Table 2.00 Table of Studies within the Central R&D Aggregated Database

CPMS Study Number	Study Number / Name	Alternative Study Number (if applicable)	Study Title
001	Study 001	PAR 01.001	
002	Study 002	PAR 02.001, 02.002, 02.003, & 02.004	
003	Study 003	PAR 03.001, 03.002, 03.003, 03.004, 03.005, & 03.006	
004	Study 004	PAR 04	A double-blind extension of protocol PAR03 (003)
005	Study 005	PAR 05	An open-label evaluation of Paroxetine in depressed outpatients
006	Study 006	PAR 06	A multi-centre, doxepin-controlled, double-blind study of Paroxetine in geriatric outpatients with major depressive disorders
007	Study 007	07-001	
009	Study 009	PAR 09	
011	Study 011	PAR 11	A multi-centre, doxepin-controlled, double-blind study of Paroxetine in geriatric outpatients with major depressive disorders
018	MDINT02 Gagiano OPEN	MDSA/29060/III/86/118 2A	To assess the tolerance of Paroxetine in short and long term therapy and to access the efficacy and tolerance in a subset of patients of whom

			therapy has failed in the past
019	MDINT03 Gagiano COMP	MDSA/29060/III/86/03	A double-blind comparison between amitriptyline and Paroxetine in major depressive disorders
020	MDUK20 Akhtar	MDUK/29060/III/84/020	Protocol to access the effectiveness and tolerance of Paroxetine in depressed patients by double blind comparison with mianserin 21-75g
022	MDUK22 Carle/Pender	MDUK/2960/III/83/022	Carle/Pender: Protocol to access the effectiveness and tolerance of Paroxetine by double-blind comparison with mianserin
024	MDUK24 Shanks	MDUK/29060/III/85/024	Shanks: Protocol to investigate the pharmacokinetics of Paroxetine in younger depressed patients
025	MDUK25 Ecclestone	MDUK/29060/III/86/025	Ecclestone: A double-blind parallel group study comparing paroxetine 30mg daily and clomipramine 100mg daily
026	MDUK26 Dorman	MDUK/29060/026	Dorman: Protocol to access the effectiveness and tolerance of Paroxetine in elderly depressed patients by double-blind comparison with mianserin
027	MDUK27 Peet / Ghadvi	MDUK/29060/III/85/027	Protocol to access the effectiveness and tolerance of Paroxetine by double-blind comparison with imipramine
028	MDUK28 Bray	MDUK/29060/III/85/028	Protocol to access the efficacy and tolerability of Paroxetine by double-blind comparison with amitriptyline in patients referred to a Psychiatric clinic (> 65 years)
029	MDUK29 Sud	MDUK/29060/III/85/029	Protocol to access the efficacy and tolerability of Paroxetine by double-blind comparison with amitriptyline in patients referred to a Psychiatric clinic (18- 65 years)

030	MDUK30 Shur	MDUK/2960/III/85/030	Protocol to access the efficacy and tolerability of Paroxetine by double-blind comparison with mianserin in patients referred to a Psychiatric clinic (18- 65 years)
032	MDUK32 Beaumont	MDUK/032	Beaumont - Protocol to access the efficacy and tolerability of Paroxetine by double-blind comparison with amitriptyline followed by an open tolerability study of Paroxetine alone in general practice
034	MDUK34 Trimble	MDUK/29060/III/85/034	Trimble - Protocol to assess the efficacy and tolerability of Paroxetine in epileptic patients with depression
035	MDUK35 Toone	MDUK/29060/III/84/035	Toone - Protocol to assess the effectiveness and tolerance of Paroxetine by double-blind comparison with amitriptyline
037	MDUK37 MC	MDUK/29060/III/85/037	Chakravarti / Siddiqui / Carle: Protocol for an open, long-term safety and tolerability study of Paroxetine in Patients suffering from depression
038	MDUK38 Chakravarti	MDUK/29060/III/85/038	Chakravarti: Protocol to access the effectiveness and tolerance of Paroxetine in depressed patients by double-blind comparison with mianserin
040	MDUK40 Ghose	MDUK/29060/III/85/040	Ghose: Protocol to investigate the pharmacokinetics of Paroxetine in elderly depressed Patients
041	MDUK41 Wade	MDUK/PAR/85/041	Protocol to access the effciacy and tolerability of Paroxetine by double-blind comparison of morning and evening dosages 18-65yrs
042	MDUK42 Wade	MDUK/29060/III/86/042	Protocol to assess the efficacy and tolerability of Paroxetine by double-blind comparison of morning and evening dosages >65 yrs

043	MDUK43 Winslow	MDUK/29060/III/85/043	Protocol to assess the effectiveness and tolerance of Paroxetine in depressed Patients by double-blind comparison with amitriptyline 18-70 yrs
044	MDUK44 Rao/Singh	MDUK/29060/III/85/044	Rao/Singh: Protocol to assess the efficacy and tolerability of Paroxetine by double-blind trial in elderly depressed patients followed by an open tolerability study
046	MDUK46 Addala	MDUK/29060/III/86/046	A protocol to assess the effectiveness and tolerability of Paroxetine in elderly depressed patients by double-blind comparison with amitriptyline
047	Study 047		A protocol to assess the effectiveness and tolerability of Paroxetine in depressed patients by double-blind comparison with Dothiepin (prothiden) 18-65 yrs
049	MDUK49 Hutchinson	MDUK/29060/III/87/049	A multicentre general practice study to compare the effectiveness and tolerability of paroxetine in elderly depressed patients by double-blind comparison with amitriptyline
057	Study 057		
059	Study 059		Comparison of pharmacodynamics and pharmacokinetics of oral Paroxetine and amitriptyline in adults with depression
060	Study 060		Comparison of pharmacodynamics and pharmacokinetics of oral Paroxetine and amitriptyline in geriatric patients with depression
061	Study 061		Comparison of Paroxetine and fluoxetine in geriatric patients with depression

062	Study 062		An interaction study of Paroxetine on lithium serum levels in depressed patients on lithium therapy
063	Study 063		A double-blind randomised trial comparing the effects on sleep of Paroxetine 30mg daily and amitriptyline 150mg daily in patients 18-65yrs
064	Study 064		A double-blind comparative multicentre study comparing Paroxetine bd with fluoxetine (Prozac) bd in depressed patients 18-65yrs
065	Study 065		A double-blind comparative study comparing Paroxetine 20-40mg od to maprotiline 50-150mg/day
067	Study 067		An open pharmacokinetic study of Paroxetine (30, 40 or 50mg daily) in the treatment of major depressive disorder 18-65yrs
068	Study 068		An open pharmacokinetic study of Paroxetine (20, 30 or 40mg daily) in the treatment of major depressive disorder >65yrs
069	Study 069		A multicentre double-blind parallel group randomised dose titration study comparing the pharmacodynamics and pharmacokinetics of paroxetine and clomipramine in patients <60yrs
070	Study 070		A multicentre double blind parallel group randomised dose titration study comparing the efficacy of paroxetine and clomipramine >60yrs
071	MDF 1729, 1730, 1731	includes MDED/29060/III/17	Clinical Study of the efficiency, the tolerance and study of the anti-depressant effect of paroxetine by daily EEG, sleep

		29M	EEG and cerebral blood flow in elderly depressed patients
072	Study 072		An open pharmacokenetic study of paroxetine [20, 30 or 40mg daily] in the treatment of major depressive disorder 18-65yr
073	Study 073		Comparison of pharmacodynamics and pharmacokinteics of oral paroxetine and amitriptyline in adult patients with depression.
074	Study 074		Study comparing the effects of oral paroxetine and amitriptyline In adult patients with depression.
076	Study 076		
077	Study 077		Study comparing the effects of oral paroxetine and amitriptyline In adult patients with depression.
078	Study 078		A multicentre double-blind randomised study comparing 20mg to 30mg of paroxetine and amitriptyline 75mg to 150mg 18-65yr
079	Study 079		A double blind comparative multicentre study comparing paroxetine BD with fluoxetine BD in depressed patients
080	Study 080		A multicentre double-blind parallel group randomised study comparing paroxetine 30mg and clomipramine 150mg in patients with major depression
081	Study 081		An open pharmacokenetic and pharmacodynamics study of paroxetine (20, 30 or 40mg daily) in the treatment of major depressive disorders 18-65yr

082	Study 082		A double-blind comparative study comparing paroxetine 20-40mg/day to maprotiline 50-150mg/day in major depression 18-65yr.
083	Study 083		
084	Study 084		A double-blind comparative study of the effects of paroxetine and clomipramine on cognitive function in elderly patients with major depression
086	Study 086		A controlled double-blind randomised parallel group study comparing the effects of paroxetine and maprotiline in the treatment of outpatients with major and minor depression [RDC]
088	DFG 123 P31	DFG/29060/III/86/123	A randomised, double-blind comparative study of paroxetine and imipramine including evaluation of effect profiles and correlation between plasma concentration and effect.
089	DFG 124 P32	DFG/29060/III/86/124M	A randomised double-blind comparative clinical study of paroxetine and imipramine including evaluation of efficacy profiles and safety
090	DFG 125 P33		A double-blind controlled group comparison of paroxetine and imipramine in the treatment of depressive states in psychiatric specialist practice
094	Study 094		A double-blind comparative study to assess the safety and tolerability of paroxetine 60mg (two dosing regimins). Short and long-term.
095	Study 095		A double-blind comparative study of the withdrawal effects following abrupt discontinuation of treatment with paroxetine

			in low or high dose or imipramine
106	Study 106		
108	Study 108		
109	Study 109		To compare the effectiveness of Paroxetine, amitriptyline and lithium in recurrent depressives for relapse
112	Study 112		A double-blind multicentre study to compare the efficacy and tolerance of Paroxetine and fluvoxamine in depressed patients
115	Study 115		
116	Study 116		
118	Study 118		
120	Study 120		
126	Study 126		PAR-116E: A long-term, open-label extension trial of Paroxetine in the treatment of outpatients with obsessive - compulsive disorders
127	Study 127		PAR-118E: A long-term, open-label extension trial of Paroxetine in the treatment of outpatients with obsessive - compulsive disorders
128	Study 128		
Study 131			A study to compare the efficacy and tolerance of fluoxetine and Paroxetine in adult patients

Study 135			Paroxetine versus fluoxetine 18-65 yrs
Study 136			
MDUK28a Bray	MDUK/29060/III/85/028 A		O28A: Protocol to assess the efficacy and tolerability of Paroxetine by double-blind comparison with amitriptyline in Patients referred to a psychiatric clinic 18-65 yrs
Study 187			
Study 189			Fluoxetine switch
Study 190			
Study 197			A double-blind comparison of the efficacy and tolerability of Paroxetine and imipramine in the treatment of depression and behavioural disturbance associated with dementia
Study 201			
Study 222			Long-term treatment of panic disorder (with/without agoraphobia) with Paroxetine: an extension trial for the fixed-dose study in daily flexible doses of 10mg, 20mg or 40mg and matching placebo
Study 223	Study 223		
228	Study 228		Long-term (9 month) extension of double-blind placebo controlled comparative study of Paroxetine and clomipramine in the treatment of panic disorders
239	Study 239		A randomised comparative study of Paroxetine in the treatment of depression as used in a clinical practice setting

241	Study 241		A double-blind study to compare the maintenance of efficacy and relapse rates in patients with obsessive compulsive disorder who responded to Paroxetine, clomipramine or placebo in the short-term study 136.
245	Study 245		A double-blind multicentre study in primary care comparing Paroxetine and clomipramine in patients with depression with associated anxiety
251	Study 251		
252	Austrian MC Open	MDED/29060/III/85/102/3/4M	Austrian open
253	MDA2 Hebenstreit	MDA/29060/III/2/3/4	An open pharmacokinetic and pharmacodynamic study of Paroxetine (20mg, 30mg or 40mg daily) in the treatment of major depressive disorder (DSM III)
254	MDA3 Hebenstreit	MDA/29060/III/2/3/4	An open pharmacokinetic and pharmacodynamic study of paroxetine (20mg, 30mg, or 40mg daily) in the treatment of major depressive disorder (DSM 111) in geriatric patients (>65 years old).
255	MDA4 Hebenstreit	MDA/29060/III/2/3/4	An open pharmacokinetic and pharmacodynamic study of paroxetine (30mg, 40mg, or 50mg daily) in the treatment of major depressive disorder (DSM 111)
256	Belgium M/C Comp	MDB/PAR/1/B/C/D/EM	A study of the efficacy and safety of paroxetine compared to mianserin in patients with depression (Part III multicentre study).
257	Belgium MC Open	MDB 29060/3/4/5/6/7/8/	Belgian open.

		9M	
258	61101 BORUP P42	RAD/Paroxetine/C/2	Open clinical evaluation of paroxetine in depressive patients
259	61102 Skausig P6	RAD/Paroxetine/C/3	Open clinical evaluation of paroxetine in depressive patients
260	61201 L Laursen P41	RAD/Paroxetine/C/4	A double-blind group comparative evaluation of paroxetine's and amitriptyline's effect in the treatment of depressive illness
261	DFG 119 DUAG P30	DFG/2960/III/85/119 DUAG	A randomised double-blind comparative clinical study including evaluation of efficacy profiles and of correlation between plasma concentration and effect.
262	DFG121 Thomsen P45 / DFG126 Pauser P46	DFG/29060/III/86/121 + 126	Paroxetine in the treatment of endogenous depression in elderly patients. Treatment of major depression in the elderly with paroxetine - an open study of efficacy and tolerance.
268	MDCH 1/2 MC OPEN	MDCH/29060/III/86/01/02	A study of the efficacy and safety of paroxetine in patients with depression.
272	MDUK04 Lavin	MDUK/29060/III/84/004	Lavin/Ghose: Protocol to assess the effectiveness and tolerance of paroxetine by double-blind comparison with amitriptyline.
273	MDUK05 Coreless		Corless: Protocol to investigate the pharmacokinetics of paroxetine in geriatric patients.
274	MDUK06 Naylor	MDUK/29060/III/82/006	

275	MDUK07 Silverstone	MDUK/2960/III/83/007	
276	MDUK09 Edwards	MD/PAR/009	
279	MDUK12 Trimble	MDUK/29060/III/83/12	
280	MDUK12a Trimble	MDUK/29060/III/83/12A	Trimble (presumably an open extension of 279)
281	MDUK13 Wade	MDUK/PAR/013	Wade: Protocol to assess the effectiveness and tolerance of paroxetine by double-blind comparison with amitriptyline.
282	MDUK14 Tyrer	MDUK/PAR/014	Tyrer: To test the efficacy of paroxetine, a 5HT re-uptake inhibitor, in resistant depression.
283	MDUK14B Tyrer	MDUK/PAR/014B	Tyrer: Protocol to assess the effectiveness and tolerance of paroxetine by double-blind comparison with placebo.
286	MDUK17a Crome		Crome: Protocol to investigate the pharmacokinetics and effectiveness of paroxetine in geriatric patients.
287	MDUK17c Crome	MDUK/29060/III/86/17C	Crome: An open, long term safety study of paroxetine in geriatric patients.
289	French M/C Comp	MDF/2960/III/84/1/2/3/4/5/6 M	MDF - French comparative - A study of the efficacy and safety of paroxetine compared to clomipramine in patients with depression.
290	MDF 1727 M/C Comp	MDF/29060/1727M	Study of the efficiency and tolerance of paroxetine and clomipramine in endogenous depression of the aged subject.

291	MDF 1728 COMP	MDF/29060/1728M	Study of the efficiency and tolerance of paroxetine and clomipramine in reactional depression in the aged subject.
292	German MC Comp	MDD/2960/III/84/01-04	Multicentre double-blind randomised study comparing the effect of oral paroxetine and oral amitriptyline in adult patients with major depression.
308	HP/81/74 Laxenaire	HP/81/74A	HP/81/74 early clinical evaluation of a new antidepressant. A double-blind parallel study comparing paroxetine 30mg daily with amitriptyline 150mg daily.
309	HP/81/162a Battegay	HP/81/162A	HP/81/162. Early clinical evaluation of a new antidepressant. A double-blind parallel study comparing paroxetine 30 mg daily with amitriptyline 100mg daily.
310	HP/81/85a Varackx-Haenen	HP/81/85A	HP/81/85. Early clinical evaluation of a new antidepressant. A double-blind parallel study comparing paroxetine 30mg daily with amitriptyline 150mg daily.
311	HP/81/126a Feldman	HP/81/126A	HP/81/126 Early clinical evaluation of a new antidepressant. An open pilot study of paroxetine 40mg daily.
312	HP/83/67 Margo	HP/83/67	HP/83/67 A Phase II pharacokinetic double blind study comparing paroxetine with amitriptyline in depressed patients
313	HP/84/35a Gaind	HP/84/35a	HP/84/35 A study to assess the efficacy and pharmacokinetics of paroxetine in depressed geriatic patients.
314	HP/82/134 Jauhar	HP/82/134	HP/82/134 A double blind parallel study comparing paroxetine 30mg daily and amitriptyline 150mg daily in depressed patients.

315	HP/81/164a Gaind	HP/81/164A	HP/81/164 Early clinical evaluation of a new antidepressant. An open pilot study of paroxetine 40mg daily.
316	HP/82/47a Vervarcke	HP/82/47A	HP/82/47 Early clinical evaluation of a new antidepressant. A double-blind parallel study comparing paroxetine 30mg daily with amitriptyline 150mg daily.
317	HP/82/65a Priest	HP/82/65A	HP/82/65 An early clinical evaluation of a new antidepressant. An open study of paroxetine 40mg od.
318	HP/82/64a Goffaux	HP/82/64A	HP/82/64 Early clinical evaluation of a new antidepressant. A double-blind parallel study comparing paroxetine 30mg daily with amitriptyline 150mg daily.
319	HP/81/148 Richou	HP/81/148A	HP/81/148 Early clinical evaluation of a new antidepressant. A double blind parallel study comparing paroxetine 30mg daily with amitriptyline 150mg daily.
327	Study 327		
329	Study 329		
331	Study 331		A study of the efficacy of paroxetine in the treatment of patients with major depression and comorbid chronic illness.
352	Study 352		
377	Study 377		
382	Study 382		
400	Study 400		

427	Study 427		
448	Study 448		
449	Study 449		
453	Study 453		
454	Study 454		
470	Study 470		A randomised, double-blind extension trial comparing paroxetine and placebo in the treatment of Generalised Social Phobia.
487	Study 487		
494	Study 494		
495	Study 495		
497	Study 497		
502	Study 502		
595	Study 595		
625	Study 625		
627	Study 627		
637	Study 637		
641	Study 641		

642	Study 642		
646	Study 646		Long term safety and efficacy in GAD.
648	Study 648		
650	Study 650		A study of the maintained efficacy and safety of paroxetine versus placebo in the long-term treatment of post traumatic stress disorder.
651	Study 651		
676	Study 676		A 16 week, double blind, placebo controlled study to investigate the efficacy and tolerability of paroxetine in the treatment of children and adolescents with Social Anxiety Disorder/Social Anxiety.
677	Study 677		A double-blind, placebo controlled, 3 arm fixed dose study of paroxetine CR continuous treatment (12.5mg and 25mg) for premenstrual dysphoric disorder.
688	Study 688		As for 677.
689	Study 689		As for 677.
701	Study 701		A multicenter double blind placebo controlled flexible dose study to evaluate the efficacy and safety of paroxetine in children with major depression.
704	Study 704		A multicentre, double-blind placebo controlled flexible dose outpatient study to evaluate the efficacy and safety of paroxetine in children and adolescents with Obsessive Compulsive Disorder

711	Study 711		A 3 month double-blind placebo controlled fixed-dose extension study of paroxetine CR (12.5mg and 25mg/day) continuous treatment for PMDD patients completing studies 29060/677,688 or 689.
785	Study 785		A double-blind, placebo controlled fixed-dosage study comparing the efficacy and tolerability of paroxetine CR and citalopram to placebo in the treatment of major depressive disorder with anxiety.
790	Study 790		A double-blind placebo controlled study of paroxetine CR in the treatment of patients with Social Anxiety Disorder.
791	Study 791		A double-blind placebo controlled study to evaluate the efficacy and tolerability of paroxetine CR in patients with Generalised Anxiety Disorder.
810	Study 810		A double-blind, placebo controlled, 3 arm fixed-dose study of 12.5mg/day and 25mg/day paroxetine CR in the treatment of major depression.
A01	DFG122 VANGTORP P47	DFG/29060/II/85/122	DFG 122 Vangtorp "DFG/29060/II/85/122 Open study - 6 weeks - paroxetine 10-30mg/day (n=5) (non-controlled)

Paroxetine EMEA

EMEA Table 2.01

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Indication

Adult Placebo Controlled Trials

On-Therapy

Indication		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
	PYE	1916	1313		
	n/PYE	0.03	0.04		0.28
Depression	n/N (%)	58/3421 (1.7%)	41/2117 (1.9%)	0.87 (0.58, 1.31)	0.53
	PYE	671	428		
	n/PYE	0.09	0.10		0.62
GAD	n/N (%)	2/1182 (0.2%)	2/985 (0.2%)	0.83 (0.12, 5.92)	1.00
	PYE	259	211		
	n/PYE	0.01	0.01		0.84
OCD	n/N (%)	1/542 (0.2%)	3/265 (1.1%)	0.16 (0.02, 1.56)	0.11
	PYE	141	61		
	n/PYE	0.01	0.05		0.092
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
	PYE	208	102		
	n/PYE	0.00	0.00		
PTSD	n/N (%)	3/786 (0.4%)	3/598 (0.5%)	0.76 (0.15, 3.78)	1.00
	PYE	174	138		
	n/PYE	0.02	0.02		0.78
Panic	n/N (%)	0/920 (0.0%)	3/780 (0.4%)		0.096
	PYE	237	186		
	n/PYE	0.00	0.02		1.00
SAD	n/N (%)	2/870 (0.2%)	3/684 (0.4%)	0.52 (0.09, 3.14)	0.66
	PYE	225	187		
	n/PYE	0.01	0.02		0.52

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

Paroxetine EMEA

EMEA Table 2.01a

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Indication

Adult Placebo Controlled Trials, Study 057

On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	27/131 (20.6%)	29/136 (21.3%)	0.96 (0.53, 1.73)	1.00
	PYE	57	62		
	n/PYE	0.47	0.46		0.95
Depression	n/N (%)	27/131 (20.6%)	29/136 (21.3%)	0.96 (0.53, 1.73)	1.00
	PYE	57	62		
	n/PYE	0.47	0.46		0.95

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

Paroxetine EMEA

EMEA Table 2.02

Incidence and Incidence Density for Possibly suicide-related AEs 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 (%)	92/8481 (1.1%)	63/5808 (1.1%)	1.00 (0.72, 1.38)	1.00
	PYE	1916	1313		
	n/PYE	0.05	0.05		1.00
Depression	n/N (%)	74/3421 (2.2%)	44/2117 (2.1%)	1.04 (0.71, 1.52)	0.92
	PYE	671	428		
	n/PYE	0.11	0.10		0.71
GAD	n/N (%)	2/1182 (0.2%)	2/985 (0.2%)	0.83 (0.12, 5.92)	1.00
	PYE	259	211		
	n/PYE	0.01	0.01		0.84
OCD	n/N (%)	3/542 (0.6%)	4/265 (1.5%)	0.36 (0.08, 1.63)	0.23
	PYE	141	61		
	n/PYE	0.02	0.07		0.14
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
	PYE	208	102		
	n/PYE	0.00	0.00		
PTSD	n/N (%)	7/786 (0.9%)	6/598 (1.0%)	0.89 (0.30, 2.65)	1.00
	PYE	174	138		
	n/PYE	0.04	0.04		0.89
Panic	n/N (%)	3/920 (0.3%)	4/780 (0.5%)	0.63 (0.14, 2.84)	0.71
	PYE	237	186		
	n/PYE	0.01	0.02		0.48
SAD	n/N (%)	3/870 (0.3%)	3/684 (0.4%)	0.79 (0.16, 3.90)	1.00
	PYE	225	187		
	n/PYE	0.01	0.02		0.82

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

Paroxetine EMEA

EMEA Table 2.02a

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Indication

Adult Placebo Controlled Trials, Study 057

On-Therapy plus 30 days post-therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	31/131 (23.7%)	31/136 (22.8%)	1.05 (0.59, 1.85)	0.89
	PYE	57	62		
	n/PYE	0.54	0.50		0.73
Depression	n/N (%)	31/131 (23.7%)	31/136 (22.8%)	1.05 (0.59, 1.85)	0.89
	PYE	57	62		
	n/PYE	0.54	0.50		0.73

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

Paroxetine EMEA

EMEA Table 2.03

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Adult Placebo Controlled Trials

On-Therapy

Intensity	Paroxetine	Placebo
Overall	66/8481 (0.8%)	55/5808 (0.9%)
Severe	26/66 (39.4%)	22/55 (40.0%)
Moderate	23/66 (34.8%)	21/55 (38.2%)
Mild	17/66 (25.8%)	11/55 (20.0%)
Unknown or Unassessed	0/66 (0.0%)	1/55 (1.8%)

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

Paroxetine EMEA

EMEA Table 2.04

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Adult Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Intensity	Paroxetine	Placebo
Overall	92/8481 (1.1%)	63/5808 (1.1%)
Severe	40/92 (43.5%)	28/63 (44.4%)
Moderate	32/92 (34.8%)	22/63 (34.9%)
Mild	20/92 (21.7%)	12/63 (19.0%)
Unknown or Unassessed	0/92 (0.0%)	1/63 (1.6%)

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

Paroxetine EMEA

EMEA Table 2.05

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Adult Placebo Controlled Trials

On-Therapy

Investigator Attribution	Paroxetine	Placebo
Overall	66/8481 (0.8%)	55/5808 (0.9%)
Related or Probably Related	7/66 (10.6%)	9/55 (16.4%)
Possibly Related	4/66 (6.1%)	2/55 (3.6%)
Unrelated or Probably Unrelated	50/66 (75.8%)	36/55 (65.5%)
Unknown or Unassessed	5/66 (7.6%)	8/55 (14.5%)

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

Paroxetine EMEA

EMEA Table 2.06

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Adult Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine	Placebo
Overall	92/8481 (1.1%)	63/5808 (1.1%)
Related or Probably Related	9/92 (9.8%)	9/63 (14.3%)
Possibly Related	5/92 (5.4%)	2/63 (3.2%)
Unrelated or Probably Unrelated	69/92 (75.0%)	44/63 (69.8%)
Unknown or Unassessed	9/92 (9.8%)	8/63 (12.7%)

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

Paroxetine EMEA

EMEA Table 2.07
Incidence and Incidence Density for Self Harm by Treatment Group and Indication
Adult Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	51/8481 (0.6%)	38/5808 (0.7%)	0.92 (0.60, 1.40)	0.75
	PYE	1916	1313		
	n/PYE	0.03	0.03		0.69
Depression	n/N (%)	45/3421 (1.3%)	33/2117 (1.6%)	0.84 (0.54, 1.32)	0.48
	PYE	671	428		
	n/PYE	0.07	0.08		0.54
GAD	n/N (%)	2/1182 (0.2%)	0/985 (0.0%)		0.50
	PYE	259	211		
	n/PYE	0.01	0.00		
OCD	n/N (%)	1/542 (0.2%)	1/265 (0.4%)	0.49 (0.03, 7.83)	0.55
	PYE	141	61		
	n/PYE	0.01	0.02		0.55
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
	PYE	208	102		
	n/PYE	0.00	0.00		
PTSD	n/N (%)	1/786 (0.1%)	1/598 (0.2%)	0.76 (0.05, 12.18)	1.00
	PYE	174	138		
	n/PYE	0.01	0.01		0.87
Panic	n/N (%)	0/920 (0.0%)	2/780 (0.3%)		0.21
	PYE	237	186		
	n/PYE	0.00	0.01		1.00
SAD	n/N (%)	2/870 (0.2%)	1/684 (0.1%)	1.57 (0.14, 17.39)	1.00
	PYE	225	187		
	n/PYE	0.01	0.01		0.68

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

Paroxetine EMEA

EMEA Table 2.07a
Incidence and Incidence Density for Self Harm by Treatment Group and Indication
Adult Placebo Controlled Trials, Study 057
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	26/131 (19.8%)	28/136 (20.6%)	0.96 (0.53, 1.74)	1.00
	PYE	57	62		
	n/PYE	0.45	0.45		0.96
Depression	n/N (%)	26/131 (19.8%)	28/136 (20.6%)	0.96 (0.53, 1.74)	1.00
	PYE	57	62		
	n/PYE	0.45	0.45		0.96

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

Paroxetine EMEA

EMEA Table 2.08
Incidence and Incidence Density for Self Harm 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 (%)	63/8481 (0.7%)	41/5808 (0.7%)	1.05 (0.71, 1.56)	0.84
	PYE	1916	1313		
	n/PYE	0.03	0.03		0.80
Depression	n/N (%)	55/3421 (1.6%)	35/2117 (1.7%)	0.97 (0.63, 1.49)	0.91
	PYE	671	428		
	n/PYE	0.08	0.08		0.99
GAD	n/N (%)	2/1182 (0.2%)	0/985 (0.0%)		0.50
	PYE	259	211		
	n/PYE	0.01	0.00		
OCD	n/N (%)	2/542 (0.4%)	1/265 (0.4%)	0.98 (0.09, 10.83)	1.00
	PYE	141	61		
	n/PYE	0.01	0.02		0.90
PMDD	n/N (%)	0/760 (0.0%)	0/379 (0.0%)		
	PYE	208	102		
	n/PYE	0.00	0.00		
PTSD	n/N (%)	1/786 (0.1%)	2/598 (0.3%)	0.38 (0.03, 4.20)	0.58
	PYE	174	138		
	n/PYE	0.01	0.01		0.45
Panic	n/N (%)	1/920 (0.1%)	2/780 (0.3%)	0.42 (0.04, 4.68)	0.60
	PYE	237	186		
	n/PYE	0.00	0.01		0.44
SAD	n/N (%)	2/870 (0.2%)	1/684 (0.1%)	1.57 (0.14, 17.39)	1.00
	PYE	225	187		
	n/PYE	0.01	0.01		0.68

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

Paroxetine EMEA

EMEA Table 2.08a

Incidence and Incidence Density for Self Harm by Treatment Group and Indication

Adult Placebo Controlled Trials, Study 057

On-Therapy plus 30 days post-therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	30/131 (22.9%)	29/136 (21.3%)	1.10 (0.61, 1.95)	0.77
	PYE	57	62		
	n/PYE	0.52	0.46		0.64
Depression	n/N (%)	30/131 (22.9%)	29/136 (21.3%)	1.10 (0.61, 1.95)	0.77
	PYE	57	62		
	n/PYE	0.52	0.46		0.64

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

Paroxetine EMEA

EMEA Table 2.09
Incidence of Self Harm by Treatment Group and Maximum Intensity
Adult Placebo Controlled Trials
On-Therapy

Intensity	Paroxetine	Placebo
Overall	51/8481 (0.6%)	38/5808 (0.7%)
Severe	19/51 (37.3%)	17/38 (44.7%)
Moderate	17/51 (33.3%)	13/38 (34.2%)
Mild	15/51 (29.4%)	7/38 (18.4%)
Unknown or Unassessed	0/51 (0.0%)	1/38 (2.6%)

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

Paroxetine EMEA

EMEA Table 2.10
Incidence of Self Harm by Treatment Group and Maximum Intensity
Adult Placebo Controlled Trials
On-Therapy plus 30 days post-therapy

Intensity	Paroxetine	Placebo
Overall	63/8481 (0.7%)	41/5808 (0.7%)
Severe	26/63 (41.3%)	19/41 (46.3%)
Moderate	20/63 (31.7%)	13/41 (31.7%)
Mild	17/63 (27.0%)	8/41 (19.5%)
Unknown or Unassessed	0/63 (0.0%)	1/41 (2.4%)

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

Paroxetine EMEA

EMEA Table 2.11
Incidence of Self Harm by Treatment Group and Investigator Attribution
Adult Placebo Controlled Trials
On-Therapy

Investigator Attribution	Paroxetine	Placebo
Overall	51/8481 (0.6%)	38/5808 (0.7%)
Related or Probably Related	4/51 (7.8%)	3/38 (7.9%)
Possibly Related	1/51 (2.0%)	1/38 (2.6%)
Unrelated or Probably Unrelated	41/51 (80.4%)	27/38 (71.1%)
Unknown or Unassessed	5/51 (9.8%)	7/38 (18.4%)

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

Paroxetine EMEA

EMEA Table 2.12
Incidence of Self Harm by Treatment Group and Investigator Attribution
Adult Placebo Controlled Trials
On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine	Placebo
Overall	63/8481 (0.7%)	41/5808 (0.7%)
Related or Probably Related	5/63 (7.9%)	3/41 (7.3%)
Possibly Related	1/63 (1.6%)	1/41 (2.4%)
Unrelated or Probably Unrelated	49/63 (77.8%)	30/41 (73.2%)
Unknown or Unassessed	8/63 (12.7%)	7/41 (17.1%)

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

Paroxetine EMEA

EMEA Table 2.13
Incidence and Incidence Density for Hostility by Treatment Group and Indication
Adult Placebo Controlled Trials
On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	24/8481 (0.3%)	16/5808 (0.3%)	1.03 (0.55, 1.94)	1.00
	PYE	1916	1313		
	n/PYE	0.01	0.01		0.93
Depression	n/N (%)	11/3421 (0.3%)	7/2117 (0.3%)	0.97 (0.38, 2.51)	1.00
	PYE	671	428		
	n/PYE	0.02	0.02		1.00
GAD	n/N (%)	1/1182 (0.1%)	1/985 (0.1%)	0.83 (0.05, 13.34)	1.00
	PYE	259	211		
	n/PYE	0.00	0.00		0.88
OCD	n/N (%)	4/542 (0.7%)	4/265 (1.5%)	0.49 (0.12, 1.96)	0.45
	PYE	141	61		
	n/PYE	0.03	0.07		0.23
PMDD	n/N (%)	2/760 (0.3%)	0/379 (0.0%)		1.00
	PYE	208	102		
	n/PYE	0.01	0.00		
PTSD	n/N (%)	1/786 (0.1%)	1/598 (0.2%)	0.76 (0.05, 12.18)	1.00
	PYE	174	138		
	n/PYE	0.01	0.01		0.87
Panic	n/N (%)	2/920 (0.2%)	2/780 (0.3%)	0.85 (0.12, 6.03)	1.00
	PYE	237	186		
	n/PYE	0.01	0.01		0.81
SAD	n/N (%)	3/870 (0.3%)	1/684 (0.1%)	2.36 (0.25, 22.77)	0.64
	PYE	225	187		
	n/PYE	0.01	0.01		0.43

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

Paroxetine EMEA

EMEA Table 2.14
Incidence and Incidence Density for Hostility 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 (%)	32/8481 (0.4%)	16/5808 (0.3%)	1.37 (0.75, 2.50)	0.38
	PYE	1916	1313		
	n/PYE	0.02	0.01		0.30
Depression	n/N (%)	12/3421 (0.4%)	7/2117 (0.3%)	1.06 (0.42, 2.70)	1.00
	PYE	671	428		
	n/PYE	0.02	0.02		0.85
GAD	n/N (%)	2/1182 (0.2%)	1/985 (0.1%)	1.67 (0.15, 18.42)	1.00
	PYE	259	211		
	n/PYE	0.01	0.00		0.69
OCD	n/N (%)	4/542 (0.7%)	4/265 (1.5%)	0.49 (0.12, 1.96)	0.45
	PYE	141	61		
	n/PYE	0.03	0.07		0.23
PMDD	n/N (%)	5/760 (0.7%)	0/379 (0.0%)		0.18
	PYE	208	102		
	n/PYE	0.02	0.00		
PTSD	n/N (%)	3/786 (0.4%)	1/598 (0.2%)	2.29 (0.24, 22.05)	0.64
	PYE	174	138		
	n/PYE	0.02	0.01		0.45
Panic	n/N (%)	2/920 (0.2%)	2/780 (0.3%)	0.85 (0.12, 6.03)	1.00
	PYE	237	186		
	n/PYE	0.01	0.01		0.81
SAD	n/N (%)	4/870 (0.5%)	1/684 (0.1%)	3.15 (0.35, 28.29)	0.39
	PYE	225	187		
	n/PYE	0.02	0.01		0.28

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

Paroxetine EMEA

EMEA Table 2.15
Incidence of Hostility by Treatment Group and Maximum Intensity
Adult Placebo Controlled Trials
On-Therapy

Intensity	Paroxetine	Placebo
Overall	24/8481 (0.3%)	16/5808 (0.3%)
Severe	11/24 (45.8%)	5/16 (31.3%)
Moderate	9/24 (37.5%)	6/16 (37.5%)
Mild	4/24 (16.7%)	5/16 (31.3%)

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

Paroxetine EMEA

EMEA Table 2.16
Incidence of Hostility by Treatment Group and Maximum Intensity
Adult Placebo Controlled Trials
On-Therapy plus 30 days post-therapy

Intensity	Paroxetine	Placebo
Overall	32/8481 (0.4%)	16/5808 (0.3%)
Severe	13/32 (40.6%)	5/16 (31.3%)
Moderate	12/32 (37.5%)	6/16 (37.5%)
Mild	7/32 (21.9%)	5/16 (31.3%)

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

Paroxetine EMEA

EMEA Table 2.17
Incidence of Hostility by Treatment Group and Investigator Attribution
Adult Placebo Controlled Trials
On-Therapy

Investigator Attribution	Paroxetine	Placebo
Overall	24/8481 (0.3%)	16/5808 (0.3%)
Related or Probably Related	7/24 (29.2%)	3/16 (18.8%)
Possibly Related	5/24 (20.8%)	3/16 (18.8%)
Unrelated or Probably Unrelated	10/24 (41.7%)	10/16 (62.5%)
Unknown or Unassessed	2/24 (8.3%)	0/16 (0.0%)

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

Paroxetine EMEA

EMEA Table 2.18
Incidence of Hostility by Treatment Group and Investigator Attribution
Adult Placebo Controlled Trials
On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine		Placebo	
Overall	32/8481	(0.4%)	16/5808	(0.3%)
Related or Probably Related	7/32	(21.9%)	3/16	(18.8%)
Possibly Related	10/32	(31.3%)	3/16	(18.8%)
Unrelated or Probably Unrelated	13/32	(40.6%)	10/16	(62.5%)
Unknown or Unassessed	2/32	(6.3%)	0/16	(0.0%)

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

Paroxetine EMEA

EMEA Table 2.19

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Control Medication Class

Adult Active Control Trials

On-Therapy

Control Medication Class		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
	PYE	1135	842		
	n/PYE	0.05	0.07		0.019
TRICYCLIC	n/N (%)	26/2953 (0.9%)	32/2754 (1.2%)	0.76 (0.45, 1.27)	0.29
	PYE	599	493		
	n/PYE	0.04	0.06		0.13
SSRI	n/N (%)	14/1200 (1.2%)	24/1218 (2.0%)	0.59 (0.30, 1.14)	0.14
	PYE	219	215		
	n/PYE	0.06	0.11		0.099
TETRACYCLIC	n/N (%)	2/527 (0.4%)	4/518 (0.8%)	0.49 (0.09, 2.68)	0.45
	PYE	68	64		
	n/PYE	0.03	0.06		0.39
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
	PYE	16	18		
	n/PYE	0.00	0.00		
OTHER	n/N (%)	13/1766 (0.7%)	3/402 (0.7%)	0.99 (0.28, 3.48)	1.00
	PYE	233	51		
	n/PYE	0.06	0.06		0.93

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

Paroxetine EMEA

EMEA Table 2.20

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Control Medication Class

Adult Active Control Trials

On-Therapy plus 30 days post-therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	79/6522 (1.2%)	76/4969 (1.5%)	0.79 (0.57, 1.08)	0.17
	PYE	1135	842		
	n/PYE	0.07	0.09		0.11
TRICYCLIC	n/N (%)	37/2953 (1.3%)	41/2754 (1.5%)	0.84 (0.54, 1.31)	0.49
	PYE	599	493		
	n/PYE	0.06	0.08		0.19
SSRI	n/N (%)	20/1200 (1.7%)	26/1218 (2.1%)	0.78 (0.43, 1.40)	0.46
	PYE	219	215		
	n/PYE	0.09	0.12		0.35
TETRACYCLIC	n/N (%)	2/527 (0.4%)	5/518 (1.0%)	0.39 (0.08, 2.02)	0.28
	PYE	68	64		
	n/PYE	0.03	0.08		0.25
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
	PYE	16	18		
	n/PYE	0.00	0.00		
OTHER	n/N (%)	20/1766 (1.1%)	4/402 (1.0%)	1.14 (0.39, 3.35)	1.00
	PYE	233	51		
	n/PYE	0.09	0.08		0.87

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

Paroxetine EMEA

EMEA Table 2.21

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Adult Active Control Trials

On-Therapy

Intensity	Paroxetine	Comparator
Overall	55/6522 (0.8%)	63/4969 (1.3%)
Severe	31/55 (56.4%)	35/63 (55.6%)
Moderate	11/55 (20.0%)	16/63 (25.4%)
Mild	7/55 (12.7%)	9/63 (14.3%)
Unknown or Unassessed	6/55 (10.9%)	3/63 (4.8%)

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

Paroxetine EMEA

EMEA Table 2.22

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Adult Active Control Trials

On-Therapy plus 30 days post-therapy

Intensity	Paroxetine	Comparator
Overall	79/6522 (1.2%)	76/4969 (1.5%)
Severe	44/79 (55.7%)	41/76 (53.9%)
Moderate	17/79 (21.5%)	17/76 (22.4%)
Mild	9/79 (11.4%)	9/76 (11.8%)
Unknown or Unassessed	9/79 (11.4%)	9/76 (11.8%)

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

Paroxetine EMEA

EMEA Table 2.23

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Adult Active Control Trials

On-Therapy

Investigator Attribution	Paroxetine	Comparator
Overall	55/6522 (0.8%)	63/4969 (1.3%)
Related or Probably Related	6/55 (10.9%)	6/63 (9.5%)
Possibly Related	5/55 (9.1%)	4/63 (6.3%)
Unrelated or Probably Unrelated	29/55 (52.7%)	43/63 (68.3%)
Unknown or Unassessed	15/55 (27.3%)	10/63 (15.9%)

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

Paroxetine EMEA

EMEA Table 2.24

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Adult Active Control Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine	Comparator
Overall	79/6522 (1.2%)	76/4969 (1.5%)
Related or Probably Related	8/79 (10.1%)	7/76 (9.2%)
Possibly Related	7/79 (8.9%)	4/76 (5.3%)
Unrelated or Probably Unrelated	41/79 (51.9%)	48/76 (63.2%)
Unknown or Unassessed	23/79 (29.1%)	17/76 (22.4%)

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

Paroxetine EMEA

EMEA Table 2.25

Incidence and Incidence Density for Self Harm by Treatment Group and Control Medication Class

Adult Active Control Trials

On-Therapy

Control Medication Class		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
	PYE	1135	842		
	n/PYE	0.03	0.04		0.12
TRICYCLIC	n/N (%)	17/2953 (0.6%)	22/2754 (0.8%)	0.72 (0.38, 1.36)	0.34
	PYE	599	493		
	n/PYE	0.03	0.04		0.16
SSRI	n/N (%)	6/1200 (0.5%)	6/1218 (0.5%)	1.02 (0.33, 3.16)	1.00
	PYE	219	215		
	n/PYE	0.03	0.03		0.98
TETRACYCLIC	n/N (%)	2/527 (0.4%)	2/518 (0.4%)	0.98 (0.14, 7.00)	1.00
	PYE	68	64		
	n/PYE	0.03	0.03		0.96
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
	PYE	16	18		
	n/PYE	0.00	0.00		
OTHER	n/N (%)	4/1766 (0.2%)	2/402 (0.5%)	0.45 (0.08, 2.49)	0.31
	PYE	233	51		
	n/PYE	0.02	0.04		0.34

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

Paroxetine EMEA

EMEA Table 2.26
Incidence and Incidence Density for Self Harm by Treatment Group and Control Medication Class
Adult Active Control Trials
On-Therapy plus 30 days post-therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	42/6522 (0.6%)	42/4969 (0.8%)	0.76 (0.49, 1.17)	0.22
	PYE	1135	842		
	n/PYE	0.04	0.05		0.17
TRICYCLIC	n/N (%)	26/2953 (0.9%)	29/2754 (1.1%)	0.83 (0.49, 1.42)	0.59
	PYE	599	493		
	n/PYE	0.04	0.06		0.26
SSRI	n/N (%)	8/1200 (0.7%)	7/1218 (0.6%)	1.16 (0.42, 3.21)	0.80
	PYE	219	215		
	n/PYE	0.04	0.03		0.82
TETRACYCLIC	n/N (%)	2/527 (0.4%)	3/518 (0.6%)	0.65 (0.11, 3.93)	0.68
	PYE	68	64		
	n/PYE	0.03	0.05		0.61
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
	PYE	16	18		
	n/PYE	0.00	0.00		
OTHER	n/N (%)	6/1766 (0.3%)	3/402 (0.7%)	0.45 (0.11, 1.82)	0.22
	PYE	233	51		
	n/PYE	0.03	0.06		0.24

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

Paroxetine EMEA

EMEA Table 2.27
Incidence of Self Harm by Treatment Group and Maximum Intensity
Adult Active Control Trials
On-Therapy

Intensity	Paroxetine	Comparator
Overall	29/6522 (0.4%)	32/4969 (0.6%)
Severe	16/29 (55.2%)	22/32 (68.8%)
Moderate	3/29 (10.3%)	7/32 (21.9%)
Mild	5/29 (17.2%)	2/32 (6.3%)
Unknown or Unassessed	5/29 (17.2%)	1/32 (3.1%)

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

Paroxetine EMEA

EMEA Table 2.28
Incidence of Self Harm by Treatment Group and Maximum Intensity
Adult Active Control Trials
On-Therapy plus 30 days post-therapy

Intensity	Paroxetine	Comparator
Overall	42/6522 (0.6%)	42/4969 (0.8%)
Severe	24/42 (57.1%)	27/42 (64.3%)
Moderate	5/42 (11.9%)	8/42 (19.0%)
Mild	6/42 (14.3%)	2/42 (4.8%)
Unknown or Unassessed	7/42 (16.7%)	5/42 (11.9%)

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

Paroxetine EMEA

EMEA Table 2.29
Incidence of Self Harm by Treatment Group and Investigator Attribution
Adult Active Control Trials
On-Therapy

Investigator Attribution	Paroxetine	Comparator
Overall	29/6522 (0.4%)	32/4969 (0.6%)
Related or Probably Related	1/29 (3.4%)	3/32 (9.4%)
Possibly Related	2/29 (6.9%)	1/32 (3.1%)
Unrelated or Probably Unrelated	14/29 (48.3%)	23/32 (71.9%)
Unknown or Unassessed	12/29 (41.4%)	5/32 (15.6%)

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

Paroxetine EMEA

EMEA Table 2.30
Incidence of Self Harm by Treatment Group and Investigator Attribution
Adult Active Control Trials
On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine	Comparator
Overall	42/6522 (0.6%)	42/4969 (0.8%)
Related or Probably Related	2/42 (4.8%)	4/42 (9.5%)
Possibly Related	3/42 (7.1%)	1/42 (2.4%)
Unrelated or Probably Unrelated	18/42 (42.9%)	27/42 (64.3%)
Unknown or Unassessed	19/42 (45.2%)	10/42 (23.8%)

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

Paroxetine EMEA

EMEA Table 2.31
Incidence and Incidence Density for Hostility by Treatment Group and Control Medication Class
Adult Active Control Trials
On-Therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	18/6522 (0.3%)	20/4969 (0.4%)	0.68 (0.36, 1.30)	0.25
	PYE	1135	842		
	n/PYE	0.02	0.02		0.21
TRICYCLIC	n/N (%)	5/2953 (0.2%)	5/2754 (0.2%)	0.93 (0.27, 3.22)	1.00
	PYE	599	493		
	n/PYE	0.01	0.01		0.76
SSRI	n/N (%)	7/1200 (0.6%)	8/1218 (0.7%)	0.89 (0.32, 2.46)	1.00
	PYE	219	215		
	n/PYE	0.03	0.04		0.77
TETRACYCLIC	n/N (%)	1/527 (0.2%)	4/518 (0.8%)	0.24 (0.03, 2.19)	0.21
	PYE	68	64		
	n/PYE	0.01	0.06		0.20
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
	PYE	16	18		
	n/PYE	0.00	0.00		
OTHER	n/N (%)	5/1766 (0.3%)	3/402 (0.7%)	0.38 (0.09, 1.59)	0.17
	PYE	233	51		
	n/PYE	0.02	0.06		0.17

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

Paroxetine EMEA

EMEA Table 2.32

Incidence and Incidence Density for Hostility by Treatment Group and Control Medication Class

Adult Active Control Trials

On-Therapy plus 30 days post-therapy

Control Medication Class		Paroxetine	Comparator	Odds Ratio (95% CI)	P value
Overall	n/N (%)	22/6522 (0.3%)	22/4969 (0.4%)	0.76 (0.42, 1.38)	0.37
	PYE	1135	842		
	n/PYE	0.02	0.03		0.32
TRICYCLIC	n/N (%)	7/2953 (0.2%)	6/2754 (0.2%)	1.09 (0.37, 3.24)	1.00
	PYE	599	493		
	n/PYE	0.01	0.01		0.94
SSRI	n/N (%)	8/1200 (0.7%)	8/1218 (0.7%)	1.02 (0.38, 2.71)	1.00
	PYE	219	215		
	n/PYE	0.04	0.04		0.97
TETRACYCLIC	n/N (%)	1/527 (0.2%)	5/518 (1.0%)	0.20 (0.02, 1.68)	0.12
	PYE	68	64		
	n/PYE	0.01	0.08		0.13
BENZODIAZEPINE	n/N (%)	0/76 (0.0%)	0/77 (0.0%)		
	PYE	16	18		
	n/PYE	0.00	0.00		
OTHER	n/N (%)	6/1766 (0.3%)	3/402 (0.7%)	0.45 (0.11, 1.82)	0.22
	PYE	233	51		
	n/PYE	0.03	0.06		0.24

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

Paroxetine EMEA

EMEA Table 2.33
Incidence of Hostility by Treatment Group and Maximum Intensity
Adult Active Control Trials
On-Therapy

Intensity	Paroxetine	Comparator
Overall	18/6522 (0.3%)	20/4969 (0.4%)
Severe	8/18 (44.4%)	4/20 (20.0%)
Moderate	8/18 (44.4%)	13/20 (65.0%)
Mild	2/18 (11.1%)	2/20 (10.0%)
Unknown or Unassessed	0/18 (0.0%)	1/20 (5.0%)

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

Paroxetine EMEA

EMEA Table 2.34
Incidence of Hostility by Treatment Group and Maximum Intensity
Adult Active Control Trials
On-Therapy plus 30 days post-therapy

Intensity	Paroxetine	Comparator
Overall	22/6522 (0.3%)	22/4969 (0.4%)
Severe	9/22 (40.9%)	5/22 (22.7%)
Moderate	10/22 (45.5%)	14/22 (63.6%)
Mild	3/22 (13.6%)	2/22 (9.1%)
Unknown or Unassessed	0/22 (0.0%)	1/22 (4.5%)

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

Paroxetine EMEA

EMEA Table 2.35
Incidence of Hostility by Treatment Group and Investigator Attribution
Adult Active Control Trials
On-Therapy

Investigator Attribution	Paroxetine	Comparator
Overall	18/6522 (0.3%)	20/4969 (0.4%)
Related or Probably Related	6/18 (33.3%)	9/20 (45.0%)
Possibly Related	2/18 (11.1%)	4/20 (20.0%)
Unrelated or Probably Unrelated	8/18 (44.4%)	5/20 (25.0%)
Unknown or Unassessed	2/18 (11.1%)	2/20 (10.0%)

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

Paroxetine EMEA

EMEA Table 2.36
Incidence of Hostility by Treatment Group and Investigator Attribution
Adult Active Control Trials
On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine	Comparator
Overall	22/6522 (0.3%)	22/4969 (0.4%)
Related or Probably Related	8/22 (36.4%)	10/22 (45.5%)
Possibly Related	3/22 (13.6%)	4/22 (18.2%)
Unrelated or Probably Unrelated	9/22 (40.9%)	5/22 (22.7%)
Unknown or Unassessed	2/22 (9.1%)	3/22 (13.6%)

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

Paroxetine EMEA

EMEA Table 2.37

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Indication

Adult Uncontrolled Trials

On-Therapy

Indication		Paroxetine
Overall	n/N (%)	42/5448 (0.8%)
	PYE	1938
	n/PYE (rate relative to exposure)	0.02
Depression	n/N (%)	33/3529 (0.9%)
	PYE	1459
	n/PYE (rate relative to exposure)	0.02
GAD	n/N (%)	2/652 (0.3%)
	PYE	96
	n/PYE (rate relative to exposure)	0.02
OCD	n/N (%)	4/424 (0.9%)
	PYE	179
	n/PYE (rate relative to exposure)	0.02
PTSD	n/N (%)	2/265 (0.8%)
	PYE	55
	n/PYE (rate relative to exposure)	0.04
Panic	n/N (%)	0/43 (0.0%)
	PYE	11
	n/PYE (rate relative to exposure)	0.00
SAD	n/N (%)	1/535 (0.2%)
	PYE	138
	n/PYE (rate relative to exposure)	0.01

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.38

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Indication

Adult Uncontrolled Trials

On-Therapy plus 30 days post-therapy

Indication		Paroxetine
Overall	n/N (%)	58/5448 (1.1%)
	PYE	1938
	n/PYE (rate relative to exposure)	0.03
Depression	n/N (%)	48/3529 (1.4%)
	PYE	1459
	n/PYE (rate relative to exposure)	0.03
GAD	n/N (%)	2/652 (0.3%)
	PYE	96
	n/PYE (rate relative to exposure)	0.02
OCD	n/N (%)	4/424 (0.9%)
	PYE	179
	n/PYE (rate relative to exposure)	0.02
PTSD	n/N (%)	2/265 (0.8%)
	PYE	55
	n/PYE (rate relative to exposure)	0.04
Panic	n/N (%)	0/43 (0.0%)
	PYE	11
	n/PYE (rate relative to exposure)	0.00
SAD	n/N (%)	2/535 (0.4%)
	PYE	138
	n/PYE (rate relative to exposure)	0.01

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.39

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Adult Uncontrolled Trials

On-Therapy

Intensity	Paroxetine
Overall	42/5448 (0.8%)
Severe	21/42 (50.0%)
Moderate	7/42 (16.7%)
Mild	4/42 (9.5%)
Unknown or Unassessed	10/42 (23.8%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.40

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Adult Uncontrolled Trials

On-Therapy plus 30 days post-therapy

Intensity	Paroxetine
Overall	58/5448 (1.1%)
Severe	29/58 (50.0%)
Moderate	12/58 (20.7%)
Mild	4/58 (6.9%)
Unknown or Unassessed	13/58 (22.4%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.41

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Adult Uncontrolled Trials

On-Therapy

Investigator Attribution	Paroxetine
Overall	42/5448 (0.8%)
Related or Probably Related	2/42 (4.8%)
Possibly Related	4/42 (9.5%)
Unrelated or Probably Unrelated	25/42 (59.5%)
Unknown or Unassessed	11/42 (26.2%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.42

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Adult Uncontrolled Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine
Overall	58/5448 (1.1%)
Related or Probably Related	4/58 (6.9%)
Possibly Related	4/58 (6.9%)
Unrelated or Probably Unrelated	33/58 (56.9%)
Unknown or Unassessed	17/58 (29.3%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.43
Incidence and Incidence Density for Self Harm by Treatment Group and Indication
Adult Uncontrolled Trials
On-Therapy

Indication		Paroxetine
Overall	n/N (%)	28/5448 (0.5%)
	PYE	1938
	n/PYE (rate relative to exposure)	0.01
Depression	n/N (%)	22/3529 (0.6%)
	PYE	1459
	n/PYE (rate relative to exposure)	0.02
GAD	n/N (%)	2/652 (0.3%)
	PYE	96
	n/PYE (rate relative to exposure)	0.02
OCD	n/N (%)	2/424 (0.5%)
	PYE	179
	n/PYE (rate relative to exposure)	0.01
PTSD	n/N (%)	2/265 (0.8%)
	PYE	55
	n/PYE (rate relative to exposure)	0.04
Panic	n/N (%)	0/43 (0.0%)
	PYE	11
	n/PYE (rate relative to exposure)	0.00
SAD	n/N (%)	0/535 (0.0%)
	PYE	138
	n/PYE (rate relative to exposure)	0.00

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.44
Incidence and Incidence Density for Self Harm by Treatment Group and Indication
Adult Uncontrolled Trials
On-Therapy plus 30 days post-therapy

Indication		Paroxetine
Overall	n/N (%)	40/5448 (0.7%)
	PYE	1938
	n/PYE (rate relative to exposure)	0.02
Depression	n/N (%)	33/3529 (0.9%)
	PYE	1459
	n/PYE (rate relative to exposure)	0.02
GAD	n/N (%)	2/652 (0.3%)
	PYE	96
	n/PYE (rate relative to exposure)	0.02
OCD	n/N (%)	2/424 (0.5%)
	PYE	179
	n/PYE (rate relative to exposure)	0.01
PTSD	n/N (%)	2/265 (0.8%)
	PYE	55
	n/PYE (rate relative to exposure)	0.04
Panic	n/N (%)	0/43 (0.0%)
	PYE	11
	n/PYE (rate relative to exposure)	0.00
SAD	n/N (%)	1/535 (0.2%)
	PYE	138
	n/PYE (rate relative to exposure)	0.01

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.45
Incidence of Self Harm by Treatment Group and Maximum Intensity
Adult Uncontrolled Trials
On-Therapy

Intensity	Paroxetine
Overall	28/5448 (0.5%)
Severe	14/28 (50.0%)
Moderate	3/28 (10.7%)
Mild	2/28 (7.1%)
Unknown or Unassessed	9/28 (32.1%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.46
Incidence of Self Harm by Treatment Group and Maximum Intensity
Adult Uncontrolled Trials
On-Therapy plus 30 days post-therapy

Intensity	Paroxetine
Overall	40/5448 (0.7%)
Severe	20/40 (50.0%)
Moderate	7/40 (17.5%)
Mild	2/40 (5.0%)
Unknown or Unassessed	11/40 (27.5%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.47

Incidence of Self Harm by Treatment Group and Investigator Attribution

Adult Uncontrolled Trials

On-Therapy

Investigator Attribution	Paroxetine
Overall	28/5448 (0.5%)
Related or Probably Related	2/28 (7.1%)
Possibly Related	2/28 (7.1%)
Unrelated or Probably Unrelated	14/28 (50.0%)
Unknown or Unassessed	10/28 (35.7%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.48

Incidence of Self Harm by Treatment Group and Investigator Attribution

Adult Uncontrolled Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine
Overall	40/5448 (0.7%)
Related or Probably Related	2/40 (5.0%)
Possibly Related	2/40 (5.0%)
Unrelated or Probably Unrelated	21/40 (52.5%)
Unknown or Unassessed	15/40 (37.5%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.49
Incidence and Incidence Density for Hostility by Treatment Group and Indication
Adult Uncontrolled Trials
On-Therapy

Indication		Paroxetine
Overall	n/N (%)	11/5448 (0.2%)
	PYE	1938
	n/PYE (rate relative to exposure)	0.01
Depression	n/N (%)	8/3529 (0.2%)
	PYE	1459
	n/PYE (rate relative to exposure)	0.01
GAD	n/N (%)	0/652 (0.0%)
	PYE	96
	n/PYE (rate relative to exposure)	0.00
OCD	n/N (%)	1/424 (0.2%)
	PYE	179
	n/PYE (rate relative to exposure)	0.01
PTSD	n/N (%)	0/265 (0.0%)
	PYE	55
	n/PYE (rate relative to exposure)	0.00
Panic	n/N (%)	0/43 (0.0%)
	PYE	11
	n/PYE (rate relative to exposure)	0.00
SAD	n/N (%)	2/535 (0.4%)
	PYE	138
	n/PYE (rate relative to exposure)	0.01

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.50
Incidence and Incidence Density for Hostility by Treatment Group and Indication
Adult Uncontrolled Trials
On-Therapy plus 30 days post-therapy

Indication		Paroxetine
Overall	n/N (%)	16/5448 (0.3%)
	PYE	1938
	n/PYE (rate relative to exposure)	0.01
Depression	n/N (%)	9/3529 (0.3%)
	PYE	1459
	n/PYE (rate relative to exposure)	0.01
GAD	n/N (%)	0/652 (0.0%)
	PYE	96
	n/PYE (rate relative to exposure)	0.00
OCD	n/N (%)	5/424 (1.2%)
	PYE	179
	n/PYE (rate relative to exposure)	0.03
PTSD	n/N (%)	0/265 (0.0%)
	PYE	55
	n/PYE (rate relative to exposure)	0.00
Panic	n/N (%)	0/43 (0.0%)
	PYE	11
	n/PYE (rate relative to exposure)	0.00
SAD	n/N (%)	2/535 (0.4%)
	PYE	138
	n/PYE (rate relative to exposure)	0.01

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

EMEA Table 2.51
Incidence of Hostility by Treatment Group and Maximum Intensity
Adult Uncontrolled Trials
On-Therapy

Intensity	Paroxetine
Overall	11/5448 (0.2%)
Severe	4/11 (36.4%)
Moderate	4/11 (36.4%)
Mild	3/11 (27.3%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.52

Incidence of Hostility by Treatment Group and Maximum Intensity

Adult Uncontrolled Trials

On-Therapy plus 30 days post-therapy

Intensity	Paroxetine
Overall	16/5448 (0.3%)
Severe	6/16 (37.5%)
Moderate	6/16 (37.5%)
Mild	4/16 (25.0%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.53

Incidence of Hostility by Treatment Group and Investigator Attribution

Adult Uncontrolled Trials

On-Therapy

Investigator Attribution	Paroxetine
Overall	11/5448 (0.2%)
Related or Probably Related	4/11 (36.4%)
Possibly Related	5/11 (45.5%)
Unrelated or Probably Unrelated	1/11 (9.1%)
Unknown or Unassessed	1/11 (9.1%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.54

Incidence of Hostility by Treatment Group and Investigator Attribution

Adult Uncontrolled Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine
Overall	16/5448 (0.3%)
Related or Probably Related	8/16 (50.0%)
Possibly Related	6/16 (37.5%)
Unrelated or Probably Unrelated	1/16 (6.3%)
Unknown or Unassessed	1/16 (6.3%)

Includes uncontrolled trials, uncontrolled extensions and paroxetine data from re-randomised phases

Paroxetine EMEA

EMEA Table 2.55

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Indication

Paediatric Placebo Controlled Trials

On-Therapy

Indication		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
	PYE	176	149		
	n/PYE	0.10	0.05		0.082
Depression	n/N (%)	14/378 (3.7%)	7/285 (2.5%)	1.53 (0.61, 3.84)	0.50
	PYE	85	61		
	n/PYE	0.16	0.11		0.43
OCD	n/N (%)	1/195 (0.5%)	0/205 (0.0%)		0.49
	PYE	41	41		
	n/PYE	0.02	0.00		
SAD	n/N (%)	3/165 (1.8%)	0/157 (0.0%)		0.25
	PYE	51	46		
	n/PYE	0.06	0.00		

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

Paroxetine EMEA

EMEA Table 2.56

Incidence and Incidence Density for Possibly suicide-related AEs 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 (%)	25/738 (3.4%)	8/647 (1.2%)	2.80 (1.25, 6.25)	0.012
	PYE	176	149		
	n/PYE	0.14	0.05		0.017
Depression	n/N (%)	20/378 (5.3%)	8/285 (2.8%)	1.93 (0.84, 4.46)	0.12
	PYE	85	61		
	n/PYE	0.24	0.13		0.16
OCD	n/N (%)	1/195 (0.5%)	0/205 (0.0%)		0.49
	PYE	41	41		
	n/PYE	0.02	0.00		
SAD	n/N (%)	4/165 (2.4%)	0/157 (0.0%)		0.12
	PYE	51	46		
	n/PYE	0.08	0.00		

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

Paroxetine EMEA

EMEA Table 2.57

Incidence and Incidence Density for Possibly suicide-related AEs by Treatment Group and Indication (Excluding DB Extension)

Paediatric Placebo Controlled Trials

On-Therapy

Indication		Paroxetine	Placebo
Overall	n/N (%)	17/738 (2.3%)	6/647 (0.9%)
	PYE	160	139
	n/PYE (rate relative to exposure)	0.11	0.04
Depression	n/N (%)	13/378 (3.4%)	6/285 (2.1%)
	PYE	69	51
	n/PYE (rate relative to exposure)	0.19	0.12
OCD	n/N (%)	1/195 (0.5%)	0/205 (0.0%)
	PYE	41	41
	n/PYE (rate relative to exposure)	0.02	0.00
SAD	n/N (%)	3/165 (1.8%)	0/157 (0.0%)
	PYE	51	46
	n/PYE (rate relative to exposure)	0.06	0.00

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

Paroxetine EMEA

EMEA Table 2.58

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Paediatric Placebo Controlled Trials

On-Therapy

Intensity	Paroxetine		Placebo	
Overall	18/738	(2.4%)	7/647	(1.1%)
Severe	8/18	(44.4%)	4/7	(57.1%)
Moderate	4/18	(22.2%)	1/7	(14.3%)
Mild	6/18	(33.3%)	2/7	(28.6%)

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

Paroxetine EMEA

EMEA Table 2.59

Incidence of Possibly suicide-related AEs by Treatment Group and Maximum Intensity

Paediatric Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Intensity	Paroxetine		Placebo	
Overall	25/738	(3.4%)	8/647	(1.2%)
Severe	11/25	(44.0%)	4/8	(50.0%)
Moderate	6/25	(24.0%)	2/8	(25.0%)
Mild	8/25	(32.0%)	2/8	(25.0%)

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

Paroxetine EMEA

EMEA Table 2.60

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Paediatric Placebo Controlled Trials

On-Therapy

Investigator Attribution	Paroxetine		Placebo	
Overall	18/738	(2.4%)	7/647	(1.1%)
Related or Probably Related	1/18	(5.6%)	1/7	(14.3%)
Possibly Related	2/18	(11.1%)	2/7	(28.6%)
Unrelated or Probably Unrelated	15/18	(83.3%)	4/7	(57.1%)

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

Paroxetine EMEA

EMEA Table 2.61

Incidence of Possibly suicide-related AEs by Treatment Group and Investigator Attribution

Paediatric Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine		Placebo	
Overall	25/738	(3.4%)	8/647	(1.2%)
Related or Probably Related	1/25	(4.0%)	1/8	(12.5%)
Possibly Related	3/25	(12.0%)	2/8	(25.0%)
Unrelated or Probably Unrelated	21/25	(84.0%)	5/8	(62.5%)

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

Paroxetine EMEA

EMEA Table 2.62

Incidence and Incidence Density for Self Harm by Treatment Group and Indication

Paediatric Placebo Controlled Trials

On-Therapy

Indication		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)	0.069
	PYE	176	149		
	n/PYE	0.09	0.03		0.072
Depression	n/N (%)	14/378 (3.7%)	5/285 (1.8%)	2.15 (0.77, 6.05)	0.16
	PYE	85	61		
	n/PYE	0.16	0.08		0.18
OCD	n/N (%)	0/195 (0.0%)	0/205 (0.0%)		
	PYE	41	41		
	n/PYE	0.00	0.00		
SAD	n/N (%)	1/165 (0.6%)	0/157 (0.0%)		1.00
	PYE	51	46		
	n/PYE	0.02	0.00		

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

Paroxetine EMEA

EMEA Table 2.63

Incidence and Incidence Density for Self Harm 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 (%)	18/738 (2.4%)	5/647 (0.8%)	3.21 (1.19, 8.70)	0.019
	PYE	176	149		
	n/PYE	0.10	0.03		0.028
Depression	n/N (%)	17/378 (4.5%)	5/285 (1.8%)	2.64 (0.96, 7.24)	0.077
	PYE	85	61		
	n/PYE	0.20	0.08		0.079
OCD	n/N (%)	0/195 (0.0%)	0/205 (0.0%)		
	PYE	41	41		
	n/PYE	0.00	0.00		
SAD	n/N (%)	1/165 (0.6%)	0/157 (0.0%)		1.00
	PYE	51	46		
	n/PYE	0.02	0.00		

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

Paroxetine EMEA

EMEA Table 2.64

Incidence and Incidence Density for Self Harm by Treatment Group and Indication (Excluding DB Extension)

Paediatric Placebo Controlled Trials

On-Therapy

Indication		Paroxetine	Placebo
Overall	n/N (%)	14/738 (1.9%)	5/647 (0.8%)
	PYE	160	139
	n/PYE (rate relative to exposure)	0.09	0.04
Depression	n/N (%)	13/378 (3.4%)	5/285 (1.8%)
	PYE	69	51
	n/PYE (rate relative to exposure)	0.19	0.10
OCD	n/N (%)	0/195 (0.0%)	0/205 (0.0%)
	PYE	41	41
	n/PYE (rate relative to exposure)	0.00	0.00
SAD	n/N (%)	1/165 (0.6%)	0/157 (0.0%)
	PYE	51	46
	n/PYE (rate relative to exposure)	0.02	0.00

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

Paroxetine EMEA

EMEA Table 2.65
Incidence of Self Harm by Treatment Group and Maximum Intensity
Paediatric Placebo Controlled Trials
On-Therapy

Intensity	Paroxetine		Placebo	
Overall	15/738	(2.0%)	5/647	(0.8%)
Severe	7/15	(46.7%)	2/5	(40.0%)
Moderate	3/15	(20.0%)	1/5	(20.0%)
Mild	5/15	(33.3%)	2/5	(40.0%)

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

Paroxetine EMEA

EMEA Table 2.66

Incidence of Self Harm by Treatment Group and Maximum Intensity

Paediatric Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Intensity	Paroxetine	Placebo
Overall	18/738 (2.4%)	5/647 (0.8%)
Severe	8/18 (44.4%)	2/5 (40.0%)
Moderate	5/18 (27.8%)	1/5 (20.0%)
Mild	5/18 (27.8%)	2/5 (40.0%)

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

Paroxetine EMEA

EMEA Table 2.67
Incidence of Self Harm by Treatment Group and Investigator Attribution
Paediatric Placebo Controlled Trials
On-Therapy

Investigator Attribution	Paroxetine		Placebo	
Overall	15/738	(2.0%)	5/647	(0.8%)
Related or Probably Related	1/15	(6.7%)	0/5	(0.0%)
Possibly Related	2/15	(13.3%)	2/5	(40.0%)
Unrelated or Probably Unrelated	12/15	(80.0%)	3/5	(60.0%)

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

Paroxetine EMEA

EMEA Table 2.68

Incidence of Self Harm by Treatment Group and Investigator Attribution

Paediatric Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine		Placebo	
Overall	18/738	(2.4%)	5/647	(0.8%)
Related or Probably Related	1/18	(5.6%)	0/5	(0.0%)
Possibly Related	3/18	(16.7%)	2/5	(40.0%)
Unrelated or Probably Unrelated	14/18	(77.8%)	3/5	(60.0%)

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

Paroxetine EMEA

EMEA Table 2.69

Incidence and Incidence Density for Hostility by Treatment Group and Indication

Paediatric Placebo Controlled Trials

On-Therapy

Indication		Paroxetine	Placebo	Odds Ratio (95% CI)	P value
Overall	n/N (%)	27/738 (3.7%)	4/647 (0.6%)	6.10 (2.12, 17.54)	<0.001
	PYE	176	149		
	n/PYE	0.15	0.03		0.001
Depression	n/N (%)	7/378 (1.9%)	1/285 (0.4%)	5.36 (0.66, 43.80)	0.15
	PYE	85	61		
	n/PYE	0.08	0.02		0.13
OCD	n/N (%)	15/195 (7.7%)	1/205 (0.5%)	17.00 (2.22, 130.0)	<0.001
	PYE	41	41		
	n/PYE	0.37	0.02		0.009
SAD	n/N (%)	5/165 (3.0%)	2/157 (1.3%)	2.42 (0.46, 12.67)	0.45
	PYE	51	46		
	n/PYE	0.10	0.04		0.32

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

Paroxetine EMEA

EMEA Table 2.70

Incidence and Incidence Density for Hostility 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 (%)	28/738 (3.8%)	4/647 (0.6%)	6.34 (2.21, 18.17)	<0.001
	PYE	176	149		
	n/PYE	0.16	0.03		<0.001
Depression	n/N (%)	8/378 (2.1%)	1/285 (0.4%)	6.14 (0.76, 49.38)	0.086
	PYE	85	61		
	n/PYE	0.09	0.02		0.099
OCD	n/N (%)	15/195 (7.7%)	1/205 (0.5%)	17.00 (2.22, 130.0)	<0.001
	PYE	41	41		
	n/PYE	0.37	0.02		0.009
SAD	n/N (%)	5/165 (3.0%)	2/157 (1.3%)	2.42 (0.46, 12.67)	0.45
	PYE	51	46		
	n/PYE	0.10	0.04		0.32

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

Paroxetine EMEA

EMEA Table 2.71

Incidence and Incidence Density for Hostility by Treatment Group and Indication (Excluding DB Extension)

Paediatric Placebo Controlled Trials

On-Therapy

Indication		Paroxetine	Placebo
Overall	n/N (%)	27/738 (3.7%)	3/647 (0.5%)
	PYE	160	139
	n/PYE (rate relative to exposure)	0.17	0.02
Depression	n/N (%)	7/378 (1.9%)	0/285 (0.0%)
	PYE	69	51
	n/PYE (rate relative to exposure)	0.10	0.00
OCD	n/N (%)	15/195 (7.7%)	1/205 (0.5%)
	PYE	41	41
	n/PYE (rate relative to exposure)	0.37	0.02
SAD	n/N (%)	5/165 (3.0%)	2/157 (1.3%)
	PYE	51	46
	n/PYE (rate relative to exposure)	0.10	0.04

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

Paroxetine EMEA

EMEA Table 2.72

Incidence of Hostility by Treatment Group and Maximum Intensity

Paediatric Placebo Controlled Trials

On-Therapy

Intensity	Paroxetine		Placebo	
Overall	27/738	(3.7%)	4/647	(0.6%)
Severe	8/27	(29.6%)	1/4	(25.0%)
Moderate	11/27	(40.7%)	2/4	(50.0%)
Mild	8/27	(29.6%)	1/4	(25.0%)

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

Paroxetine EMEA

EMEA Table 2.73
Incidence of Hostility by Treatment Group and Maximum Intensity
Paediatric Placebo Controlled Trials
On-Therapy plus 30 days post-therapy

Intensity	Paroxetine		Placebo	
Overall	28/738	(3.8%)	4/647	(0.6%)
Severe	10/28	(35.7%)	1/4	(25.0%)
Moderate	10/28	(35.7%)	2/4	(50.0%)
Mild	8/28	(28.6%)	1/4	(25.0%)

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

Paroxetine EMEA

EMEA Table 2.74

Incidence of Hostility by Treatment Group and Investigator Attribution

Paediatric Placebo Controlled Trials

On-Therapy

Investigator Attribution	Paroxetine		Placebo	
Overall	27/738	(3.7%)	4/647	(0.6%)
Related or Probably Related	5/27	(18.5%)	0/4	(0.0%)
Possibly Related	12/27	(44.4%)	0/4	(0.0%)
Unrelated or Probably Unrelated	10/27	(37.0%)	3/4	(75.0%)
Unknown or Unassessed	0/27	(0.0%)	1/4	(25.0%)

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

Paroxetine EMEA

EMEA Table 2.75

Incidence of Hostility by Treatment Group and Investigator Attribution

Paediatric Placebo Controlled Trials

On-Therapy plus 30 days post-therapy

Investigator Attribution	Paroxetine		Placebo	
Overall	28/738	(3.8%)	4/647	(0.6%)
Related or Probably Related	5/28	(17.9%)	0/4	(0.0%)
Possibly Related	12/28	(42.9%)	0/4	(0.0%)
Unrelated or Probably Unrelated	11/28	(39.3%)	3/4	(75.0%)
Unknown or Unassessed	0/28	(0.0%)	1/4	(25.0%)

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

EMEA Table 2.76
Emergent Suicidal Ideation (HAMD Item 3) by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase

Paroxetine		Placebo		Odds Ratio	95% CI	P-value
n/N	(%)	n/N	(%)			
31/2325	1.3	18/1515	1.2	1.12	(0.63, 2.02)	0.77

Denominators are the number of patients without suicide ideation at baseline, and with at least one post-baseline efficacy assessment

The Odds Ratio represents the odds of responding on Paroxetine compared to subjects on placebo

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

EMEA Table 2.77
Emergent Suicidal Ideation (HAMD Item 3) by Treatment Group
Adult Active Controlled Trials
Randomised Phase

Paroxetine		Comparator		Odds Ratio	95% CI	P-value
n/N	(%)	n/N	(%)			
31/2737	1.1	24/1974	1.2	0.93	(0.54, 1.59)	0.79

Denominators are the number of patients without suicide ideation at baseline, and with at least one post-baseline efficacy assessment

The Odds Ratio represents the odds of responding on Paroxetine compared to subjects on the comparator

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

EMEA Table 2.78
Emergent Suicidal Ideation (HAMD Item 3) by Treatment Group
Paediatric Placebo Controlled Trials
Randomised Phase

Paroxetine		Placebo		Odds Ratio	95% CI	P-value
n/N	(%)	n/N	(%)			
5/154	3.2	1/146	0.7	4.87	(0.56, 42.16)	0.22

Denominators are the number of patients without suicide ideation at baseline, and with at least one post-baseline efficacy assessment

The Odds Ratio represents the odds of responding on Paroxetine compared to subjects on placebo

Includes studies 329 and placebo controlled phase of 453

EMEA Table 2.79
Change from Baseline in HAM-D Item 3 and MADRS Item 10 by Treatment Group
Adult Placebo Controlled Trials
Randomised Phase LOCF

	Paroxetine			Placebo			Treatment Difference*	95% CI	P-Value
	N	LS Mean	Std. Error	N	LS Mean	Std. Error			
HAMD	3114	-0.53	0.01	1982	-0.36	0.01	-0.17	(-0.21, -0.13)	<0.01
MADRS	3238	-0.43	0.01	2416	-0.23	0.02	-0.20	(-0.24, -0.16)	<0.01

* Treatment Difference is 'Paroxetine – Placebo'. Negative Differences Correspond to Paroxetine Treatment Benefit

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

EMEA Table 2.80
Change from Baseline in HAM-D Item 3 and MADRS Item 10 by Treatment Group
Adult Active Controlled Trials
Randomised Phase LOCF

	Paroxetine			Comparator			Treatment Difference*	95% CI	P-Value
	N	LS Mean	Std. Error	N	LS Mean	Std. Error			
HAMD	**4057**	**-0.78**	**0.01**	**2949**	**-0.72**	**0.01**	**-0.06**	**(-0.09, -0.03)**	**<0.01**
MADRS	**1957**	**-0.86**	**0.02**	**1848**	**-0.81**	**0.02**	**-0.05**	**(-0.10, 0.01)**	**0.10**

* Treatment Difference is 'Paroxetine – Comparator'. Negative Differences Correspond to Paroxetine Treatment Benefit

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

EMEA Table 2.81
Change from Baseline in HAM-D Item 3 and MADRS Item 10 by Treatment Group
Paediatric Placebo Controlled Trials
Randomised Phase LOCF

	Paroxetine			Placebo			Treatment Difference*	95% CI	P-Value
	N	LS Mean	Std. Error	N	LS Mean	Std. Error			
HAMD	177	-0.27	0.04	180	-0.28	0.04	0.01	(-0.11, 0.13)	0.85
MADRS	179	-0.92	0.09	91	-1.03	0.12	0.12	(-0.17, 0.41)	0.43

* Treatment Difference is 'Paroxetine – Placebo'. Negative Differences Correspond to Paroxetine Treatment Benefit

Includes studies 329, 377 and placebo controlled phase of 453

EMEA Table 2.82
Time to onset of Possibly suicide-related AEs by Treatment Group
Adult Placebo Controlled Trials
On-Therapy

Time period	Paroxetine (N=8481)	Placebo (N=5808)
Total no. of pts with event	66	55
Week 1	9 (13.6%)	10 (18.2%)
Week 2	4 (6.1%)	7 (12.7%)
Week 3	5 (7.6%)	4 (7.3%)
Week 4	15 (22.7%)	6 (10.9%)
Week 5	6 (9.1%)	3 (5.5%)
Week 6	3 (4.5%)	3 (5.5%)
Week 7	8 (12.1%)	2 (3.6%)
Week 8	3 (4.5%)	3 (5.5%)
Week 9	4 (6.1%)	3 (5.5%)
Week 10	3 (4.5%)	4 (7.3%)
Week 11	1 (1.5%)	1 (1.8%)
Week 12	0 (0.0%)	1 (1.8%)
Week 13-16	3 (4.5%)	3 (5.5%)
Week 17-20	2 (3.0%)	1 (1.8%)
Week 21-24	0 (0.0%)	2 (3.6%)
Week 25-52	0 (0.0%)	1 (1.8%)
Week 53+	0 (0.0%)	1 (1.8%)

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

Paroxetine EMEA

EMEA Table 2.83
Time to onset of Possibly suicide-related AEs by Treatment Group
Adult Placebo Controlled Trials
30 Day Follow-up period

Time period	Paroxetine (N=8481)	Placebo (N=5808)
Total no. of pts with event	26	8
Week 1	20 (76.9%)	2 (25.0%)
Week 2	4 (15.4%)	2 (25.0%)
Week 3	1 (3.8%)	4 (50.0%)
Week 4	1 (3.8%)	0 (0.0%)

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

EMEA Table 2.84
Time to onset of Possibly suicide-related AEs by Treatment Group
Adult Active Control Trials
On-Therapy

Time period	Paroxetine (N=6522)	Comparator (N=4969)
Total no. of pts with event	55	63
Week 1	14 (25.5%)	13 (20.6%)
Week 2	4 (7.3%)	11 (17.5%)
Week 3	5 (9.1%)	9 (14.3%)
Week 4	12 (21.8%)	11 (17.5%)
Week 5	6 (10.9%)	2 (3.2%)
Week 6	3 (5.5%)	2 (3.2%)
Week 7	4 (7.3%)	5 (7.9%)
Week 8	1 (1.8%)	2 (3.2%)
Week 9	2 (3.6%)	2 (3.2%)
Week 10	0 (0.0%)	1 (1.6%)
Week 11	1 (1.8%)	0 (0.0%)
Week 12	2 (3.6%)	1 (1.6%)
Week 13-16	1 (1.8%)	1 (1.6%)
Week 17-20	0 (0.0%)	1 (1.6%)
Week 21-24	0 (0.0%)	0 (0.0%)
Week 25-52	0 (0.0%)	2 (3.2%)
Week 53+	0 (0.0%)	0 (0.0%)

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

EMEA Table 2.85
Time to onset of Possibly suicide-related AEs by Treatment Group
Adult Active Control Trials
30 Day Follow-up period

Time period	Paroxetine (N=6522)	Comparator (N=4969)
Total no. of pts with event	24	13
Week 1	15 (62.5%)	8 (61.5%)
Week 2	4 (16.7%)	1 (7.7%)
Week 3	2 (8.3%)	3 (23.1%)
Week 4	3 (12.5%)	0 (0.0%)
Week 5	0 (0.0%)	1 (7.7%)

EMEA Table 2.86
Time to onset of Possibly suicide-related AEs by Treatment Group
Paediatric Placebo Controlled Trials
On-Therapy

Time period	Paroxetine (N=738)	Placebo (N=647)
Total no. of pts with event	18	7
Week 1	0 (0.0%)	1 (14.3%)
Week 2	2 (11.1%)	0 (0.0%)
Week 3	0 (0.0%)	0 (0.0%)
Week 4	3 (16.7%)	0 (0.0%)
Week 5-6	6 (33.3%)	2 (28.6%)
Week 7-8	1 (5.6%)	1 (14.3%)
Week 9-12	4 (22.2%)	1 (14.3%)
Week 13+	2 (11.1%)	2 (28.6%)

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

Paroxetine EMEA

EMEA Table 2.87

Time to onset of Possibly suicide-related AEs by Treatment Group

Paediatric Placebo Controlled Trials

30 Day Follow-up period

Time period	Paroxetine (N=738)	Placebo (N=647)
Total no. of pts with event	7	1
Week 1	6 (85.7%)	1 (100.0%)
Week 2	1 (14.3%)	0 (0.0%)
Week 3	0 (0.0%)	0 (0.0%)
Week 4	0 (0.0%)	0 (0.0%)

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

EMEA Table 2.88
Time to onset of Self Harm by Treatment Group
Adult Placebo Controlled Trials
On-Therapy

Time period	Paroxetine (N=8481)	Placebo (N=5808)
Total no. of pts with event	51	38
Week 1	5 (9.8%)	7 (18.4%)
Week 2	3 (5.9%)	4 (10.5%)
Week 3	4 (7.8%)	3 (7.9%)
Week 4	9 (17.6%)	2 (5.3%)
Week 5	6 (11.8%)	3 (7.9%)
Week 6	3 (5.9%)	2 (5.3%)
Week 7	6 (11.8%)	1 (2.6%)
Week 8	3 (5.9%)	2 (5.3%)
Week 9	4 (7.8%)	3 (7.9%)
Week 10	3 (5.9%)	2 (5.3%)
Week 11	1 (2.0%)	1 (2.6%)
Week 12	0 (0.0%)	1 (2.6%)
Week 13-16	2 (3.9%)	2 (5.3%)
Week 17-20	2 (3.9%)	1 (2.6%)
Week 21-24	0 (0.0%)	2 (5.3%)
Week 25-52	0 (0.0%)	1 (2.6%)
Week 53+	0 (0.0%)	1 (2.6%)

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

Paroxetine EMEA

EMEA Table 2.89
Time to onset of Self Harm by Treatment Group
Adult Placebo Controlled Trials
30 Day Follow-up period

Time period	Paroxetine (N=8481)	Placebo (N=5808)
Total no. of pts with event	12	3
Week 1	9 (75.0%)	1 (33.3%)
Week 2	3 (25.0%)	0 (0.0%)
Week 3	0 (0.0%)	2 (66.7%)
Week 4	0 (0.0%)	0 (0.0%)

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

EMEA Table 2.90
Time to onset of Self Harm by Treatment Group
Adult Active Control Trials
On-Therapy

Time period	Paroxetine (N=6522)	Comparator (N=4969)
Total no. of pts with event	29	32
Week 1	6 (20.7%)	4 (12.5%)
Week 2	1 (3.4%)	2 (6.3%)
Week 3	2 (6.9%)	4 (12.5%)
Week 4	6 (20.7%)	9 (28.1%)
Week 5	3 (10.3%)	1 (3.1%)
Week 6	2 (6.9%)	1 (3.1%)
Week 7	2 (6.9%)	5 (15.6%)
Week 8	1 (3.4%)	0 (0.0%)
Week 9	2 (6.9%)	1 (3.1%)
Week 10	0 (0.0%)	1 (3.1%)
Week 11	1 (3.4%)	0 (0.0%)
Week 12	2 (6.9%)	1 (3.1%)
Week 13-16	1 (3.4%)	1 (3.1%)
Week 17-20	0 (0.0%)	1 (3.1%)
Week 21-24	0 (0.0%)	0 (0.0%)
Week 25-52	0 (0.0%)	1 (3.1%)
Week 53+	0 (0.0%)	0 (0.0%)

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

EMEA Table 2.91
Time to onset of Self Harm by Treatment Group
Adult Active Control Trials
30 Day Follow-up period

Time period	Paroxetine (N=6522)	Comparator (N=4969)
Total no. of pts with event	13	10
Week 1	10 (76.9%)	7 (70.0%)
Week 2	3 (23.1%)	1 (10.0%)
Week 3	0 (0.0%)	1 (10.0%)
Week 4	0 (0.0%)	0 (0.0%)
Week 5	0 (0.0%)	1 (10.0%)

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

Paroxetine EMEA

EMEA Table 2.92
Time to onset of Self Harm by Treatment Group
Paediatric Placebo Controlled Trials
On-Therapy

Time period	Paroxetine (N=738)	Placebo (N=647)
Total no. of pts with event	15	5
Week 1	0 (0.0%)	1 (20.0%)
Week 2	2 (13.3%)	0 (0.0%)
Week 3	0 (0.0%)	0 (0.0%)
Week 4	2 (13.3%)	0 (0.0%)
Week 5-6	5 (33.3%)	2 (40.0%)
Week 7-8	1 (6.7%)	0 (0.0%)
Week 9-12	4 (26.7%)	1 (20.0%)
Week 13+	1 (6.7%)	1 (20.0%)

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

Paroxetine EMEA

EMEA Table 2.93
Time to onset of Self Harm by Treatment Group
Paediatric Placebo Controlled Trials
30 Day Follow-up period

Time period	Paroxetine (N=738)	Placebo (N=647)
Total no. of pts with event	3	0
Week 1	3 (100.0%)	0 (0.0%)
Week 2	0 (0.0%)	0 (0.0%)
Week 3	0 (0.0%)	0 (0.0%)
Week 4	0 (0.0%)	0 (0.0%)

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

EMEA Table 2.94
Time to onset of Hostility by Treatment Group
Adult Placebo Controlled Trials
On-Therapy

Time period	Paroxetine (N=8481)	Placebo (N=5808)
Total no. of pts with event	24	16
Week 1	3 (12.5%)	5 (31.3%)
Week 2	2 (8.3%)	0 (0.0%)
Week 3	0 (0.0%)	3 (18.8%)
Week 4	3 (12.5%)	1 (6.3%)
Week 5	1 (4.2%)	0 (0.0%)
Week 6	1 (4.2%)	1 (6.3%)
Week 7	3 (12.5%)	1 (6.3%)
Week 8	0 (0.0%)	0 (0.0%)
Week 9	3 (12.5%)	0 (0.0%)
Week 10	1 (4.2%)	0 (0.0%)
Week 11	2 (8.3%)	0 (0.0%)
Week 12	2 (8.3%)	0 (0.0%)
Week 13-16	2 (8.3%)	2 (12.5%)
Week 17-20	1 (4.2%)	0 (0.0%)
Week 21-24	0 (0.0%)	1 (6.3%)
Week 25-52	0 (0.0%)	2 (12.5%)
Week 53+	0 (0.0%)	0 (0.0%)

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

Paroxetine EMEA

EMEA Table 2.95
Time to onset of Hostility by Treatment Group
Adult Placebo Controlled Trials
30 Day Follow-up period

Time period	Paroxetine (N=8481)	Placebo (N=5808)
Total no. of pts with event	8	0
Week 1	5 (62.5%)	0 (0.0%)
Week 2	1 (12.5%)	0 (0.0%)
Week 3	1 (12.5%)	0 (0.0%)
Week 4	1 (12.5%)	0 (0.0%)

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

Paroxetine EMEA

EMEA Table 2.96
Time to onset of Hostility by Treatment Group
Adult Active Control Trials
On-Therapy

Time period	Paroxetine (N=6522)	Comparator (N=4969)
Total no. of pts with event	18	20
Week 1	3 (16.7%)	4 (20.0%)
Week 2	5 (27.8%)	2 (10.0%)
Week 3	3 (16.7%)	4 (20.0%)
Week 4	0 (0.0%)	0 (0.0%)
Week 5	0 (0.0%)	4 (20.0%)
Week 6	1 (5.6%)	3 (15.0%)
Week 7	1 (5.6%)	0 (0.0%)
Week 8	0 (0.0%)	0 (0.0%)
Week 9	1 (5.6%)	2 (10.0%)
Week 10	0 (0.0%)	0 (0.0%)
Week 11	2 (11.1%)	0 (0.0%)
Week 12	1 (5.6%)	0 (0.0%)
Week 13-16	1 (5.6%)	0 (0.0%)
Week 17-20	0 (0.0%)	0 (0.0%)
Week 21-24	0 (0.0%)	0 (0.0%)
Week 25-52	0 (0.0%)	1 (5.0%)
Week 53+	0 (0.0%)	0 (0.0%)

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

Paroxetine EMEA

EMEA Table 2.97
Time to onset of Hostility by Treatment Group
Adult Active Control Trials
30 Day Follow-up period

Time period	Paroxetine (N=6522)	Comparator (N=4969)
Total no. of pts with event	4	2
Week 1	3 (75.0%)	1 (50.0%)
Week 2	1 (25.0%)	1 (50.0%)
Week 3	0 (0.0%)	0 (0.0%)
Week 4	0 (0.0%)	0 (0.0%)

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

EMEA Table 2.98
Time to onset of Hostility by Treatment Group
Paediatric Placebo Controlled Trials
On-Therapy

Time period	Paroxetine (N=738)	Placebo (N=647)
Total no. of pts with event	27	4
Week 1	3 (11.1%)	0 (0.0%)
Week 2	1 (3.7%)	1 (25.0%)
Week 3	5 (18.5%)	1 (25.0%)
Week 4	3 (11.1%)	0 (0.0%)
Week 5-6	4 (14.8%)	1 (25.0%)
Week 7-8	2 (7.4%)	0 (0.0%)
Week 9-12	8 (29.6%)	0 (0.0%)
Week 13+	1 (3.7%)	1 (25.0%)

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

Paroxetine EMEA

EMEA Table 2.99
Time to onset of Hostility by Treatment Group
Paediatric Placebo Controlled Trials
30 Day Follow-up period

Time period	Paroxetine (N=738)	Placebo (N=647)
Total no. of pts with event	1	0
Week 1	1 (100.0%)	0 (0.0%)
Week 2	0 (0.0%)	0 (0.0%)
Week 3	0 (0.0%)	0 (0.0%)
Week 4	0 (0.0%)	0 (0.0%)

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

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
329.002.00055	P: PHOTOSENSITIVITY V: SUNBURN,APPROPRIATE TO DEGREE OF EXPOSURE(BEACH)	20 (-136)	13JUL1994 (15JUL1994)	3 DAYS	INT	1	MIL	NO	UNR	No	No
	P: HOSTILITY V: ALLEGATIONS OF SEXUAL AGGRESSION	32 (-124)	25JUL1994 (25JUL1994)	<1 DAY	CON	.	MIL	NO	UNR	No	No
329.002.00106	P: ABDOMINAL PAIN V: STOMACH ACHES	8 (-40)	03AUG1995 (08AUG1995)	6 DAYS	INT	10	MIL	NO	REL	No	No
	P: DRY MOUTH V: DRY MOUTH	8 (-40)	03AUG1995 (20AUG1995)	18 DAYS	CON	.	MIL	NO	REL	No	No
	P: HOSTILITY V: OPPOSITIONAL DEFIANT DISORDER	51 (3)	15SEP1995 (30SEP1995)	16 DAYS	CON	.	SEV	NO	PBU	No	Yes
329.005.00119	P: ASTHENIA V: FATIGUE	1 (-140)	11JUL1995 (14JUL1995)	4 DAYS	CON	.	MOD	NO	POS	No	No
	P: HEADACHE V: HEADACHE	7 (-134)	17JUL1995 (17JUL1995)	<1 DAY	CON	.	MOD	NO	POS	Yes	No
	P: ABDOMINAL PAIN V: STOMACH ACHE	10 (-131)	20JUL1995 (23JUL1995)	4 DAYS	INT	2	MIL	NO	PBU	No	No
	P: HOSTILITY V: PHYSICAL FIGHT M: PHYSICAL FIGHT {AGGRESSION}	18 (-123)	28JUL1995 (28JUL1995)	<1 DAY	INT	1	MIL	NO	PBU	No	No
	P: HEADACHE V: HEADACHE	41 (-100)	20AUG1995 (20AUG1995)	<1 DAY	INT	2	MOD	NO	PBU	No	No

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

* Rel Days from AE Onset Date to Start of Study Med. + 1 (Rel Days from AE Onset Date to End of Study Med.)
Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
329.005.00119	P: RESPIRATORY DISORDER V: COLD SXS M: COLD SYMPTOMS	79 (-62)	27SEP1995 (30SEP1995)	4 DAYS	CON	.	MOD	NO	PBU	Yes	No
	P: ABDOMINAL PAIN V: "STOMACH ACHE" N AND V M: "STOMACH ACHE"	105 (-36)	23OCT1995 (27OCT1995)	5 DAYS	INT	5	MOD	NO	PBU	No	No
	P: VOMITING V: "STOMACH ACHE" N AND V M: NAUSEA AND VOMITING	105 (-36)	23OCT1995 (27OCT1995)	5 DAYS	INT	5	MOD	NO	PBU	No	No
329.005.00300	P: DRY MOUTH V: DRY MOUTH	6 (-51)	24SEP1996 (20OCT1996)	27 DAYS	CON	.	MOD	NO	REL	No	No
	P: SOMNOLENCE V: SLEEPINESS (IN AM)	13 (-44)	01OCT1996 (11OCT1996)	11 DAYS	CON	.	MOD	NO	REL	No	No
	P: SOMNOLENCE V: SLEEPINESS (IN AM)	24 (-33)	12OCT1996 (.)		CON	.	SEV	NO	REL	No	No
	P: HOSTILITY V: OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	30 (-27)	18OCT1996 (24OCT1996)	7 DAYS	INT	6	SEV	NO	PBU	No	No
	P: DRY MOUTH V: DRY MOUTH	33 (-24)	21OCT1996 (30OCT1996)	10 DAYS	CON	.	MIL	NO	REL	No	No
	P: HOSTILITY V: OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	37 (-20)	25OCT1996 (.)		CON	.	MOD	NO	PBU	No	No
	P: HEADACHE V: HEADACHE	55 (-2)	12NOV1996 (12NOV1996)	<1 DAY	CON	.	MOD	NO	UNR	No	No

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

* Rel Days from AE Onset Date to Start of Study Med. + 1 (Rel Days from AE Onset Date to End of Study Med.)
Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
329.006.00038	P: SINUSITIS V: COLD-SINUS SYMPTOMS	8 (-49)	22FEB1995 (03MAR1995)	10 DAYS	CON	.	MIL	NO	UNR	No	No
	P: HOSTILITY V: ANGRY(PATIENT NOTICED)	29 (-28)	15MAR1995 (22MAR1995)	8 DAYS	CON	.	MIL	NO	POS	No	No
	P: CHEST PAIN V: CHEST PAIN-APPROXIMATELY 3 OCCASIONS-INTENSE JAB THEN REMITS	41 (-16)	27MAR1995 (29MAR1995)	3 DAYS	INT	3	SEV	NO	POS	No	No
	P: EMOTIONAL LABILITY V: ATTEMPTED SUICIDE M: ATTEMPTED SUICIDE {INTENTIONAL}	57 (0)	12APR1995 (12APR1995)	<1 DAY	INT	1	SEV	STP	UNR	No	Yes
	P: CONSTIPATION V: CONSTIPATION	57 (0)	12APR1995 (14APR1995)	3 DAYS	CON	.	MOD	STP	UNR	No	No
	P: DIZZINESS V: DIZZINESS	57 (0)	12APR1995 (14APR1995)	3 DAYS	CON	.	MOD	STP	UNR	No	No
	P: HEADACHE V: HEADACHE	57 (0)	12APR1995 (14APR1995)	3 DAYS	CON	.	MOD	STP	UNR	No	No
	P: MYALGIA V: MUSCLE ACHE AND WEAKNESS M: MUSCLE ACHE	57 (0)	12APR1995 (14APR1995)	3 DAYS	CON	.	MOD	STP	UNR	No	No
	P: MYASTHENIA V: MUSCLE ACHE AND WEAKNESS M: MUSCLE WEAKNESS	57 (0)	12APR1995 (14APR1995)	3 DAYS	CON	.	MOD	STP	UNR	No	No
329.009.00201	P: INSOMNIA V: INITIAL INSOMNIA	23 (-36)	28FEB1996 (.)		CON	.	MOD	NO	POS	No	No

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

* Rel Days from AE Onset Date to Start of Study Med. + 1 (Rel Days from AE Onset Date to End of Study Med.)
Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
329.009.00201	P: NAUSEA V: NAUSEA	31 (-28)	07MAR1996 (07MAR1996)	<1 DAY	CON	.	MIL	NO	PBU	No	No
	P: VOMITING V: VOMITING	31 (-28)	07MAR1996 (07MAR1996)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: SOMNOLENCE V: SOMNOLENCE	50 (-9)	26MAR1996 (.)		CON	.	MIL	NO	POS	No	No
	P: INFECTION V: TONSILLITIS (STREP PHARYNGITIS)	56 (-3)	01APR1996 (.)		CON	.	MIL	NO	UNR	Yes	No
	P: WEIGHT GAIN V: WEIGHT GAIN (11 LBS) M: WEIGHT GAIN {11LBS}[WEIGHT GAIN]	57 (-2)	02APR1996 (.)		CON	.	MOD	NO	POS	No	No
	P: AGITATION V: AGITATION	58 (-1)	03APR1996 (.)		CON	.	SEV	STP	POS	No	Yes
	P: HOSTILITY V: AGGRESSIVE ASSAULTIVE BEHAVIOR	58 (-1)	03APR1996 (.)		CON	.	SEV	STP	POS	Yes	Yes
	P: PARANOID REACTION V: PARANOIA	58 (-1)	03APR1996 (.)		CON	.	MOD	STP	POS	No	Yes
	P: RHINITIS V: CONGESTION M: NASAL CONGESTION	62 (3)	07APR1996 (09APR1996)	3 DAYS	CON	.	MOD	NO	UNR	Yes	No
377.005.00260	P: DIZZINESS V: DIZZINESS	1 (-84)	26SEP1996 (18NOV1996)	54 DAYS	CON	.	MOD	NO	PBU	No	No
	P: ASTHENIA V: TIREDNESS	1 (-84)	26SEP1996 (31DEC1996)	97 DAYS	CON	.	MIL	NO	POS	No	No

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

* Rel Days from AE Onset Date to Start of Study Med. + 1 (Rel Days from AE Onset Date to End of Study Med.)
Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
377.005.00260	P: DRY MOUTH V: DRY MOUTH	3 (-82)	28SEP1996 (.)	CON		.	MIL	NO	REL	No	No
	P: HOSTILITY V: AGGRESSION VIOLENT OUTBURSTS	15 (-70)	10OCT1996 (10NOV1996)	32 DAYS	CON	.	SEV	NO	PBU	No	No
	P: MYOCLONUS V: TIC IN THE LEG PACING	15 (-70)	10OCT1996 (12NOV1996)	34 DAYS	CON	.	MIL	NO	POS	No	No
	P: HEADACHE V: HEADACHE	22 (-63)	17OCT1996 (11NOV1996)	26 DAYS	CON	.	MIL	NO	PBU	No	No
453.011.00015	P: SOMNOLENCE V: DAYTIME SLEEPINESS	-115 (-200)	27FEB1998 (20APR1998)	53 DAYS	CON	.	MIL	NO	POS	No	No
	P: RESPIRATORY DISORDER V: URI M: UPPER RESPIRATORY INFECTION	-107 (-192)	07MAR1998 (11MAR1998)	5 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: CONCENTRATION IMPAIRED V: INATTENTIVENESS	-80 (-165)	03APR1998 (.)	CON		.	MIL	NO	POS	No	No
	P: TRAUMA V: ABRASION ON CHIN SECONDARY TO BIKE FALL	-72 (-157)	11APR1998 (14APR1998)	4 DAYS	CON	.	MIL	NO	UNR	No	No
	P: CONSTIPATION V: CONSTIPATION	-63 (-148)	20APR1998 (.)	CON		.	MIL	NO	POS	No	No
	P: CONSTIPATION V: CONSTIPATION	-63 (-148)	20APR1998 (26MAY1998)	37 DAYS	CON	.	MIL	NO	POS	No	No
	P: ALLERGIC REACTION V: ALLERGIES (SEASONAL)	0 (-85)	22JUN1998 (.)	CON		.	MIL	NO	UNR	No	No

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

* Rel Days from AE Onset Date to Start of Study Med. + 1 (Rel Days from AE Onset Date to End of Study Med.)
Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
453.011.00015	P: ALLERGIC REACTION V: SEASONAL ALLERGIES	0 (-85)	22JUN1998 (22JUN1998)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: EOSINOPHILIA V: INCREASED EOSINOPHILS	0 (-85)	22JUN1998 (17SEP1998)	88 DAYS	CON	.	MIL	NO	PBU	No	No
	P: HYPERKINESIA V: HYPERACTIVITY	5 (-80)	27JUN1998 (.)	CON		.	MOD	STP	POS	No	No
	P: HERPES ZOSTER V: CHICKEN POX	19 (-66)	11JUL1998 (17JUL1998)	7 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: HOSTILITY V: AGGRESSIVENESS	71 (-14)	01SEP1998 (.)	CON		.	MIL	STP	POS	No	No
453.017.00334	P: CONCENTRATION IMPAIRED V: WORSENED CONCENTRATION	-90 (-102)	12SEP1997 (30SEP1997)	19 DAYS	CON	.	MIL		POS	No	No
	P: CONCENTRATION IMPAIRED V: WORSENED DISTRACTIBILITY	-90 (-102)	12SEP1997 (30SEP1997)	19 DAYS	CON	.	MIL		POS	No	No
	P: EMOTIONAL LABILITY V: LABILE MOOD	-90 (-102)	12SEP1997 (30SEP1997)	19 DAYS	CON	.	MIL		POS	No	No
	P: HYPERKINESIA V: WORSENED HYPERACTIVITY	-90 (-102)	12SEP1997 (30SEP1997)	19 DAYS	CON	.	MIL		POS	No	No
	P: WEIGHT GAIN V: WEIGHT GAIN	-71 (-83)	01OCT1997 (.)	CON		.	MIL	NO	POS	No	No
	P: CONCENTRATION IMPAIRED V: INCREASED ADHD SYMPTOMS M: INCREASED ATTENTION DEFICIT HYPERACTIVITY DISORDER SYMPTOMS	-10 (-22)	01DEC1997 (.)	CON		.	MOD	NO	UNR	No	No

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

* Rel Days from AE Onset Date to Start of Study Med. + 1 (Rel Days from AE Onset Date to End of Study Med.)
Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
453.017.00334	P: CONCENTRATION IMPAIRED V: INCREASED ATTENTION DEFICIT HYPERACTIVITY DISORDER SYMPTOMS	-10 (-22)	01DEC1997 (.)	CON		.	MOD	NO	UNR	No	No
	P: CONCENTRATION IMPAIRED V: INCREASED ADHD SYMPTOMS M: INCREASED ATTENTION DEFICIT HYPERACTIVITY DISORDER SYMPTOMS	-10 (-22)	01DEC1997 (02JAN1998)	33 DAYS	CON	.	MOD	NO	UNR	No	No
	P: ANXIETY V: INCREASED ANXIETY BEHAVIORS	5 (-7)	16DEC1997 (01JAN1998)	17 DAYS	CON	.	MIL	NO	POS	No	No
	P: HOSTILITY V: INCREASED OPPOSITIONAL BEHAVIORS M: INCREASED OPPOSITIONAL BEHAVIORS {AGGRESSIVE BEHAVIOR}	5 (-7)	16DEC1997 (01JAN1998)	17 DAYS	CON	.	MOD	NO	PBU	No	No
453.018.00027	P: INFECTION V: INFLUENZA	-122 (-155)	31MAR1997 (01APR1997)	2 DAYS	CON	.	MIL			No	No
	P: ABDOMINAL PAIN V: STOMACH ACHE	-113 (-146)	09APR1997 (10APR1997)	2 DAYS	CON	.	MIL	NO	POS	No	No
	P: HEADACHE V: HEADACHE	-113 (-146)	09APR1997 (10APR1997)	2 DAYS	CON	.	MIL	NO	POS	No	No
	P: DYSPEPSIA V: UPSET STOMACH (1ST REPORTED 5/21/97) M: UPSET STOMACH	-107 (-140)	15APR1997 (22MAY1997)	38 DAYS	CON	.	MIL	NO	POS	Yes	No
	P: TRAUMA V: SUTURE DUE TO DOG BITE (WRIST)	-98 (-131)	24APR1997 (24APR1997)	<1 DAY	CON	.	MIL	NO	UNR	No	No

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

* Rel Days from AE Onset Date to Start of Study Med. + 1 (Rel Days from AE Onset Date to End of Study Med.)
Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
453.018.00027	P: ASTHENIA V: FATIGUE	-92 (-125)	30APR1997 (.)		CON	.	MIL	NO	POS	No	No
	P: ASTHENIA V: FATIGUE	-92 (-125)	30APR1997 (30AUG1997)	123 DAYS	CON	.	MIL	NO	POS	No	No
	P: DIZZINESS V: DIZZINESS	-90 (-123)	02MAY1997 (06MAY1997)	5 DAYS	CON	.	MOD	NO	POS	No	No
	P: ABNORMAL VISION V: DIFFICULTY FOCUSING VISION	-88 (-121)	04MAY1997 (05MAY1997)	2 DAYS	CON	.	MIL	NO	POS	No	No
	P: FLATULENCE V: FLATULENCE	-87 (-120)	05MAY1997 (.)		CON	.	MIL	NO	POS	No	No
	P: NAUSEA V: NAUSEA	-87 (-120)	05MAY1997 (05MAY1997)	<1 DAY	CON	.	MIL	NO	POS	No	No
	P: HEADACHE V: HEADACHE	-87 (-120)	05MAY1997 (06MAY1997)	2 DAYS	CON	.	MOD	NO	POS	Yes	No
	P: FLATULENCE V: FLATULENCE	-87 (-120)	05MAY1997 (01AUG1997)	89 DAYS	CON	.	MIL	NO	POS	No	No
	P: HYPERKINESIA V: AKATHISIA	-83 (-116)	09MAY1997 (.)		CON	.	MIL	NO	REL	No	No
	P: HYPERKINESIA V: AKATHISIA	-83 (-116)	09MAY1997 (11SEP1997)	126 DAYS	CON	.	MIL	NO	REL	No	No
	P: HOSTILITY V: AGGRESSIVE OUTBURSTS	-76 (-109)	16MAY1997 (31MAY1997)	16 DAYS	INT	4	MOD		POS	No	No

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

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Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
453.018.00027	P: DIZZINESS V: DIZZINESS	-51 (-84)	10JUN1997 (10JUN1997)	<1 DAY	CON	.	MIL	NO	POS	No	No
	P: PALPITATION V: HEART PALPITATIONS	-51 (-84)	10JUN1997 (10JUN1997)	<1 DAY	CON	.	MIL	NO	POS	No	No
	P: SWEATING V: SWEATING	-51 (-84)	10JUN1997 (10JUN1997)	<1 DAY	CON	.	MIL	NO	POS	No	No
	P: TRAUMA V: PULLED L THUMB PLAYING HOCKEY M: PULLED LEFT THUMB PLAYING HOCKEY	-34 (-67)	27JUN1997 (27JUN1997)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: RESPIRATORY DISORDER V: COMMON COLD SYMPTOMS	-31 (-64)	30JUN1997 (19JUL1997)	20 DAYS	CON	.	MIL	NO	UNR	No	No
	P: HOSTILITY V: AGGRESSIVE OUTBURSTS	-17 (-50)	14JUL1997 (16JUL1997)	3 DAYS	INT	2	MOD	NO	POS	No	No
	P: INFECTION V: STREP THROAT M: STREPTOCOCCUS THROAT	-11 (-44)	20JUL1997 (25JUL1997)	6 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: HOSTILITY V: AGGRESSIVE OUTBURST	0 (-33)	31JUL1997 (31JUL1997)	<1 DAY	CON	.	MOD	NO	POS	No	No
	P: CONTACT DERMATITIS V: POISON IVY	1 (-32)	01AUG1997 (16AUG1997)	16 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: HOSTILITY V: AGGRESSIVE OUTBURST	19 (-14)	19AUG1997 (19AUG1997)	<1 DAY	CON	.	SEV	STP	PBU	No	No
	P: RHINITIS V: SEASONAL RHINITIS	20 (-13)	20AUG1997 (24AUG1997)	5 DAYS	CON	.	MIL	NO	UNR	Yes	No

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453.018.00027	P: URINARY INCONTINENCE V: ENURESIS, NOCTURNAL	25 (-8)	25AUG1997 (.)	CON		.	MIL	NO	UNR	No	No
	P: DIZZINESS V: LIGHTHEADEDNESS	42 (9)	11SEP1997 (25SEP1997)	15 DAYS	INT	3	MIL	NO	UNR	No	No
	P: TINNITUS V: TINNITUS	49 (16)	18SEP1997 (.)	CON		.	MIL	NO	UNR	No	No
453.018.00029	P: RESPIRATORY DISORDER V: COMMON COLD SYMPTOMS	-105 (-230)	14MAY1997 (15JUN1997)	33 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: HEADACHE V: HEADACHE	-103 (-228)	16MAY1997 (19MAY1997)	4 DAYS	INT	3	MIL	NO	POS	No	No
	P: WEIGHT GAIN V: WEIGHT GAIN	-98 (-223)	21MAY1997 (.)	CON		.	MIL	NO	POS	No	No
	P: FLATULENCE V: FLATULENCE	-84 (-209)	04JUN1997 (.)	CON		.	MIL	NO	PBU	No	No
	P: FLATULENCE V: FLATULENCE	-84 (-209)	04JUN1997 (15OCT1997)	134 DAYS	CON	.	MIL	NO	PBU	No	No
	P: EPISTAXIS V: BLOOD, L NOSTRIL, WHEN BLOWING NOSE M: BLOOD, LEFT NOSTRIL, WHEN BLOWING NOSE	-76 (-201)	12JUN1997 (.)	CON		.	MIL	NO	POS	No	No
	P: TRAUMA V: LACERATION, R LEG M: LACERATION, RIGHT LEG	-76 (-201)	12JUN1997 (12JUN1997)	<1 DAY	CON	.	MIL	NO	UNR	Yes	No

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453.018.00029	P: EPISTAXIS V: BLOOD, L NOSTRIL, WHEN BLOWING NOSE M: BLOOD, LEFT NOSTRIL, WHEN BLOWING NOSE	-76 (-201)	12JUN1997 (11SEP1997)	92 DAYS	CON	.	MIL	NO	POS	No	No
	P: CONJUNCTIVITIS V: CONJUNCTIVITIS, L EYE M: CONJUNCTIVITIS, LEFT EYE	-75 (-200)	13JUN1997 (16JUN1997)	4 DAYS	CON	.	MIL	NO	PBU	Yes	No
	P: INSOMNIA V: INITIAL INSOMNIA	-58 (-183)	30JUN1997 (13AUG1997)	45 DAYS	CON	.	MIL	NO	POS	No	No
	P: EPISTAXIS V: BLOOD, R NOSTRIL, WHEN BLOWING NOSE M: BLOOD, RIGHT NOSTRIL, WHEN BLOWING NOSE	-49 (-174)	09JUL1997 (.)		CON	.	MIL	NO	POS	No	No
	P: EPISTAXIS V: BLOOD, R NOSTRIL, WHEN BLOWING NOSE M: BLOOD, RIGHT NOSTRIL, WHEN BLOWING NOSE	-49 (-174)	09JUL1997 (11SEP1997)	65 DAYS	CON	.	MIL	NO	POS	No	No
	P: INSOMNIA V: INITIAL INSOMNIA	-13 (-138)	14AUG1997 (.)		CON	.	MOD		POS	No	No
	P: INSOMNIA V: INITIAL INSOMNIA	-13 (-138)	14AUG1997 (19JAN1998)	159 DAYS	CON	.	MOD		POS	No	No
	P: INSOMNIA V: MIDDLE INSOMNIA	-4 (-129)	23AUG1997 (24SEP1997)	33 DAYS	CON	.	MIL	NO	POS	No	No
	P: HYPERKINESIA V: AKATHISIA	9 (-116)	05SEP1997 (28JAN1998)	146 DAYS	CON	.	MIL	NO	POS	No	No
	P: HOSTILITY V: INCREASE IN OPPOSITIONAL DEFIANT BEHAVIOR	27 (-98)	23SEP1997 (.)		CON	.	MOD	NO	POS	No	No

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453.018.00029	P: OTITIS MEDIA V: DOUBLE EAR INFECTION	37 (-88)	03OCT1997 (12OCT1997)	10 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: NAUSEA V: NAUSEA	53 (-72)	19OCT1997 (19OCT1997)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: FEVER V: FEVER	54 (-71)	20OCT1997 (20OCT1997)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: PUSTULAR RASH V: IMPETIGO	82 (-43)	17NOV1997 (20NOV1997)	4 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: OTITIS MEDIA V: EAR INFECTION, L EAR M: EAR INFECTION, LEFT EAR	82 (-43)	17NOV1997 (25NOV1997)	9 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: ASTHENIA V: FATIGUE	103 (-22)	08DEC1997 (06JAN1998)	30 DAYS	CON	.	MIL	NO	POS	No	No
453.021.00129	P: ASTHMA V: SINUS INFECTION ASTHMA M: ASTHMA	-92 (-152)	11MAY1997 (28MAY1997)	18 DAYS	CON	.	MOD	NO	PBU	Yes	No
	P: SINUSITIS V: SINUS INFECTION ASTHMA M: SINUS INFECTION	-92 (-152)	11MAY1997 (28MAY1997)	18 DAYS	CON	.	MOD	NO	PBU	Yes	No
	P: TRAUMA V: ELECTRIC SHOCK M: ELECTRIC SHOCK {INJURY}	-60 (-120)	12JUN1997 (12JUN1997)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: HOSTILITY V: SEVERE MANIC BEHAVIORS INCREASED AGGRESSION M: INCREASED AGGRESSION	59 (-1)	09OCT1997 (09OCT1997)	<1 DAY	CON	.	SEV	STP	POS	No	Yes

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453.021.00129	P: MANIC REACTION V: SEVERE MANIC BEHAVIORS INCREASED AGGRESSION M: SEVERE MANIC BEHAVIORS	59 (-1)	09OCT1997 (09OCT1997)	<1 DAY	CON	.	SEV	STP	POS	No	Yes
453.024.00039	P: DIARRHEA V: LOOSE STOOL	-107 (-219)	05APR1997 (05APR1997)	<1 DAY	CON	.	MIL	NO	PBU	No	No
	P: CONSTIPATION V: CONSTIPATION	-106 (-218)	06APR1997 (08APR1997)	3 DAYS	CON	.	MIL	NO	PBU	No	No
	P: DIARRHEA V: LOOSE STOOL	-91 (-203)	21APR1997 (22APR1997)	2 DAYS	INT	2	MIL	NO	PBU	No	No
	P: DIARRHEA V: LOOSE STOOL	-81 (-193)	01MAY1997 (02MAY1997)	2 DAYS	INT	2	MIL	NO	PBU	No	No
	P: OTITIS MEDIA V: EAR INFECTION L EAR M: EAR INFECTION LEFT EAR	-30 (-142)	21JUN1997 (30JUN1997)	10 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: PALPITATION V: PALPITATION	-1 (-113)	20JUL1997 (20JUL1997)	<1 DAY	CON	.	MIL	NO	PBU	No	No
	P: VASODILATATION V: FEELS WARM	1 (-111)	22JUL1997 (.)		CON	INT 20	MIL	NO	POS	No	No
	P: VASODILATATION V: FEELS WARM	1 (-111)	22JUL1997 (15OCT1997)	86 DAYS	INT	45	MIL	NO	POS	No	No
	P: HOSTILITY V: ANGRY MOOD	77 (-35)	06OCT1997 (.)		CON	INT 16	MOD	NO	POS	No	No
	P: NERVOUSNESS V: IRRITABLE MOOD	77 (-35)	06OCT1997 (.)		CON	INT 16	MOD	NO	POS	No	No

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676.002.24034	P: URINARY INCONTINENCE V: INTERMITTENT BEDWETTING	14 (-55)	22JUN2000 (28JUN2000)	7 DAYS	CON	.	MOD	NO	UNR	No	No
	P: HEADACHE V: INCREASED INTERMITTENT HEADACHES	25 (-44)	03JUL2000 (21JUL2000)	19 DAYS	CON	.	MOD	NO	PBU	Yes	No
	P: INSOMNIA V: INSOMNIA --INITIAL AND MIDDLE	29 (-40)	07JUL2000 (13AUG2000)	38 DAYS	CON	.	MOD	NO	UNR	No	No
	P: URINARY INCONTINENCE V: INTERMITTENT BED WETTING	47 (-22)	25JUL2000 (09AUG2000)	16 DAYS	CON	.	MOD	NO	UNR	No	No
	P: HOSTILITY V: INCREASED AGGRESSION	50 (-19)	28JUL2000 (17AUG2000)	21 DAYS	CON	.	MOD		PBU	No	No
	P: ABDOMINAL PAIN V: STOMACH ACHE	69 (0)	16AUG2000 (16AUG2000)	<1 DAY	CON	.	MIL	NO	PBU	No	No
676.006.24145	P: HEADACHE V: HEADACHE	6 (-122)	29AUG2000 (30AUG2000)	2 DAYS	CON	.	MIL	NO	POS	No	No
	P: DYSPEPSIA V: INDIGESTION	18 (-110)	10SEP2000 (10SEP2000)	<1 DAY	CON	.	MOD	NO	UNR	Yes	No
	P: DYSMENORRHEA V: MENSTRUAL CRAMPS	20 (-108)	12SEP2000 (12SEP2000)	<1 DAY	CON	.	SEV	NO	UNR	Yes	No
	P: SOMNOLENCE V: DAYTIME DROWSINESS	22 (-106)	14SEP2000 (22SEP2000)	9 DAYS	CON	.	MIL	NO	POS	No	No
	P: DECREASED APPETITE V: DECREASE IN APPETITE	22 (-106)	14SEP2000 (10OCT2000)	27 DAYS	CON	.	MOD	NO	POS	No	No

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676.006.24145	P: PHARYNGITIS V: SORE THROAT	41 (-87)	03OCT2000 (04OCT2000)	2 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: DYSMENORRHEA V: MENSTRUAL CRAMPS	55 (-73)	17OCT2000 (17OCT2000)	<1 DAY	CON	.	SEV	NO	UNR	Yes	No
	P: HOSTILITY V: OPPOSITIONAL DEFIANT BEHAVIOR	70 (-58)	01NOV2000 (01NOV2000)	<1 DAY	CON	.	MIL		PBU	No	No
	P: DYSMENORRHEA V: MENSTRUAL CRAMPS	96 (-32)	27NOV2000 (28NOV2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: DIZZINESS V: DIZZINESS	119 (-9)	20DEC2000 (02JAN2001)	14 DAYS	CON	.	SEV	NO	REL	Yes	No
	P: MYOCLONUS V: MYOCLONIC JERKS	119 (-9)	20DEC2000 (07JAN2001)	19 DAYS	INT	25	MOD	NO	REL	No	No
	P: DIZZINESS V: DIZZINESS	133 (5)	03JAN2001 (07JAN2001)	5 DAYS	CON	.	MIL	NO	REL	No	No
	P: MYOCLONUS V: MYOCLONIC JERKS	138 (10)	08JAN2001 (09JAN2001)	2 DAYS	INT	5	MIL	NO	REL	No	No
676.007.24177	P: HOSTILITY V: BEHAVIORAL DISINHIBITION M: BEHAVIORAL DISINHIBITION {DISOBEDIANT INCREASE OPPOSITIONAL BEHAVIOUR}	57 (-59)	04APR2000 (15MAY2000)	42 DAYS	CON	.	MIL		REL	No	No
676.023.17877	P: FECAL INCONTINENCE V: INCREASE IN BLADDER AND BOWEL INCONTINENCE M: INCREASE IN BOWEL INCONTINENCE	1 (-55)	02AUG2000 (04AUG2000)	3 DAYS	INT	3	MIL	NO	POS	No	No

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676.023.17877	P: URINARY INCONTINENCE V: INCREASE IN BLADDER AND BOWEL INCONTINENCE M: INCREASE IN BLADDER INCONTINENCE	1 (-55)	02AUG2000 (04AUG2000)	3 DAYS	INT	3	MIL	NO	POS	No	No
	P: ABDOMINAL PAIN V: STOMACH ACHE	1 (-55)	02AUG2000 (05AUG2000)	4 DAYS	CON	.	MIL	NO	POS	No	No
	P: HEADACHE V: HEADACHE	1 (-55)	02AUG2000 (08AUG2000)	7 DAYS	INT	3	MIL	NO	POS	No	No
	P: HOSTILITY V: DISINHIBITED M: DISINHIBITED {PATIENT BECOMING MORE AGGRESSIVE TOWARDS HIS PARENTS}	7 (-49)	08AUG2000 (.)		CON	.	MOD	STP	REL	No	No
	P: RASH V: RASH	10 (-46)	11AUG2000 (15AUG2000)	5 DAYS	INT	1	MIL	NO	UNR	No	No
	P: MANIC REACTION V: HYPOMANIA	14 (-42)	15AUG2000 (.)		CON	.	SEV		REL	No	No
	P: HOSTILITY V: OPPOSITIONAL M: OPPOSITIONAL {ACTING DEFIANT TOWARDS PARENTS}	18 (-38)	19AUG2000 (.)		CON	.	MOD		REL	No	No
	P: NEUROSIS V: IMPULSIVE	18 (-38)	19AUG2000 (02SEP2000)	15 DAYS	CON	.	MOD		REL	No	No
	P: PRURITUS V: ITCHY BACK	29 (-27)	30AUG2000 (.)		CON	.	MIL	STP	POS	No	No
	P: CONJUNCTIVITIS V: CONJUNCTIVITIS	55 (-1)	25SEP2000 (25SEP2000)	<1 DAY	CON	.	MIL	NO	UNR	No	No

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676.023.17877	P: ALBUMINURIA V: PROTEIN IN URINE	56 (0)	26SEP2000 (.)	CON	.		MIL	NO	UNR	No	No
	P: DYSMENORRHEA V: MENSTRUAL CRAMPS	165 (109)	13JAN2001 (13JAN2001)	<1 DAY	CON	.	MIL	NO	UNR	Yes	No
676.023.17879	P: COUGH INCREASED V: SLIGHT COUGH	-2 (-137)	11NOV2000 (.)	CON	.		MIL			Yes	No
	P: ASTHENIA V: MORE TIRED	3 (-132)	16NOV2000 (30NOV2000)	15 DAYS	CON	.	MIL	NO	POS	No	No
	P: DRY MOUTH V: DRY MOUTH	15 (-120)	28NOV2000 (.)	CON	.		MIL	NO	POS	No	No
	P: THIRST V: FEELS THIRSTY	15 (-120)	28NOV2000 (07DEC2000)	10 DAYS	INT	5	MIL	NO	POS	No	No
	P: INSOMNIA V: INSOMNIA	18 (-117)	01DEC2000 (.)	CON	.		MOD		PBU	No	No
	P: RASH V: LEG RASH	20 (-115)	03DEC2000 (.)	CON	.		MIL	NO	POS	No	No
	P: DYSMENORRHEA V: MENSTRUAL CRAMPS	26 (-109)	09DEC2000 (09DEC2000)	<1 DAY	CON	.	MOD	NO	UNR	Yes	No
	P: VOMITING V: VOMITING	28 (-107)	11DEC2000 (13DEC2000)	3 DAYS	INT	3	MIL	NO	UNR	No	No
	P: HEADACHE V: HEADACHE	30 (-105)	13DEC2000 (13DEC2000)	<1 DAY	INT	1	MIL	NO	PBU	No	No

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Paediatric Placebo Controlled Trials

Treatment Group : PAROXETINE

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
676.023.17879	P: INFECTION V: STREP THROAT M: STREPTOCOCCAL THROAT	30 (-105)	13DEC2000 (25DEC2000)	13 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: NAUSEA V: NAUSEA, VOMITING M: NAUSEA	49 (-86)	01JAN2001 (03JAN2001)	3 DAYS	CON	.	MOD	NO	UNR	No	No
	P: VOMITING V: NAUSEA, VOMITING M: VOMITING	49 (-86)	01JAN2001 (03JAN2001)	3 DAYS	CON	.	MOD	NO	UNR	No	No
	P: DYSMENORRHEA V: MENSTRUAL CRAMPS	51 (-84)	03JAN2001 (03JAN2001)	<1 DAY	CON	.	MIL	NO	UNR	Yes	No
	P: DYSMENORRHEA V: MENSTRUAL CRAMPS	61 (-74)	13JAN2001 (13JAN2001)	<1 DAY	CON	.	MIL	NO	UNR	Yes	No
	P: NAUSEA V: NAUSEA	61 (-74)	13JAN2001 (14JAN2001)	2 DAYS	CON	.	MIL	NO	UNR	No	No
	P: INFECTION V: STREP THROAT	83 (-52)	04FEB2001 (09FEB2001)	6 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: HOSTILITY V: AGGRESSIVE BEHAVIOR (SHOVED SCHOOLMATE)	87 (-48)	08FEB2001 (08FEB2001)	<1 DAY	INT	1	MOD	NO	POS	No	No
	P: HEADACHE V: HEADACHE	103 (-32)	24FEB2001 (28FEB2001)	5 DAYS	CON	.	MOD	NO	POS	Yes	No
	P: ALLERGIC REACTION V: SEASONAL ALLERGIES	129 (-6)	22MAR2001 (.)		CON	.	MIL	NO	UNR	Yes	No

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

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676.023.17879	P: PHARYNGITIS V: THROAT IRRITATION	129 (-6)	22MAR2001 (22MAR2001)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: CONJUNCTIVITIS V: CONJUNCTIVITIS	130 (-5)	23MAR2001 (26MAR2001)	4 DAYS	CON	.	MOD	NO	UNR	Yes	No
701.148.27660	P: HOSTILITY V: INCREASED AGGRESSION	2 (-28)	19NOV2000 (20DEC2000)	32 DAYS	CON	.	SEV	STP	POS	No	No
	P: TREMOR V: SHAKY FEELING	3 (-27)	20NOV2000 (28NOV2000)	9 DAYS	INT	2	MIL	NO	POS	No	No
	P: PURPURA V: BRUISING ON RIGHT CHEEK	5 (-25)	22NOV2000 (.)	CON		.	MOD	NO	UNR	No	No
	P: HEADACHE V: HEADACHE	22 (-8)	09DEC2000 (09DEC2000)	<1 DAY	CON	.	MOD	NO	PBU	Yes	No
	P: MELENA V: BLOODY STOOL	22 (-8)	09DEC2000 (09DEC2000)	<1 DAY	INT	2	MIL	NO	PBU	No	No
	P: TREMOR V: TREMOR IN RIGHT HAND	24 (-6)	11DEC2000 (11DEC2000)	<1 DAY	CON	.	MIL	NO	UNR	No	No
704.005.27054	P: HOSTILITY V: DISINHIBITED/OPPOSITIONAL M: OPPOSITIONAL{INCREASINGLY DIFFICULT TO GET ALONG WITH & ARGUMENTATIVE}	42 (-35)	28AUG2000 (.)	CON		.	MOD		POS	No	No
	P: PERSONALITY DISORDER V: DISINHIBITED/OPPOSITIONAL M: DISINHIBITED{CHARACTER CHANGE NOTICED BY PARENTS}	42 (-35)	28AUG2000 (.)	CON		.	MOD		POS	No	No

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704.005.27054	P: HOSTILITY V: DISINHIBITED/OPPOSITIONAL M: OPPOSITIONAL{INCREASINGLY DIFFICULT TO GET ALONG WITH & ARGUMENTATIVE}	42 (-35)	28AUG2000 (15SEP2000)	19 DAYS	CON	.	MOD		POS	No	No
	P: PERSONALITY DISORDER V: DISINHIBITED/OPPOSITIONAL M: DISINHIBITED{CHARACTER CHANGE NOTICED BY PARENTS}	42 (-35)	28AUG2000 (15SEP2000)	19 DAYS	CON	.	MOD		POS	No	No
	P: HEADACHE V: HEADACHES	52 (-25)	07SEP2000 (07SEP2000)	<1 DAY	INT	1	MIL	NO	POS	No	No
704.009.25504	P: ABDOMINAL PAIN V: STOMACH ACHE	0 (-94)	28NOV2000 (28NOV2000)	<1 DAY	INT	1	MIL			No	No
	P: EMOTIONAL LABILITY V: CRYING	18 (-76)	16DEC2000 (16DEC2000)	<1 DAY	INT	1	MOD	NO	PBU	No	No
	P: HOSTILITY V: PHYSICAL AGGRESSION	18 (-76)	16DEC2000 (16DEC2000)	<1 DAY	INT	1	MOD	NO	PBU	No	No
	P: RESPIRATORY DISORDER V: COMMON COLD	73 (-21)	09FEB2001 (.)		CON	.	MIL	NO	UNR	Yes	No
704.015.27044	P: CONCENTRATION IMPAIRED V: DISTRACTIBLE	2 (-54)	27SEP2000 (.)		CON	.	MIL	NO	POS	No	No
	P: CONCENTRATION IMPAIRED V: INATTENTIVE	2 (-54)	27SEP2000 (.)		CON	.	MIL	NO	POS	No	No
	P: DRY MOUTH V: DRY MOUTH	2 (-54)	27SEP2000 (.)		CON	.	MIL	NO	POS	No	No

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704.015.27044	P: HYPERKINESIA V: HYPERACTIVE	2 (-54)	27SEP2000 (.)	CON		.	MIL	NO	POS	No	No
	P: NAUSEA V: NAUSEA	2 (-54)	27SEP2000 (.)	CON		.	MIL	NO	POS	No	No
	P: SWEATING V: DIAPHORESIS	2 (-54)	27SEP2000 (28SEP2000)	2 DAYS	CON	.	MIL	NO	POS	No	No
	P: TREMOR V: TREMULOUS	2 (-54)	27SEP2000 (30SEP2000)	4 DAYS	CON	.	MIL	NO	POS	No	No
	P: SINUSITIS V: SINUS INFECTION	12 (-44)	07OCT2000 (.)	CON		.	MIL	NO	UNR	Yes	No
	P: MYALGIA V: MYALGIA IN LEGS	12 (-44)	07OCT2000 (08OCT2000)	2 DAYS	INT	1	MIL	NO	UNR	Yes	No
	P: SINUSITIS V: SINUS INFECTION	12 (-44)	07OCT2000 (21OCT2000)	15 DAYS	INT	1	MIL	NO	UNR	Yes	No
	P: HOSTILITY V: OPPOSITIONAL DEFIANT DISORDER	14 (-42)	09OCT2000 (.)	CON		.	MIL	STP	REL	No	No
	P: HOSTILITY V: OPPOSITIONAL DEFIANT DISORDER	14 (-42)	09OCT2000 (14NOV2000)	37 DAYS	CON	.	MIL	STP	REL	No	No
	P: URINARY INCONTINENCE V: ENURESIS	23 (-33)	18OCT2000 (.)	CON		.	MIL	NO	POS	No	No
	P: BACK PAIN V: MULTIPLE ACHES M: MULTIPLE ACHES {BACKACHE}	23 (-33)	18OCT2000 (19OCT2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No

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704.015.27044	P: HEADACHE V: MULTIPLE ACHES M: MULTIPLE ACHES {HEADACHE}	23 (-33)	18OCT2000 (19OCT2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: NAUSEA V: MULTIPLE ACHES M: MULTIPLE ACHES {SICK TO STOMACH}	23 (-33)	18OCT2000 (19OCT2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: PAIN V: MULTIPLE ACHES M: MULTIPLE ACHES {LEG ACHE}	23 (-33)	18OCT2000 (19OCT2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: MYALGIA V: MYALGIA IN LEGS	29 (-27)	24OCT2000 (25OCT2000)	2 DAYS	INT	1	MIL	NO	UNR	Yes	No
	P: TRAUMA V: DOG BITE UPPER LIP	34 (-22)	29OCT2000 (30OCT2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: HEADACHE V: HEADACHE	43 (-13)	07NOV2000 (.)	CON		.	MIL	NO	POS	No	No
	P: ULCERATIVE STOMATITIS V: ORAL ULCER	43 (-13)	07NOV2000 (.)	CON		.	MIL	NO	UNR	Yes	No
	P: RHINITIS V: ALLERGIC RHINITIS	43 (-13)	07NOV2000 (11NOV2000)	5 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: INFECTION V: VIRAL SYNDROME	43 (-13)	07NOV2000 (16NOV2000)	10 DAYS	CON	.	MIL	NO	UNR	Yes	No
704.015.27095	P: TOOTH DISORDER V: TOOTHACHE	8 (-49)	29NOV2000 (30NOV2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No

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704.015.27095	P: FEVER V: FEVER	10 (-47)	01DEC2000 (02DEC2000)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: HOSTILITY V: DISRUPTIVE BEHAVIOR M: DISRUPTIVE BEHAVIOUR{AGGRESSIVE BEHAVIOUR}	17 (-40)	08DEC2000 (.)		CON	.	MIL	NO	REL	No	No
	P: SOMNOLENCE V: SEDATION	17 (-40)	08DEC2000 (15DEC2000)	8 DAYS	CON	.	MIL	NO	REL	No	No
	P: DECREASED APPETITE V: DECREASED APPETITE	17 (-40)	08DEC2000 (17DEC2000)	10 DAYS	CON	.	MIL	NO	REL	No	No
	P: HYPERKINESIA V: HYPERACTIVITY	17 (-40)	08DEC2000 (17DEC2000)	10 DAYS	CON	.	MOD		REL	No	No
704.016.25451	P: ULCERATIVE STOMATITIS V: CANKER SORE	6 (-64)	06APR2000 (21APR2000)	16 DAYS	CON	.	MIL	NO	UNR	No	No
	P: HYPERKINESIA V: HYPERACTIVITY	19 (-51)	19APR2000 (22APR2000)	4 DAYS	CON	.	MIL		POS	No	No
	P: HOSTILITY V: ANGRY	68 (-2)	07JUN2000 (12JUN2000)	6 DAYS	CON	.	MOD	NO	REL	No	No
	P: PERSONALITY DISORDER V: DISINHIBITED M: DISINHIBITED{MORE IMPULSIVE LESS INHIBITED}{CHARACTER CHANGE}	68 (-2)	07JUN2000 (12JUN2000)	6 DAYS	CON	.	MOD	NO	REL	No	No
704.019.25384	P: HEADACHE V: HEADACHE	-1 (-44)	09FEB2000 (10FEB2000)	2 DAYS	CON	.	MOD			Yes	No

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704.019.25384	P: FEVER V: FEVER	0 (-43)	10FEB2000 (10FEB2000)	<1 DAY	CON	.	MIL			Yes	No
	P: RHINITIS V: NASAL CONGESTION	0 (-43)	10FEB2000 (10FEB2000)	<1 DAY	CON	.	MIL			No	No
	P: PHARYNGITIS V: SORE THROAT	6 (-37)	16FEB2000 (16FEB2000)	<1 DAY	CON	.	MIL	NO	PBU	No	No
	P: ABDOMINAL PAIN V: HEARTBURN/STOMACH ACHE M: STOMACH ACHE	12 (-31)	22FEB2000 (22FEB2000)	<1 DAY	CON	.	MOD	NO	PBU	Yes	No
	P: DYSPEPSIA V: HEARTBURN/STOMACH ACHE M: HEARTBURN	12 (-31)	22FEB2000 (22FEB2000)	<1 DAY	CON	.	MOD	NO	PBU	Yes	No
	P: HEADACHE V: HEADACHE	12 (-31)	22FEB2000 (22FEB2000)	<1 DAY	CON	.	MOD	NO	PBU	Yes	No
	P: VOMITING V: EMESIS	19 (-24)	29FEB2000 (29FEB2000)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: ABDOMINAL PAIN V: STOMACH ACHE	19 (-24)	29FEB2000 (01MAR2000)	2 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: AGITATION V: AGITATION	22 (-21)	03MAR2000 (.)		CON	.	SEV	NO	POS	No	No
	P: AGITATION V: INCREASED AGITATION	22 (-21)	03MAR2000 (.)		CON	.	SEV	NO	POS	No	No
	P: HOSTILITY V: AGGRESSIVE BEHAVIOUR	22 (-21)	03MAR2000 (07MAR2000)	5 DAYS	INT	5	SEV		POS	No	No

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704.019.25384	P: DYSPEPSIA V: UPSET STOMACH	25 (-18)	06MAR2000 (06MAR2000)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: HEADACHE V: HEADACHE	25 (-18)	06MAR2000 (06MAR2000)	<1 DAY	CON	.	MOD	NO	POS	No	No
	P: DECREASED APPETITE V: DECREASED APPETITE	26 (-17)	07MAR2000 (.)	CON		.	MIL	NO	POS	No	No
	P: INSOMNIA V: SLEEP DISTURBANCE	26 (-17)	07MAR2000 (.)	CON		.	MOD	NO	POS	No	No
	P: DECREASED APPETITE V: DECREASED APPETITE	26 (-17)	07MAR2000 (27MAR2000)	21 DAYS	CON	.	MIL	NO	POS	No	No
	P: INSOMNIA V: SLEEP DISTURBANCE	26 (-17)	07MAR2000 (27MAR2000)	21 DAYS	CON	.	MOD	NO	POS	No	No
	P: HEADACHE V: INTERMITTENT HEADACHES	44 (1)	25MAR2000 (31MAR2000)	7 DAYS	INT	14	MOD	NO	UNR	Yes	No
	P: VOMITING V: EMESIS	44 (1)	25MAR2000 (31MAR2000)	7 DAYS	INT	28	SEV	NO	UNR	Yes	No
	P: VOMITING V: EMESIS	55 (12)	05APR2000 (05APR2000)	<1 DAY	CON	.	MOD	NO	UNR	No	No
704.019.25386	P: ABDOMINAL PAIN V: ABDOMINAL PAIN	25 (-11)	25SEP2000 (25SEP2000)	<1 DAY	CON	.	MIL	NO	UNR	No	No
	P: VOMITING V: EMESIS	25 (-11)	25SEP2000 (25SEP2000)	<1 DAY	CON	.	MIL	NO	UNR	No	No

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704.019.25386	P: HOSTILITY V: AGGRESSIVE BEHAVIOR	26 (-10)	26SEP2000 (27SEP2000)	2 DAYS	INT	2	MOD		POS	No	No
704.048.27175	P: NAUSEA V: NAUSEA	7 (-63)	28MAR2001 (29MAR2001)	2 DAYS	CON	.	MOD	NO	UNR	No	No
	P: VOMITING V: VOMITING	7 (-63)	28MAR2001 (29MAR2001)	2 DAYS	CON	.	MOD	NO	UNR	No	No
	P: TOOTH CARIES V: TOOTH CAVITY	26 (-44)	16APR2001 (16APR2001)	<1 DAY	CON	.	MOD	NO	UNR	Yes	No
	P: STOMATITIS V: PAIN IN MOUTH	27 (-43)	17APR2001 (17APR2001)	<1 DAY	CON	.	MOD	NO	UNR	Yes	No
	P: ABDOMINAL PAIN V: ABDOMINAL PAIN	39 (-31)	29APR2001 (01MAY2001)	3 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: HOSTILITY V: AGGRESSIVE BEHAVIOR	55 (-15)	15MAY2001 (30MAY2001)	16 DAYS	CON	.	MOD	NO	POS	No	No
	P: HOSTILITY V: HOSTILE BEHAVIOR	55 (-15)	15MAY2001 (30MAY2001)	16 DAYS	CON	.	MOD	NO	POS	No	No
	P: NERVOUSNESS V: IRRITABLE BEHAVIOR	55 (-15)	15MAY2001 (30MAY2001)	16 DAYS	CON	.	MOD	NO	POS	No	No
	P: HOSTILITY V: IRRITABLE/HOSTILE AGGRESSIVE BEHAVIOUR WORSENED M: IRRITABLE/HOSTILE/AGGRESSIVE BEHAVIOR WORSENED {OPPOSITIONAL DEFIANT}	71 (1)	31MAY2001 (01JUN2001)	2 DAYS	CON	.	SEV	NO	PBU	No	Yes
704.055.28174	P: NAUSEA V: NAUSEA	13 (-61)	07FEB2001 (07FEB2001)	<1 DAY	INT	1	MIL	NO	UNR	No	No

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704.055.28174	P: HOSTILITY V: "TIME -OUT" HOSPITALIZATION (AGGRESSIVE BEHAVIOUR)	39 (-35)	05MAR2001 (22MAR2001)	18 DAYS	CON	.	SEV	NO	UNR	No	Yes
	P: AGITATION V: AGITATION	40 (-34)	06MAR2001 (13MAR2001)	8 DAYS	INT	2	MOD	NO	UNR	Yes	No
	P: OTITIS EXTERNA V: OTITIS MEDIA & EXTERNA M: OTITIS EXTERNA	40 (-34)	06MAR2001 (15MAR2001)	10 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: OTITIS MEDIA V: OTITIS MEDIA & EXTERNA M: OTITIS MEDIA	40 (-34)	06MAR2001 (15MAR2001)	10 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: HOSTILITY V: AGGRESSIVE BEHAVIOUR	63 (-11)	29MAR2001 (23APR2001)	26 DAYS	CON	.	SEV	NO	UNR	No	Yes
	P: OTITIS EXTERNA V: EAR, OTITIS EXTERNA M: LEFT EAR, OTITIS EXTERNA	64 (-10)	30MAR2001 (08APR2001)	10 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: OTITIS MEDIA V: EAR, OTITIS MEDIA W/EFFUSION M: LEFT EAR, OTITIS MEDIA WITH EFFUSION	64 (-10)	30MAR2001 (08APR2001)	10 DAYS	CON	.	MOD	NO	UNR	Yes	No

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Event Course [Eve. Crse]: INT = Intermittent, CON = Constant
Intensity [Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken With Respect to Investigational Drug [Act]: NO = None, RED = Dose reduced, INC = Dose increased, STP = Drug stopped
Relationship to Investigational Drug [Rel]: REL = Related, PSR = Possibly Related, PBU = Probably Unrelated, UNR = Unrelated

EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PLACEBO

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
329.002.00241	P: VOMITING V: NAUSEA AND VOMITING	27 (-81)	03MAR1996 (05MAR1996)	3 DAYS	INT	2	MIL	NO	PBU	No	No
	P: COUGH INCREASED V: COUGH	64 (-44)	09APR1996 (30APR1996)	22 DAYS	CON	.	MOD	NO	UNR	Yes	No
	P: EMOTIONAL LABILITY V: PT. HOSPITALIZED FOR HOMICIDAL SUICIDAL IDEATIO N M: PT. HOSPITALIZED FOR SUICIDAL IDEATION	108 (0)	23MAY1996 (.)		CON	.	SEV	STP	PBU	Yes	Yes
	P: HOSTILITY V: PT. HOSPITALIZED FOR HOMICIDAL SUICIDAL IDEATIO N M: PT. HOSPITALIZED FOR HOMICIDAL IDEATION	108 (0)	23MAY1996 (.)		CON	.	SEV	STP	PBU	No	Yes
676.007.24189	P: PHARYNGITIS V: SORE THROAT	14 (-99)	24JAN2001 (25JAN2001)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: RHINITIS V: NASAL CONGESTION	14 (-99)	24JAN2001 (25JAN2001)	2 DAYS	CON	.	MIL	NO	UNR	No	No
	P: HEADACHE V: HEADACHE	20 (-93)	30JAN2001 (31JAN2001)	2 DAYS	CON	.	MIL	NO	UNR	Yes	No
	P: SINUSITIS V: SINUS CONGESTION	20 (-93)	30JAN2001 (31JAN2001)	2 DAYS	CON	.	MIL	NO	UNR	No	No
	P: HOSTILITY V: INCREASED AGGRESSION	20 (-93)	30JAN2001 (01FEB2001)	3 DAYS	CON	.	MOD	NO		No	No
	P: SINUSITIS V: SINUS CONGESTION	35 (-78)	14FEB2001 (14MAR2001)	29 DAYS	CON	.	MOD	NO	UNR	Yes	No

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EMEA Listing 2.01
Adverse Events of Patients with on Therapy plus 30 days Hostility
By Treatment Group
Paediatric Placebo Controlled Trials

Treatment Group : PLACEBO

Subject	P: Preferred Term V: Verbatim Text M: Modified Term	Days Rel To Start (Stop) Of Study Med*	Onset (End) Date	Dur.	Eve. Crse	No. Epi.	Int	Act	Rel	Corr. Ther?	SAE?
676.017.24452	P: ACNE V: INCREASED ACNE (STAPH. INFECTION) M: INCREASED ACNE	8 (-40)	03MAY2000 (.)	CON	.		MOD	NO	PBU	Yes	No
	P: HOSTILITY V: INCREASED ANGER	8 (-40)	03MAY2000 (.)	CON	.		MIL	NO	PBU	No	No
	P: INFECTION V: INCREASED ACNE (STAPH. INFECTION) M: STAPHYLOCOCCUS INFECTION	8 (-40)	03MAY2000 (.)	CON	.		MOD	NO	PBU	Yes	No
	P: NERVOUSNESS V: INCREASED IRRITABILITY	8 (-40)	03MAY2000 (.)	CON	.		MIL	NO	PBU	No	No
	P: OTITIS EXTERNA V: OTITIS EXTERNA	22 (-26)	17MAY2000 (31MAY2000)	15 DAYS	CON	.	MOD	NO	UNR	Yes	No
704.055.28171	P: ABDOMINAL PAIN V: STOMACH PAIN	12 (-74)	07JAN2001 (.)	CON	.		MIL	NO	UNR	No	No
	P: NAUSEA V: NAUSEA	12 (-74)	07JAN2001 (08JAN2001)	2 DAYS	INT	1	MIL	NO	UNR	No	No
	P: ABDOMINAL PAIN V: STOMACH PAIN	12 (-74)	07JAN2001 (10JAN2001)	4 DAYS	INT	1	MIL	NO	UNR	No	No
	P: HOSTILITY V: TIME-OUT HOSPITALIZATION (AGGRESSIVE BEHAVIOUR)	42 (-44)	06FEB2001 (20FEB2001)	15 DAYS	CON	.	MOD	NO	UNR	No	Yes

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