

Medicine summary -reboxetine (to end January 2009)

			Case Group	Death Outcomes	Sole
Case Count			219	0	177
Reaction Count	Blood and lymphatic system disorders	Haemolytic anaemia	1	0	1
		Lymphadenopathy	2	0	1
Blood and lymphatic system disorders		3	0	2	
Cardiac disorders	Cardiac disorders	Arrhythmia	1	0	1
		Bradycardia	1	0	1
		Tachycardia	8	0	5
		Atrial fibrillation	1	0	1
		Atrial flutter	1	0	0
		Supraventricular tachycardia	2	0	2
		Ventricular extrasystoles	1	0	1
		Palpitations	8	0	8
		Myocardial infarction	1	0	1
		Cardiac failure congestive	1	0	1
		Congestive cardiomyopathy	1	0	1
		Cardiomegaly	1	0	1
		Cardiac disorders	27	0	23
		Ear and labyrinth disorders	Ear and labyrinth disorders	Tinnitus	1
Ear and labyrinth disorders	1			0	1
Endocrine disorders	Endocrine disorders	Inappropriate antidiuretic hormone secretion	2	0	2
		Endocrine disorders	2	0	2
Eye disorders	Eye disorders	Dry eye	2	0	2
		Mydriasis	1	0	0
		Vision blurred	1	0	1
		Visual impairment	1	0	0
		Eye disorders	5	0	3
Gastrointestinal disorders	Gastrointestinal disorders	Rectal haemorrhage	1	0	1
		Haematemesis	1	0	1
		Reflux oesophagitis	1	0	1
		Constipation	20	0	18
		Gastrooesophageal reflux disease	1	0	1
		Dyspepsia	2	0	2
		Epigastric discomfort	1	0	1
		Abdominal distension	2	0	1
		Abdominal pain	5	0	3
		Abdominal pain lower	2	0	2
		Abdominal pain upper	1	0	1
		Abdominal discomfort	1	0	1
		Nausea	17	0	13
		Vomiting	8	0	7
		Lip swelling	1	0	0
		Dry mouth	9	0	9

Medicine summary -reboxetine (to end January 2009)

			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Glossitis	1	0	1
		Tongue ulceration	1	0	1
		Swollen tongue	2	0	1
		Gastrointestinal disorders	77	0	65
	General disorders and administration site conditions	Pyrexia	2	0	1
		Asthenia	2	0	2
		Fatigue	5	0	4
		Malaise	2	0	2
		Irritability	3	0	3
		Local swelling	1	0	1
		Oedema	1	0	0
		Oedema peripheral	1	0	1
		Chest pain	5	0	5
		Pain	2	0	2
		Chills	6	0	3
		Feeling abnormal	1	0	1
		Feeling cold	2	0	2
		Feeling jittery	1	0	1
		Drug interaction	1	0	0
		Drug ineffective	7	0	6
		General disorders and administration site conditions	42	0	34
	Hepatobiliary disorders	Hepatic function abnormal	1	0	0
		Hepatomegaly	1	0	1
		Liver tenderness	1	0	1
		Hepatitis	1	0	0
		Hepatobiliary disorders	4	0	2
	Immune system disorders	Anaphylactic reaction	1	0	1
		Anaphylactic shock	1	0	1
		Immune system disorders	2	0	2
	Infections and infestations	Orchitis	1	0	1
		Rhinitis	1	0	1
		Urinary tract infection	1	0	1
		Infections and infestations	3	0	3
Injury, poisoning and procedural complications	Drug exposure during pregnancy	3	0	2	
	Fall	4	0	3	
	Chillblains	3	0	2	
	Overdose	1	0	0	
	Injury, poisoning and procedural complications	11	0	7	
Investigations	Echocardiogram abnormal	1	0	0	
	Ejection fraction decreased	1	0	0	
	Electrocardiogram ST segment depression	1	0	1	

Medicine summary -reboxetine (to end January 2009)

			Case Group	Death Outcomes	Sole
Reaction Count	Investigations	Heart rate increased	3	0	3
		Blood pressure decreased	1	0	1
		Blood pressure increased	6	0	5
		Blood creatine phosphokinase increased	1	0	0
		Blood alkaline phosphatase increased	1	0	1
		Platelet adhesiveness decreased	1	0	0
		Hepatic enzyme increased	1	0	1
		Weight decreased	9	0	7
		Semen analysis abnormal	1	0	1
		Spermatozoa abnormal	1	0	1
		Blood osmolarity decreased	1	0	1
		Investigations	29	0	22
	Metabolism and nutrition disorders	Decreased appetite	4	0	4
		Hypophagia	1	0	1
		Polydipsia	1	0	0
		Hyponatraemia	8	0	7
		Dehydration	1	0	0
		Metabolism and nutrition disorders	15	0	12
	Musculoskeletal and connective tissue disorders	Myalgia	3	0	1
		Neck pain	1	0	1
		Pain in extremity	1	0	1
		Musculoskeletal and connective tissue disorders	5	0	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prolactin-producing pituitary tumour	1	0	1
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0	1
	Nervous system disorders	Haemorrhage intracranial	1	0	1
		Hypertensive encephalopathy	1	0	1
		Hypoxic encephalopathy	1	0	1
		Headache	11	0	9
		Amnesia	3	0	2
		Disturbance in attention	2	0	2
		Mental impairment	1	0	1
		Akathisia	2	0	1
		Extrapyramidal disorder	1	0	0
Cogwheel rigidity		1	0	0	
Tremor		4	0	4	
Balance disorder		1	0	1	
Coma		1	0	0	
Depressed level of consciousness		1	0	0	
Lethargy		3	0	3	
Loss of consciousness		1	0	1	

Medicine summary -reboxetine (to end January 2009)

			Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Somnolence	1	0	0	
		Syncope	5	0	3	
		Dizziness	20	0	16	
		Dizziness postural	1	0	1	
		Myoclonus	1	0	1	
		Presyncope	1	0	1	
		Crying	1	0	0	
		Formication	1	0	1	
		Paraesthesia	3	0	2	
		Dysgeusia	1	0	1	
		Hypoaesthesia	1	0	1	
		Adrenergic syndrome	1	0	0	
		Neuroleptic malignant syndrome	1	0	0	
		Serotonin syndrome	2	0	1	
		Petit mal epilepsy	1	0	0	
		Grand mal convulsion	1	0	1	
		Convulsion	4	0	2	
		Poor quality sleep	1	0	0	
			Nervous system disorders	82	0	58
		Pregnancy, puerperium and perinatal conditions		Foetal growth retardation	1	0
Foetal malpresentation	1			0	1	
Antepartum haemorrhage	1			0	1	
Umbilical cord prolapse	1			0	1	
Pregnancy, puerperium and perinatal conditions	4			0	3	
Psychiatric disorders		Agitation	9	0	6	
		Anxiety	5	0	3	
		Nervousness	1	0	0	
		Tension	1	0	1	
		Restlessness	2	0	2	
		Tic	1	0	0	
		Confusional state	5	0	4	
		Disorientation	1	0	0	
		Delirium	3	0	1	
		Depression	4	0	2	
		Depersonalisation	2	0	2	
		Dissociation	1	0	1	
		Hallucination	1	0	1	
		Hallucination, visual	1	0	1	
		Thinking abnormal	3	0	3	
		Hypomania	1	0	1	
		Mania	2	0	1	

Medicine summary -reboxetine (to end January 2009)

			Case Group	Death Outcomes	Sole	
Reaction Count	Psychiatric disorders	Affect lability	1	0	0	
		Anger	2	0	2	
		Euphoric mood	1	0	1	
		Mood swings	1	0	1	
		Apathy	1	0	1	
		Aggression	12	0	10	
		Homicidal ideation	2	0	2	
		Paranoia	1	0	0	
		Mental status changes	1	0	1	
		Withdrawal syndrome	1	0	1	
		Psychotic disorder	1	0	0	
		Premature ejaculation	2	0	2	
		Disturbance in sexual arousal	1	0	1	
		Libido decreased	2	0	2	
		Libido increased	3	0	2	
		Insomnia	17	0	13	
		Nightmare	2	0	2	
		Sleep disorder	3	0	3	
		Self injurious behaviour	1	0	0	
		Suicidal ideation	10	0	7	
		Suicide attempt	1	0	0	
	Psychiatric disorders	109	0	80		
Reaction Count	Renal and urinary disorders	Anuria	1	0	1	
		Dysuria	10	0	10	
		Micturition disorder	4	0	4	
		Pollakiuria	4	0	4	
		Urinary hesitation	11	0	9	
		Urinary incontinence	3	0	2	
		Urinary retention	13	0	11	
		Urine flow decreased	3	0	3	
		Proteinuria	1	0	1	
		Nocturia	1	0	1	
		Polyuria	1	0	0	
			Renal and urinary disorders	52	0	46
		Reaction Count	Reproductive system and breast disorders	Breast discharge	1	0
Breast pain	1			0	1	
Nipple pain	1			0	1	
Menstrual disorder	1			0	1	
Metrorrhagia	1			0	1	
Menorrhagia	1			0	1	
Penile discharge	1			0	1	
Penile pain	1			0	1	

Medicine summary -reboxetine (to end January 2009)

			Case Group	Death Outcomes	Sole	
Reaction Count	Reproductive system and breast disorders	Penile size reduced	1	0	1	
		Penis disorder	2	0	2	
		Scrotal disorder	1	0	1	
		Scrotal swelling	1	0	1	
		Ejaculation delayed	2	0	2	
		Ejaculation disorder	11	0	11	
		Erectile dysfunction	9	0	8	
		Female sexual arousal disorder	1	0	1	
		Sexual dysfunction	1	0	1	
		Spermatorrhoea	1	0	1	
		Testicular disorder	1	0	0	
		Testicular pain	5	0	5	
			Reproductive system and breast disorders	44	0	42
		Respiratory, thoracic and mediastinal disorders	Neonatal asphyxia	1	0	1
	Neonatal respiratory depression		1	0	1	
	Pulmonary hypertension		1	0	0	
	Apnoea		1	0	1	
	Dyspnoea		3	0	3	
	Rhinorrhoea		1	0	1	
	Epistaxis		1	0	1	
	Sinus congestion		1	0	1	
			Respiratory, thoracic and mediastinal disorders	10	0	9
	Skin and subcutaneous tissue disorders		Angioedema	1	0	1
		Urticaria	7	0	6	
		Urticaria papular	1	0	1	
		Blister	1	0	1	
		Erythema multiforme	1	0	1	
		Stevens-Johnson syndrome	1	0	1	
		Skin burning sensation	1	0	1	
		Swelling face	2	0	2	
		Erythema	1	0	0	
		Skin exfoliation	1	0	1	
		Photosensitivity reaction	2	0	2	
		Pruritus	4	0	4	
		Rash	5	0	5	
		Rash macular	1	0	0	
		Rash maculo-papular	1	0	0	
		Rash vesicular	1	0	0	
		Acne	1	0	1	
		Hyperhidrosis	17	0	17	
		Night sweats	1	0	0	
			Skin and subcutaneous tissue disorders	50	0	44

Medicine summary -reboxetine (to end January 2009)

			Case Group	Death Outcomes	Sole		
Reaction Count	Surgical and medical procedures	Therapy regimen changed	1	0	0		
		Surgical and medical procedures	1	0	0		
	Vascular disorders	Raynaud's phenomenon	2	0	2		
		Peripheral coldness	1	0	1		
		Circulatory collapse	1	0	0		
		Hypotension	5	0	3		
		Orthostatic hypotension	1	0	1		
		Deep vein thrombosis	1	0	0		
		Flushing	3	0	2		
		Hot flush	3	0	2		
		Pallor	2	0	2		
		Hypertension	6	0	5		
		Phlebitis	1	0	1		
		Vascular disorders	26	0	19		
		Reaction			605	0	483