

Table 4.10 Summary of reported methods of smoking cessation prior to varenicline in the Responder population.

Previous Treatment	Number	Proportion of 3,307 patients (%)
No Medication	684	21
Nicotine Replacement Therapy	1,464	44
Bupropion (Zyban®)	309	9
Other	415	12
Method not reported	1,036	31
Total	3,908	

Table 4.23 Summary of causality assessment for psychiatric adverse events by clinical groupings for patients in the Medsafe cohort

Psychiatric system organ class		Number of events ¹	Events assessed as having causal relationship ² with varenicline			
Clinical sub-group	Event		1	2	3	Total (%)
Sleep disorders	Insomnia	85		35	47	82 (96%)
	Insomnia worse	2			2	2 (100%)
	Sleep disturbance	48		16	31	47 (98%)
	Sleep disturbance worse	1			1	1 (100%)
	Somnambulism	1		1		1 (100%)
	Dreams	59		28	30	58 (98%)
	Paroniria	59		35	24	59 (100%)
	Sub-group total	255	0	115	135	250 (98%)
Tiredness events	Exhaustion	2			1	1 (50%)
	Fatigue	55		22	29	51 (93%)
	Somnolence	20		10	9	19 (95%)
	Heavy feeling	1		1		1 (100%)
	Malaise	17		8	7	15 (88%)
	Weakness	1			1	1 (100%)
	Sub-group total	96	0	41	47	88 (92%)
Depression	Depression	106	1	48	49	98 (92%)
	Depression worse	48		18	29	47 (98%)
	Tearful	6	1	3	2	6 (100%)
	Motivation impaired	3		2	1	3 (100%)
	Sub-group total	163	2	71	81	154 (94%)
Mood disorders	Mood swings	20		14	6	20 (100%)
	Emotional lability	7		5	2	7 (100%)
	Mood elevation	3			2	2 (67%)
	Mood altered	7		1	6	7 (100%)
	Hypomania	2			2	2 (100%)
	Sub-group total	39	0	20	18	38 (97%)
Anxiety disorders	Anxiety	32		15	17	32 (100%)
	Anxiety worse	10		5	3	8 (80%)
	Irritability	28		18	9	27 (96%)
	Irritability worse	2		1	1	2 (100%)
	Panic	9		4	5	9 (100%)
	Panic worse	1		1		1 (100%)

Psychiatric system organ class		Number of events ¹	Events assessed as having causal relationship ² with varenicline			
Clinical sub-group	Event		1	2	3	Total (%)
	Stress reaction	20		1	8	9 (45%)
	Stress reaction worse	1				0 (0%)
	Restlessness	2		1	1	2 (100%)
	Sub-group total	105	0	46	44	90 (86%)
Aggressive reactions	Agitation	7		3	3	6 (86%)
	Aggression	13		10	3	13 (100%)
	Sub-group total	20	0	13	6	19 (95%)
Cognitive changes	Depersonalisation	21		13	8	21 (100%)
	Attitude change	1		1		1 (100%)
	Behaviour abnormal	1			1	1 (100%)
	Concentration impaired	18		10	6	16 (89%)
	Function impaired	1		1		1 (100%)
	Thinking abnormal	3		3		3 (100%)
	Confusion	4		2	1	3 (75%)
	Disorientation	1	1			1 (100%)
	Sub-group total	50	1	30	16	47 (94%)
Psychotic events	Hallucinations	4		2	2	4 (100%)
	Psychosis	1			1	1 (100%)
	Manic depressive psychosis	2			2	2 (100%)
	Psychotic reaction	2			1	1 (50%)
	Paranoia	5		4	1	5 (100%)
	Sub-group total	14	0	6	7	13 (93%)
Alcohol/Substance abuse	Drug abuse worse	1				0 (0%)
	Substance abuse worse	1				0 (0%)
	Alcohol abuse	3			1	1 (33%)
	Alcohol abuse worse	3			1	1 (33%)
	Sub-group total	8	0	0	2	2 (25%)
Other	Memory impairment	6		5	1	6 (100%)
	Speech disorder	2		2		2 (100%)
	Anorexia	1		1		1 (100%)
	Sub-group total	9	0	8	1	9 (100%)
Total		759	3	350	357	710 (94%)

Notes

1. Includes all on med and off med events
2. Causal relationship as defined in Methods section (page 20)
1= definite/certain, 2= probable, 3 = possible