/

Study	Baseline level of suicidal risk by HAM-D item 3 (H) or MADRS item 10 (M): Number of patients included in the analyses "N" by treatment group paroxetine/active comparator/placebo	Mean score - HAM-D Item 3 (H) by treatment group	SD (H)	Min (H)	Max (H)
064	49/50/0 (H); 49/50/0 (M)	1.04/1.20/0	0.76/0.86/0	0/0/0	3/3/0/
065	28/32/0 (H); 28/32/0 (M)	1.57/0.78/0	1.03/0.75/0	0/0/0	4/3/0/
069	45/46/0 (H); 45/46/0 (M)	1.93/1.70/0	0.99/0.89/0	0/0/0	4/3/0/
070	32/30/0 (M)				
071	9/9/0/ (H)	1.56/1.11/0	1.01/1.05/0	0/0/0	3/3/0/
073	6/4/0/ (H); 6/4/0/ (M)	1.83/1.00/0	1.47/2.00/0	0/0/0	4/4/0/
074	20/19/0 (H)	1.50/1.37/0	1.28/1.42/0	0/0/0	4/4/0/
076	4/4/4 (H)	0.25/1.00/0.00	0.50/1.41/0.00	0/0/0	1/3/0/
077	46/46/0 (H)	1.80/1.83/0	1.15/0.97/0	0/0/0	4/4/0/
078	46/45/0 (H)	1.30/1.00/0	0.81/0.85/0	0/0/0	3/3/0/
079	45/45/0 (H); 45/45/0 (M)	1.13/1.20/0	0.76/0.76/0	0/0/0	3/3/0/
080	10/13/0 (H); 10/11/0 (M)	1.40/1.62/0	1.07/1.12/0	0/0/0	3/4/0/
082	37/34/0 (H); 37/34/0 (M)	0.95/0.91/0	0.78/0.51/0	0/0/0	3/2/0/
083	68/0/67 (H)	0.01/0/0.01	0.12/0/0.12	0/0/0	1/0/1
084	6/5/0/ (M)				
086	271/274/0 (H)	0.59/0.67/0	0.73/0.71/0	0/0/0	3/3/0/
088	15/15/0 (H)	1.53/1.13/0	1.06/0.74/0	0/0/0	4/2/0/
089	26/34/0 (H); 26/34/0 (M)	1.27/1.74/0	0.78/0.99/0	0/0/0	3/4/0/
090	77/75/0 (H)	1.06/0.97/0	0.71/0.75/0	0/0/0	2/2/0/
095	134/68 (H)	1.05/1.03/0	0.84/0.91/0	0/0/0	3/4/0/
106	16/0/17 (M)				
108	60/0/60 (H)	0.02/0/0.02	0.13/0/0.13	0/0/0	1/0/1
109					
112	55/65/0 (H)	1.42/1.42/0	0.92/1.03/0	0/0/0	3/4/0/
115	283/288/117 (H)	1.13/1.14/1.13	0.91/0.91/0.92	0/0/0	3/3/3/
116	259/0/89 (H)	0.24/0/0.21	0.55/0/0.46	0/0/0	3/0/2

Study	Baseline level of suicidal risk by HAM-D item 3 (H) or MADRS item 10 (M): Number of patients included in the analyses "N" by treatment group paroxetine/active comparator/placebo	Mean score - HAM-D Item 3 (H) by treatment group	SD (H)	Min (H)	Max (H)
126 (Ext. of 116)					
118	82/82/77 (H)	0.21/0.17/0.16	0.49/0.41/0.43	0/0/0	2/2/2/
127 (Ext. of 118)					
120	209/0/69 (M)				
222 (Ext. of 120)					
128	357/351/140 (H)	1.12/1.09/1.15	0.95/0.99/0.89	0/0/0	3/3/3/
131	100/99/0 (H)	0.85/0.76/0	0.99/0.96/0	0/0/0	3/3/0/
135	60/62/0 (H)	0.70/1.00/0	0.93/1.01/0	0/0/0	3/4/0/
136	201/99/99 (M)				
241 (Ext. of 136)					
184	14/14/0 (H)	1.07/1.14/0	0.62/0.77/0	0/0/0	2/2/0/
187	123/122/123 (M)				
228 (Ext. of 187)					
190	61/0/64 (H)	0.00/0/0.03	0.00/0/0.18	0/0/0	0/0/1
197	99/99/0 (M)				

Study	Baseline level of suicidal risk by HAM-D item 3 (H) or MADRS item 10 (M): Number of patients included in the analyses "N" by treatment group paroxetine/active comparator/placebo	Mean score - HAM-D Item 3 (H) by treatment group	SD (H)	Min (H)	Max (H)
201	57/0/60 (H)	0.04/0/0.07	0.19/0/0.25	0/0/0	1/0/1
223	76/76/71 (M)				
239	1727/393/0 (H)	0.94/0.89/0	1.06/0.99/0	0/0/0	4/3/0/
245	516/510/0 (M)				
251	125/0/129 (H)	0.94/0/0.94	0.80/0/0.80	0/0/0	2/0/3
256	39/34/0 (H)	1.82/1.56/0	1.19/1.13/0	0/0/0	4/4/0/
260	21/23/0 (H)	1.33/1.61/0	1.06/0.99/0	0/0/0	3/3/0/
261	62/58/0 (H)	1.21/1.21/0	1.06/0.95/0	0/0/0	4/4/0/
272	5/3/0/ (H)	1.20/0.33/0	0.84/0.58/0	0/0/0	2/1/0/
274	22/0/23 (H)	0.86/0/1.09	0.89/0/0.85	0/0/0	2/0/2
275	4/4/3 (H)	1.25/0.50/1.67	0.96/1.00/1.53	0/0/0	2/2/3/
276	20/0/21 (H)	1.50/0/1.67	0.95/0/1.02	0/0/0	3/0/3
279	21/16/10 (H)	1.62/2.06/1.30	1.02/1.18/1.06	0/0/0	3/3/3/
281	104/96/0 (H)	1.01/0.99/0	0.99/0.97/0	0/0/0	4/3/0/
289	37/39/0 (H)	2.05/2.00/0	1.37/1.49/0	0/0/0	4/4/0/
290	40/38/0 (H)	2.03/1.84/0	1.07/1.03/0	0/0/0	4/4/0/
291	41/42/0 (M)				
292	44/43/0 (H)	1.48/1.49/0	1.15/1.24/0	0/0/0	4/4/0/
308	10/12/0/ (H)	2.00/1.83/0	1.25/0.94/0	0/0/0	4/3/0/
309	10/10/0/ (H)	1.20/2.00/0	0.63/1.15/0	0/1/0	2/4/0/
310	9/10/0/ (H)	2.00/1.90/0	1.12/1.20/0	0/0/0	3/3/0/
312	2/2/0/ (H)	1.50/0.50/0	0.71/0.71/0	1/0/0	2/1/0/
314	9/8/0/ (H)	1.11/0.88/0	0.33/0.64/0	1/0/0	2/2/0/
316	9/8/0/ (H)	1.89/1.38/0	0.93/1.06/0	0/0/0	3/3/0/
318	9/12/0/ (H)	1.67/1.42/0	1.32/1.00/0	0/0/0	4/3/0/
319	1/1/0/ (H)	1.00/2.00/0		1/2/0/	1/2/0/

Study	Baseline level of suicidal risk by HAM-D item 3 (H) or MADRS item 10 (M): Number of patients included in the analyses "N" by treatment group paroxetine/active comparator/placebo	Mean score - HAM-D Item 3 (H) by treatment group	SD (H)	Min (H)	Max (H)
327	81/0/85 (H)	0.44/0/0.42	0.61/0/0.59	0/0/0	2/0/2
329	93/0/88 (H)	0.82/0/1.13	0.94/0/0.96	0/0/0	3/0/3
331	41/40/0 (H)	1.15/1.08/0	0.82/0.97/0	0/0/0	3/3/0/
352	35/39/43 (H)	1.03/0.95/1.02	1.07/0.97/0.94	0/0/0	3/3/3/
377	181/0/95 (M)				
382					
470 (Ext. of 382)					
400					
427					
448	212/0/103 (H)	1.09/0/103	0.87/0/0.81	0/0/0	3/0/3
449	223/0/110 (H)	1.01/0/1.15	0.91/0/1.03	0/0/0	3/0/3
453	96/0/98 (H)	0.08/0/0.09	0.35/0/0.38	0/0/0	2/0/2
454					
487	214/0/109 (H)	0.80/0/0.78	0.76/0/0.81	0/0/0	3/0/3
494					

Study	Baseline level of suicidal risk by HAM-D item 3 (H) or MADRS item 10 (M): Number of patients included in the analyses "N" by treatment group paroxetine/active comparator/placebo	Mean score - HAM-D Item 3 (H) by treatment group	SD (H)	Min (H)	Max (H)
495					
497					
502					
595	162/0/161 (H)	0.05/0/0.07	0.22/0/0.30	0/0/0	1/0/2
625	112/0/117 (M)				
627	157/0/161 (M)				
637	187/0/185 (M)				
641	386/0/180 (M)				
642	164/0/166 (M)				
646	278/0/288 (M)				
648	163/0/160 (M)				
650	88/0/88 (M)				
651	375/0/187 (M)				
676					
677					
688					
689					
711 (Ext. of 677, 688 & 689)					

Study	Baseline level of suicidal risk by HAM-D item 3 (H) or MADRS item 10 (M): Number of patients included in the analyses "N" by treatment group paroxetine/active comparator/placebo	Mean score - HAM-D Item 3 (H) by treatment group	SD (H)	Min (H)	Max (H)
701					
704					
785	197/205/105 (M)				
790	186/0/184 (H)	0.01/0/0.05	0.07/0/0.23	0/0/0	1/0/1
791	167/0/166 (M)				
810	306/0/148 (H)	0.74/0/0.89	0.73/0/0.77	0/0/0	3/0/3

Study	Mean score - MADRS Item 10 (M) by treatment group	SD (M)	Min (M)	Max (M)
001	1.56/0/1.80	0.82/0/0.96	0/0/0	3/0/3
002	2.03/0/2.00	0,96/0/0.96	0/0/0	5/0/5
003	1.76/1.85/1.79	1.09/1.00/1.09	0/0/0	4/4/4/
006 and 011	1.88/1.91/0, 1.32/1.51/0	1.17/1.28/0, 0.73/0.94/0	0/0/0, 0/0/0	4/5/0/, 4/4/0/
007	3.00/3.15/2.55	1.08/1.14/0.82	1/1/2/	4/5/4/
009	1.54/0/1.47	1.06/0/1.05	0/0/0	4/0/3
019				
020				
022				
025				
026				
027				
028				
029				
030				
032				
035				
038				
043				
046				
047				
049				
057	1.94/0/1.91	1.41/0/1.55	0/0/0	6/0/6
059	1.96/1.80/0	1.1./1.12/0	0/0/0	4/6/0/
060	1.72/1.45/0	1.10/1.02/0	0/0/0	5/4/0/
061	2.30/2.12/0	1.06/1.11/0	1/0/0	4/4/0/
063	1.48/1.58/0	1.12/1.26/0	0/0/0	4/4/0/

Study	Mean score - MADRS Item 10 (M) by treatment group	SD (M)	Min (M)	Max (M)
064	1.61/1.68/0	1.04/1.22/0	0/0/0	4/4/0/
065	2.14/1.72/0	1.43/0.85/0	0/1/0	4/4/0/
069	2.56/2.54/0	1.41/1.15/0	1/1/0/	6/6/0/
070	1.53/1.77/0	0.92/1.36/0	0/0/0	4/5/0/
071				
073	3.00/1.75/0	1.55/1.50/0	1/1/0/	5/4/0/
074				
076				
077				
078				
079	1.49/1.62/0	0.66/0.68/0	1/1/0/	3/3/0/
080	2.10/2.55/0	0.99/1.21/0	1/1/0/	4/4/0/
082	1.59/1.62/0	0.96/0.55/0	0/1/0	4/3/0/
083				
084	2.33/2.00/0	1.21/1.00/0	1/1/0/	4/3/0/
086				
088				
089	2.31/2.65/0	1.09/1.12/0	0/1/0	4/5/0/
090				
095				
106	2.63/0/2.47	1.78/0/1.37	0/0/0	6/0/6
108				
109				
112				
115				
116				

Study	Mean score - MADRS Item 10 (M) by treatment group	SD (M)	Min (M)	Max (M)
126 (Ext. of 116)				
118				
127 (Ext. of 118)				
120	0.52/0/0.36	0.79/0/0.64	0/0/0	4/0/3
222 (Ext. of 120)				
128				
131				
135				
136	0.67/0.51/0.67	0.94/0.64/0.89	0/0/0	5/2/4/
241 (Ext. of 136)				
184				
187	0.37/0.44/0.39	0.61/0.69/0.64	0/0/0	3/3/3/
228 (Ext. of 187)				
190				
197	1.23/1.17/0	1.07/1.05/0	0/0/0	4/4/0/

Study	Mean score - MADRS Item 10 (M) by treatment group	SD (M)	Min (M)	Max (M)
201				
223	0.34/0.45/0.44	0.68/0.91/0.84	0/0/0	3/4/4/
239				
245	1.57/1.42/0	1.10/1.08/0	0/0/0	6/6/0/
251				
256				
260				
261				
272				
274				
275				
276				
279				
281				
289				
290				
291	1.59/1.40/0	1.32/1.11/0	0/0/0	5/4/0/
292				
308				
309				
310				
312				
314				
316				
318				
319				

Study	Mean score - MADRS Item 10 (M) by treatment group	SD (M)	Min (M)	Max (M)
327				
329				
331				
352				
377	1.76/0/1.66	1.38/0/1.48	0/0/0	5/0/5
382				
470 (Ext. of 382)				
400				
427				
448				
449				
453				
454				
487				
494				

Study	Mean score - MADRS Item 10 (M) by treatment group	SD (M)	Min (M)	Max (M)
495				
497				
502				
595				
625	1.16/0/1.02	1.04/0/1.03	0/0/0	4/0/4
627	0.92/0/1.00	1.07/0/1.12	0/0/0	4/0/4
637	0.20/0/0.20	0.44/0/0.44	0/0/0	2/0/2
641	0.16/0/0.16	0.39/0/0.41	0/0/0	2/0/2
642	0.14/0/0.16	0.38/0/0.40	0/0/0	2/0/2
646	0.03/0/0.01	0.17/0/0.12	0/0/0	1/0/1
648	0.72/0/0.66	1.01/0/0.85	0/0/0	4/0/4
650	0.14/0/0.13	0.46/0/0.40	0/0/0	3/0/2
651	0.96/0/0.90	0.99/0/0.89	0/0/0	4/0/4
676				
677				
688				
689				
711 (Ext. of 677, 688 & 689)				

Study	Mean score - MADRS Item 10 (M) by treatment group	SD (M)	Min (M)	Max (M)
701				
704				
785	1.61/1.56/1.49	1.07/1.05/1.08	0/0/0	4/5/4/
790				
791	0.17/0/0.19	0.41/0/0.47	0/0/0	2/0/2
810				

Study	Previous exposure to paroxetine - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*	Previous exposure to any SSRI - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*
001	0/25 (0.0%); -; 0/25 (0.0%)	0/25 (0.0%); -; 0/25 (0.0%)
002	0/170 (0.0%); -; 0/171 (0.0%)	0/170 (0.0%); -; 0/171 (0.0%)
003	0/241 (0.0%); 0/241 (0.0%); 0/244 (0.0%)	0/241 (0.0%); 0/241 (0.0%); 0/244 (0.0%)
006 and 011	0/33 (0.0%); 0/33 (0.0%); - : 0/103 (0.0%); 0/103 (0.0%); -	0/33 (0.0%); 0/33 (0.0%); - : 0/103 (0.0%); 0/103 (0.0%); -
007	0/13 (0.0%); 0/13 (0.0%); 0/12 (0.0%)	0/13 (0.0%); 0/13 (0.0%); 0/12 (0.0%)
009	0/421 (0.0%); - ; 0/53 (0.0%)	0/421 (0.0%); - ; 0/53 (0.0%)
019	0/31 (0.0%); 0/35 (0.0%); -	0/31 (0.0%); 0/35 (0.0%); -
020	0/24 (0.0%); 0/24 (0.0%); -	0/24 (0.0%); 0/24 (0.0%); -
022	0/16 (0.0%); 0/17 (0.0%); -	0/16 (0.0%); 0/17 (0.0%); -
025	0/4 (0.0%); 0/4 (0.0%); -	0/4 (0.0%); 0/4 (0.0%); -
026	0/30 (0.0%); 0/30 (0.0%); -	0/30 (0.0%); 0/30 (0.0%); -
027	0/17 (0.0%); 0/15 (0.0%); -	0/17 (0.0%); 0/15 (0.0%); -
028	0/8 (0.0%); 0/6 (0.0%); -	0/8 (0.0%); 0/6 (0.0%); -
029	0/4 (0.0%); 0/5 (0.0%); -	0/4 (0.0%); 0/5 (0.0%); -
030	0/21 (0.0%); 0/19 (0.0%); -	0/21 (0.0%); 0/19 (0.0%); -
032	0/30 (0.0%); 0/30 (0.0%); -	0/30 (0.0%); 0/30 (0.0%); -
035	0/3 (0.0%); 0/4 (0.0%); -	0/3 (0.0%); 0/4 (0.0%); -
038	0/32 (0.0%); 0/29 (0.0%); -	0/32 (0.0%); 0/29 (0.0%); -
043	0/15 (0.0%); 0/18 (0.0%); -	0/15 (0.0%); 0/18 (0.0%); -
046	0/21 (0.0%); 0/22 (0.0%); -	0/21 (0.0%); 0/22 (0.0%); -
047	0/46 (0.0%); 0/49 (0.0%); -	0/46 (0.0%); 0/49 (0.0%); -
049	0/62 (0.0%); 0/32 (0.0%); -	0/62 (0.0%); 0/32 (0.0%); -
057	0/131 (0.0%); -; 0/136 (0.0%)	3/131 (2.29%); -; 2/136 (1.47%)
059	0/72 (0.0%); 0/71 (0.0%); -	0/72 (0.0%); 0/71 (0.0%); -
060	0/44 (0.0%); 0/47 (0.0%); -	0/44 (0.0%); 1/47 (2.13%); -
061	0/54 (0.0%); 0/52 (0.0%); -	1/54 (1.85%); 1/52 (1.92%); -
063	0/21 (0.0%); 0/19 (0.0%); -	0/21 (0.0%); 0/19 (0.0%); -

Study	Previous exposure to paroxetine - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*	Previous exposure to any SSRI - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*
064	0/49 (0.0%); 0/50 (0.0%); -	1/49 (2.04%); 1/50 (2.00%); -
065	0/28 (0.0%); 0/32 (0.0%); -	1/28 (3.57%); 0/32 (0.0%); -
069	0/45 (0.0%); 0/46 (0.0%); -	0/45 (0.0%); 1/46 (2.17%); -
070	0/32 (0.0%); 0/30 (0.0%); -	0/32 (0.0%); 0/30 (0.0%); -
071	0/9 (0.0%); 0/9 (0.0%); -	0/9 (0.0%); 0/9 (0.0%); -
073	0/6 (0.0%); 0/4 (0.0%); -	0/6 (0.0%); 0/4 (0.0%); -
074	0/20 (0.0%); 0/20 (0.0%); -	0/20 (0.0%); 0/20 (0.0%); -
076	0/4 (0.0%); 0/4 (0.0%); 0/4 (0.0%)	0/4 (0.0%); 0/4 (0.0%); 0/4 (0.0%)
077	0/46 (0.0%); 0/46 (0.0%); -	0/46 (0.0%); 0/46 (0.0%); -
078	0/155 (0.0%); 0/153 (0.0%); -	0/155 (0.0%); 0/153 (0.0%); -
079	0/45 (0.0%); 0/45 (0.0%); -	1/45 (2.22%); 0/45 (0.0%); -
080	0/10 (0.0%); 0/13 (0.0%); -	1/10 (10.0%); 0/13 (0.0%); -
082	0/37 (0.0%); 0/34 (0.0%); -	0/37 (0.0%); 1/34 (2.94%); -
083	68/68 (100.0%); -; 67/67 (100.0%)	68/68 (100.0%); -; 67/67 (100.0%)
084	0/6 (0.0%); 0/5 (0.0%); -	0/6 (0.0%); 0/5 (0.0%); -
086	0/271 (0.0%); 0/275 (0.0%); -	0/271 (0.0%); 0/275 (0.0%); -
088	0/16 (0.0%); 0/15 (0.0%); -	0/16 (0.0%); 0/15 (0.0%); -
089	0/26 (0.0%); 0/34 (0.0%); -	0/26 (0.0%); 0/34 (0.0%); -
090	0/79 (0.0%); 0/78 (0.0%); -	0/79 (0.0%); 0/78 (0.0%); -
095	0/134 (0.0%); 0/68 (0.0%); -	0/134 (0.0%); 0/68 (0.0%); -
106	0/18 (0.0%); -; 0/18 (0.0%)	0/18 (0.0%); -; 0/18 (0.0%)
108	0/60 (0.0%); -; 0/60 (0.0%)	0/60 (0.0%); -; 0/60 (0.0%)
109	0/65 (0.0%); 0/67 (0.0%); -	5/65 (7.69%); 1/67 (1.49%); -
112	0/55 (0.0%); 0/65 (0.0%); -	1/55 (1.82%); 1/65 (1.54%); -
115	0/283 (0.0%); 0/288 (0.0%); 0/117 (0.0%)	0/283 (0.0%); 0/288 (0.0%); 0/117 (0.0%)
116	0/259 (0.0%); -; 0/89 (0.0%)	0/259 (0.0%); -; 0/89 (0.0%)

Study	Previous exposure to paroxetine - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*	Previous exposure to any SSRI - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*
126 (Ext. of 116)		
118	0/82 (0.0%); 0/82 (0.0%); 0/77 (0.0%)	0/82 (0.0%); 0/82 (0.0%); 0/77 (0.0%)
127 (Ext. of 118)		
120	0/209 (0.0%); -; 0/69 (0.0%)	0/209 (0.0%); -; 0/69 (0.0%)
222 (Ext. of 120)		
128	0/357 (0.0%); 0/351 (0.0%); 0/140 (0.0%)	0/357 (0.0%); 0/351 (0.0%); 0/140 (0.0%)
131	0/100 (0.0%); 0/99 (0.0%); -	5/100 (5.00%); 1/99 (1.01%); -
135	0/60 (0.0%); 0/62 (0.0%); -	0/60 (0.0%); 0/62 (0.0%); -
136	0/201 (0.0%); 0/99 (0.0%); 0/99 (0.0%)	9/201 (4.48%); 2/99 (2.02%); 3/99 (3.03%)
241 (Ext. of 136)		
184	0/14 (0.0%); 0/14 (0.0%); -	0/14 (0.0%); 0/14 (0.0%); -
187	0/123 (0.0%); 0/122 (0.0%); 0/123 (0.0%)	0/123 (0.0%); 0/122 (0.0%); 0/123 (0.0%)
228 (Ext. of 187)		
190	61/61 (100.0%); -; 64/64 (100.0%)	61/61 (100.0%); -; 64/64 (100.0%)
197	0/99 (0.0%); 0/99 (0.0%); -	1/99 (1.01%); 1/99 (1.01%); -

Study	Previous exposure to paroxetine - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*	Previous exposure to any SSRI - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*
201	0/57 (0.0%); -; 0/60 (0.0%)	2/57 (3.51%); -; 0/60 (0.0%)
223	0/76 (0.0%); 0/77 (0.0%); 0/71 (0.0%)	0/76 (0.0%); 0/77 (0.0%); 0/71 (0.0%)
239	0/1766 (0.0%); 0/402 (0.0%); -	4/1766 (0.21%); 0/402 (0.25%); -
245	0/517 (0.0%); 1/510 (0.20%); -	7/517 (1.35%); 9/510 (1.76%); -
251	0/125 (0.0%); -; 0/129 (0.0%)	0/125 (0.0%); -; 0/129 (0.0%)
256	0/39 (0.0%); 0/34 (0.0%); -	0/39 (0.0%); 0/34 (0.0%); -
260	0/21 (0.0%); 0/23 (0.0%); -	0/21 (0.0%); 0/23 (0.0%); -
261	0/62 (0.0%); 0/58 (0.0%); -	0/62 (0.0%); 0/58 (0.0%); -
272	0/5 (0.0%); 0/3 (0.0%); -	0/5 (0.0%); 0/3 (0.0%); -
274	0/22 (0.0%); -; 0/23 (0.0%)	0/22 (0.0%); -; 0/23 (0.0%)
275	0/4 (0.0%); 0/4 (0.0%); 0/3 (0.0%)	0/4 (0.0%); 0/4 (0.0%); 0/3 (0.0%)
276	0/20 (0.0%); -; 0/21 (0.0%)	0/20 (0.0%); -; 0/21 (0.0%)
279	0/21 (0.0%); 0/16 (0.0%); 0/10 (0.0%)	0/21 (0.0%); 0/16 (0.0%); 0/10 (0.0%)
281	0/106 (0.0%); 0/98 (0.0%); -	0/106 (0.0%); 0/98 (0.0%); -
289	0/42 (0.0%); 0/44 (0.0%); -	0/42 (0.0%); 0/44 (0.0%); -
290	0/40 (0.0%); 0/39 (0.0%); -	0/40 (0.0%); 0/39 (0.0%); -
291	0/41 (0.0%); 0/42 (0.0%); -	0/41 (0.0%); 0/42 (0.0%); -
292	0/46 (0.0%); 0/44 (0.0%); -	0/46 (0.0%); 0/44 (0.0%); -
308	0/10 (0.0%); 0/12 (0.0%); -	0/10 (0.0%); 0/12 (0.0%); -
309	0/11 (0.0%); 0/10 (0.0%); -	0/11 (0.0%); 0/10 (0.0%); -
310	0/9 (0.0%); 0/10 (0.0%); -	0/9 (0.0%); 0/10 (0.0%); -
312	0/2 (0.0%); 0/2 (0.0%); -	0/2 (0.0%); 0/2 (0.0%); -
314	0/10 (0.0%); 0/8 (0.0%); -	0/10 (0.0%); 0/8 (0.0%); -
316	0/9 (0.0%); 0/8 (0.0%); -	0/9 (0.0%); 0/8 (0.0%); -
318	0/9 (0.0%); 0/12 (0.0%); -	0/9 (0.0%); 0/12 (0.0%); -
319	0/1 (0.0%); 0/1 (0.0%); -	0/1 (0.0%); 0/1 (0.0%); -

Study	Previous exposure to paroxetine - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*	Previous exposure to any SSRI - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*
327	1/81 (1.23%); -; 2/85 (2.35%)	27/81 (33.3%); -; 30/85 (35.3%)
329	0/93 (0.0%); -; 0/88 (0.0%)	2/93 (2.15%); -; 1/88 (1.14%)
331	2/41 (4.88%); 1/40 (2.50%); -	8/41 (19.5%); 5/40 (12.5%); -
352	3/35 (8.57%); 4/39 (10.3%); 4/43 (9.30%)	19/35 (54.3%); 23/39 (59.0%); 21/43 (48.8%)
377	0/181 (0.0%); -; 0/95 (0.0%)	2/181 (1.10%); -; 0/95 (0.0%)
382	0/94 (0.0%); -; 1/93 (1.08%)	4/94 (4.26%); -; 3/93 (3.23%)
470 (Ext. of 382)		
400	0/31 (0.0%); -; 0/17 (0.0%)	0/31 (0.0%); -; 0/17 (0.0%)
427	0/29 (0.0%); -; 0/9 (0.0%)	0/29 (0.0%); -; 0/9 (0.0%)
448	12/212 (5.66%); -; 6/103 (5.83%)	96/212 (45.3%); -; 48/103 (46.6%)
449	20/223 (8.97%); -; 7/110 (6.36%)	93/223 (41.7%); -; 46/110 (41.8%)
453	96/96 (100.0%); -; 98/98 (100.0%)	96/96 (100.0%); -; 98/98 (100.0%)
454	3/289 (1.04%); -; 0/95 (0.0%)	22/289 (7.61%); -; 5/95 (5.26%)
487	13/214 (6.07%); -; 5/109 (4.59%)	72/214 (33.6%); -; 33/109 (30.3%)
494	8/141 (5.67%); -; 7/148 (4.73%)	36/141 (25.5%); -; 34/148 (23.0%)

Study	Previous exposure to paroxetine - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*	Previous exposure to any SSRI - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*
495	8/162 (4.94%); -; 10/165 (6.06%)	34/162 (21.0%); -; 56/165 (33.9%)
497	7/149 (4.70%); -; 8/144 (5.56%)	29/149 (19.5%); -; 31/144 (21.5%)
502	7/139 (5.04%); -; 5/151 (3.31%)	31/139 (22.3%); -; 27/151 (17.9%)
595	162/162 (100.0%); -; 161/161 (100.0%)	162/162 (100.0%); -; 161/161 (100.0%)
625	4/112 (3.57%); -; 1/117 (0.85%)	8/112 (7.14%); -; 9/117 (7.69%)
627	5/160 (3.13%); -; 5/162 (3.09%)	27/160 (16.9%); -; 29/162 (17.9%)
637	1/187 (0.53%); -; 5/185 (2.70%)	11/187 (5.88%); -; 9/185 (4.86%)
641	0/386 (0.0%); -; 2/180 (1.1%)	18/386 (4.66%); -; 10/180 (5.56%)
642	0/164 (0.0%); -; 3/166 (1.81%)	5/164 (3.05%); -; 11/166 (6.63%)
646	278/278 (100.0%); -; 288/288 (100.0%)	278/278 (100.0%); -; 288/288 (100.0%)
648	2/163 (1.23%); -; 2/160 (1.25%)	12/163 (7.36%); -; 7/160 (4.38%)
650	88/88 (100.0%); -; 88/88 (100.0%)	88/88 (100.0%); -; 88/88 (100.0%)
651	9/375 (2.40%); -; 2/188 (1.06%)	38/375 (10.1%); -; 18/188 (9.57%)
676	4/165 (2.42%); -; 6/157 (3.82%)	10/165 (6.06%); -; 12/157 (7.64%)
677	0/212 (0.0%); -; 0/109 (0.0%)	0/212 (0.0%); -; 0/109 (0.0%)
688	0/242 (0.0%); -; 0/119 (0.0%)	0/242 (0.0%); -; 0/119 (0.0%)
689	0/246 (0.0%); -; 0/125 (0.0%)	0/246 (0.0%); -; 0/125 (0.0%)
711 (Ext. of 677, 688 & 689)		

Study	Previous exposure to paroxetine - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*	Previous exposure to any SSRI - n/N (%) by treatment group Paroxetine; Comparator; Placebo *'-' indicates that one of these treatment groups wasn't present in a study*
701	6/104 (5.77%); -; 3/102 (2.94%)	23/104 (22.1%); -; 16/102 (15.69%)
704	6/99 (6.06%); -; 5/107 (4.67%)	18/99 (18.18%); -; 24/107 (22.43%)
785	7/197 (3.55%); 5/206 (2.43%); 2/105 (1.90%)	20/197 (10.2%); 22/206 (10.7%); 11/105 (10.5%)
790	3/186 (1.61%); -; 0/184 (0.0%)	20/186 (10.8%); -; 14/184 (7.61%)
791	4/167 (2.40%); -; 4/166 (2.41%)	11/167 (6.59%); -; 16/166 (9.64%)
810	13/306 (4.25%); -; 2/148 (1.35%)	43/306 (14.0%); -; 15/148 (10.1%)