

mirtazapine to end January 2009

			Case Group	Death Outcomes	Sole	
Case Count			657	12	500	
Medicine	Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0	2
			Bone marrow failure	2	0	2
			Pancytopenia	6	0	3
			Haemolytic anaemia	1	0	1
			Thrombocytopenia	7	1	2
			Lymphadenopathy	1	0	1
			Leukopenia	5	0	3
			Lymphopenia	1	0	1
			Agranulocytosis	5	1	3
			Febrile neutropenia	1	0	1
			Neutropenia	21	1	16
			Blood and lymphatic system disorders	52	3	35
			Cardiac disorders	Arrhythmia	1	0
		Bradycardia		1	0	0
		Extrasystoles		1	0	1
		Tachycardia		4	0	3
		Atrial fibrillation		4	0	4
		Sinus tachycardia		1	0	1
		Carditis		1	0	1
		Palpitations		9	0	5
		Cardiac valve disease		1	0	1
		Angina pectoris		1	0	1
		Myocardial infarction		3	1	1
		Cardiac failure		3	0	3
		Myocarditis		2	0	0
		Cardiac disorders		32	1	22
		Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	1
			Syndactyly	1	0	1
			Congenital, familial and genetic disorders	2	0	2
		Ear and labyrinth disorders	Hearing impaired	1	0	1
			Hyperacusis	2	0	2
			Tinnitus	6	0	4
			Vertigo	4	0	3
			Ear and labyrinth disorders	13	0	10
		Endocrine disorders	Inappropriate antidiuretic hormone secretion	8	0	6
			Endocrine disorders	8	0	6
		Eye disorders	Dry eye	2	0	2
			Eye pain	1	0	1
			Eye swelling	2	0	2
			Ocular discomfort	1	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Eye disorders	Glaucoma	1	0	1
			Conjunctivitis	1	0	1
			Ocular hyperaemia	2	0	1
			Oculogyric crisis	1	0	0
			Mydriasis	2	0	1
			Abnormal sensation in eye	1	0	1
			Photophobia	1	0	1
			Blindness	1	0	1
			Night blindness	1	0	1
			Visual acuity reduced	1	0	1
			Myopia	1	0	1
			Diplopia	1	0	1
			Photopsia	1	0	1
			Vision blurred	5	0	5
			Visual impairment	3	0	2
			Eye disorders	29	0	25
			Gastrointestinal disorders	Gingivitis	1	0
		Pancreatitis		2	0	1
		Haematemesis		1	0	0
		Melaena		1	0	0
		Reflux oesophagitis		1	0	0
		Diarrhoea		11	0	7
		Constipation		3	0	3
		Irritable bowel syndrome		1	0	1
		Ileus paralytic		1	0	1
		Eructation		1	0	0
		Abdominal distension		7	0	6
		Flatulence		3	0	3
		Abdominal pain		6	0	4
		Dysphagia		2	0	2
		Faecal incontinence		2	0	2
		Nausea		19	0	12
		Vomiting		7	0	3
		Intestinal obstruction		2	0	2
		Intestinal perforation		1	0	1
		Lip swelling		1	0	1
		Hypoaesthesia oral		2	0	2
		Palatal oedema		1	0	1
		Mouth ulceration		4	0	4
		Ascites		2	0	1
		Dry mouth		8	0	6
		Glossitis	1	0	1	

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Gastrointestinal disorders	Swollen tongue	1	0	1	
			Tongue oedema	1	0	1	
			Gastrointestinal disorders	93	0	67	
		General disorders and administration site conditions	Hypothermia	2	1	0	
			Pyrexia	11	0	7	
			Death	1	1	0	
			Sudden death	1	1	1	
			Asthenia	5	0	3	
			Fatigue	11	0	8	
			Malaise	12	0	4	
			Gait disturbance	4	0	4	
			Condition aggravated	1	0	1	
			Developmental delay	1	0	1	
			Influenza like illness	1	0	1	
			Irritability	13	0	10	
			Swelling	1	0	1	
			Face oedema	4	0	4	
			Generalised oedema	5	0	4	
			Gravitational oedema	9	0	7	
			Oedema	13	0	12	
			Oedema peripheral	31	0	29	
			Pitting oedema	2	0	1	
			Chest pain	5	0	5	
			Pain	7	0	7	
			Chest discomfort	1	0	1	
			Chills	3	0	0	
			Feeling abnormal	6	0	6	
			Feeling cold	1	0	0	
			Hunger	1	0	1	
			Thirst	3	0	2	
			Drug interaction	5	0	0	
			Drug ineffective	4	0	2	
			Paradoxical drug reaction	2	0	1	
			Therapeutic response decreased	1	0	1	
			Therapeutic response unexpected with drug substitution	4	0	4	
			Drug withdrawal syndrome	2	0	2	
			General disorders and administration site conditions	173	3	130	
			Hepatobiliary disorders	Biliary colic	1	0	1
				Cholecystitis	1	0	1
		Cholestasis		1	0	0	
		Hepatitis cholestatic		2	0	2	

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Hepatobiliary disorders	Jaundice	4	0	3
			Hepatic function abnormal	9	0	7
			Hepatic failure	1	1	0
			Autoimmune hepatitis	1	0	0
			Hepatic steatosis	1	1	0
			Hepatitis	2	0	1
			Hepatotoxicity	1	0	0
			Hepatobiliary disorders	24	2	15
		Immune system disorders	Hypersensitivity	3	0	3
			Anaphylactoid reaction	1	0	0
			Hypogammaglobulinaemia	1	0	1
			Immune system disorders	5	0	4
		Infections and infestations	Bacterial infection	1	0	0
			Cellulitis	2	0	1
			Pneumonia	2	1	1
			Sepsis	3	2	0
			Urinary tract infection	1	0	1
			Infections and infestations	9	3	3
		Injury, poisoning and procedural complications	Drug toxicity	1	1	0
			Fall	4	0	2
			Road traffic accident	1	0	0
			Contusion	2	0	2
			Medication error	1	0	1
			Overdose	2	0	2
			Injury, poisoning and procedural complications	11	1	7
		Investigations	Ejection fraction decreased	1	0	0
			Electrocardiogram QT interval	1	0	1
			Electrocardiogram QT prolonged	2	0	2
			Electrocardiogram ST segment elevation	1	0	1
			Electrocardiogram abnormal	1	0	1
			Heart rate increased	1	0	1
			Blood pressure increased	1	0	1
			Blood pressure systolic decreased	1	0	1
			Blood prolactin increased	1	0	0
			Blood creatine phosphokinase increased	1	0	1
			Troponin increased	2	0	1
			Blood lactate dehydrogenase increased	1	0	1
			Lipase increased	1	0	0
			International normalised ratio increased	1	0	0

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole
		Red blood cell sedimentation rate increased	1	0	1
		Platelet count decreased	2	0	2
		Lymphocyte count decreased	1	0	1
		Neutrophil count decreased	1	0	1
		White blood cell count decreased	1	0	1
		Alanine aminotransferase increased	1	0	1
		Ammonia increased	1	0	0
		Aspartate aminotransferase increased	1	0	1
		Hepatic enzyme increased	1	0	1
		Liver function test abnormal	12	0	8
		Blood cholesterol increased	3	0	1
		Total cholesterol/HDL ratio decreased	1	0	0
		Blood triglycerides increased	2	0	0
		Intraocular pressure increased	1	0	1
		Body temperature decreased	1	0	0
		Weight decreased	1	0	1
		Weight increased	22	0	20
		Blood albumin increased	1	0	0
		C-reactive protein increased	2	0	2
		Urine analysis abnormal	1	0	1
		Sperm count decreased	1	0	0
		Anticonvulsant drug level decreased	1	0	0
		Drug level above therapeutic	1	0	0
		Blood sodium decreased	1	0	1
		Serum ferritin increased	1	0	1
		Blood electrolytes abnormal	1	0	1
		Blood osmolarity decreased	2	0	2
		Investigations	81	0	59
		Metabolism and nutrition disorders			
		Acidosis	1	1	0
		Anorexia	6	0	4
		Increased appetite	13	0	13
		Abnormal weight gain	1	0	1
		Electrolyte imbalance	1	0	1
		Hyperkalaemia	1	0	1
		Hypokalaemia	3	0	0
		Hyponatraemia	24	0	14
		Dehydration	1	0	1
		Fluid retention	6	0	5
		Alcohol intolerance	1	0	1
		Diabetes mellitus	1	0	1
		Diabetes mellitus inadequate control	1	0	1
		Hyperglycaemia	1	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Metabolism and nutrition disorders	Hypoglycaemia	1	0	1
			Hyperlipidaemia	4	0	3
			Metabolism and nutrition disorders	66	1	48
		Musculoskeletal and connective tissue disorders	Bone pain	2	0	2
			Arthritis	3	0	3
			Polyarthritis	2	0	2
			Temporomandibular joint syndrome	1	0	1
			Arthralgia	33	0	31
			Joint swelling	6	0	6
			Osteoarthritis	6	0	6
			Myalgia	28	0	25
			Muscle disorder	1	0	1
			Muscle fatigue	1	0	1
			Muscle spasms	6	0	5
			Muscle twitching	2	0	1
			Muscular weakness	5	0	4
			Myopathy	1	0	1
			Rhabdomyolysis	2	0	1
			Mobility decreased	1	0	0
			Musculoskeletal stiffness	1	0	0
			Back pain	4	0	3
			Pain in extremity	4	0	4
			Bursitis	1	0	1
			Musculoskeletal and connective tissue disorders	110	0	98
		Nervous system disorders	Cerebellar infarction	1	0	0
			Cerebral haemorrhage	1	0	0
			Cerebrovascular accident	1	0	0
			Cerebrovascular disorder	1	0	1
			Vertebral artery stenosis	1	0	0
			Parosmia	1	0	1
			Encephalopathy	1	0	0
			Headache	16	0	11
			Migraine	1	0	0
			Brain oedema	1	0	0
Amnesia	6		0	4		
Memory impairment	3		0	2		
Cognitive disorder	1		0	0		
Disturbance in attention	6		0	5		
Akathisia	11		0	7		
Akinesia	1		0	1		
Bradykinesia	1		0	0		
Clumsiness	2	0	2			

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Medicine	Reaction Count	Nervous system disorders	Case Group	Death Outcomes	Sole
		Dyskinesia	5	0	3
		Extrapyramidal disorder	1	0	0
		Hyperkinesia	15	0	14
		Movement disorder	1	0	0
		Psychomotor hyperactivity	1	0	1
		Tardive dyskinesia	2	0	2
		Dystonia	2	0	2
		Gait spastic	1	0	1
		Paralysis	1	0	1
		Parkinsonian gait	1	0	0
		Parkinsonism	1	0	1
		Asterixis	1	0	0
		Tremor	20	0	12
		Hyperreflexia	1	0	0
		Ataxia	9	0	5
		Balance disorder	2	0	1
		Coordination abnormal	1	0	0
		Coma	1	0	0
		Aphasia	1	0	1
		Altered state of consciousness	1	1	0
		Consciousness fluctuating	1	0	0
		Depressed level of consciousness	1	0	0
		Lethargy	8	0	7
		Loss of consciousness	3	0	1
		Sedation	9	0	7
		Somnolence	45	1	37
		Syncope	7	0	2
		Dizziness	29	0	24
		Myoclonus	3	0	3
		Hyperaesthesia	1	0	1
		Paraesthesia	19	0	15
		Ageusia	1	0	1
		Dysgeusia	3	0	3
		Hypoaesthesia	6	0	5
		Restless legs syndrome	18	0	18
		Sensory disturbance	2	0	1
		Sensory loss	2	0	2
		Dysarthria	5	0	3
		Dysphasia	2	0	1
		Repetitive speech	1	0	0
		Speech disorder	3	0	1
		Hemianopia	2	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Nervous system disorders	Tunnel vision	1	0	1
			Visual field defect	1	0	1
			Hypertonia	4	0	1
			Hypotonia	1	0	1
			Neuroleptic malignant syndrome	2	0	1
			Serotonin syndrome	15	0	3
			Muscle contractions involuntary	1	0	0
			Myasthenic syndrome	1	0	1
			Neuropathy peripheral	1	0	1
			Grand mal convulsion	12	0	8
			Convulsion	27	0	18
			Sleep paralysis	2	0	1
			Hypersomnia	1	0	1
			Nervous system disorders	364	2	249
		Psychiatric disorders	Agitation	44	1	27
			Anxiety	10	0	7
			Nervousness	4	0	4
			Tension	1	0	1
			Panic attack	5	0	1
			Neurosis	1	0	1
			Obsessive-compulsive disorder	2	0	2
			Restlessness	13	0	7
			Tic	1	0	0
			Verbigeration	1	0	0
			Confusional state	30	0	18
			Disorientation	10	0	6
			Delirium	9	0	6
			Depression	13	0	11
			Depressed mood	1	0	1
			Depersonalisation	6	0	5
			Delusion	1	0	1
			Hallucination	19	0	15
			Hallucination, auditory	2	0	1
			Hallucination, tactile	1	0	1
			Hallucination, visual	3	0	3
			Jamais vu	1	0	0
Thinking abnormal	4	0	3			
Eating disorder	1	0	0			
Impulsive behaviour	1	0	0			
Hypomania	1	0	1			
Mania	6	0	5			
Affect lability	2	0	2			

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Psychiatric disorders	Inappropriate affect	1	0	0
			Anger	7	0	7
			Dysphoria	1	0	0
			Emotional disorder	1	0	0
			Euphoric mood	4	0	2
			Frustration	1	0	1
			Mood altered	2	0	2
			Mood swings	3	0	3
			Apathy	2	0	2
			Aggression	18	0	15
			Homicidal ideation	3	0	1
			Paranoia	10	0	6
			Personality change	1	0	1
			Social avoidant behaviour	1	0	1
			Violence-related symptom	2	0	1
			Abnormal behaviour	3	0	2
			Mental disorder	1	0	0
			Drug dependence	2	0	2
			Withdrawal syndrome	7	0	5
			Psychotic disorder	3	0	3
			Premature ejaculation	1	0	0
			Libido decreased	2	0	2
			Loss of libido	2	0	1
			Insomnia	20	0	13
			Abnormal dreams	5	0	3
			Nightmare	25	0	22
			Somnambulism	1	0	0
			Sleep disorder	3	0	2
			Completed suicide	2	2	1
			Intentional self-injury	3	0	2
			Self injurious behaviour	1	0	0
			Suicidal ideation	21	0	13
			Suicide attempt	10	1	3
			Psychiatric disorders	362	4	245
		Renal and urinary disorders	Renal failure	1	0	1
			Renal failure acute	3	0	1
			Renal impairment	1	0	0
			Pollakiuria	3	0	3
			Urinary incontinence	3	0	3
			Urinary retention	10	0	8
			Polyuria	1	0	1
			Renal pain	1	0	1

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Medicine	Reaction Count			Case Group	Death Outcomes	Sole
		Renal and urinary disorders	Renal and urinary disorders	23	0	18
		Reproductive system and breast disorders	Breast engorgement	1	0	1
			Breast pain	1	0	1
			Breast tenderness	1	0	1
			Menstruation irregular	1	0	1
			Metrorrhagia	1	0	1
			Ejaculation failure	1	0	1
			Erectile dysfunction	1	0	0
			Vaginal haemorrhage	1	0	1
			Reproductive system and breast disorders	8	0	7
		Respiratory, thoracic and mediastinal disorders	Asthma	1	0	1
			Pleural effusion	1	0	0
			Pulmonary hypertension	2	1	1
			Pulmonary embolism	1	0	1
			Dyspnoea	6	0	4
			Dyspnoea exertional	1	0	1
			Respiratory distress	1	0	1
			Sleep apnoea syndrome	1	0	1
			Cough	1	0	1
			Hiccups	1	0	0
			Respiratory failure	2	1	1
			Oropharyngeal pain	3	0	3
			Snoring	1	0	1
			Throat irritation	1	0	1
			Stridor	1	0	0
			Nasal congestion	1	0	0
			Epistaxis	1	0	1
			Pharyngeal oedema	1	0	1
			Respiratory, thoracic and mediastinal disorders	27	2	19
		Skin and subcutaneous tissue disorders	Angioedema	1	0	1
			Periorbital oedema	3	0	3
			Urticaria	6	0	6
			Lichenoid keratosis	1	0	1
			Dermatitis bullous	2	0	2
			Swelling face	4	0	2
			Eczema	1	0	1
			Erythema	2	0	2
			Rash erythematous	3	0	3
			Rash papular	3	0	3
			Photosensitivity reaction	2	0	2
		Pruritus	10	0	8	

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			Case Group	Death Outcomes	Sole		
Medicine	Reaction Count	Skin and subcutaneous tissue disorders	Pruritus generalised	1	0	1	
			Dermatitis psoriasiform	1	0	1	
			Rash	17	0	13	
			Rash macular	1	0	0	
			Rash maculo-papular	8	0	6	
			Skin hyperpigmentation	1	0	1	
			Acne	2	0	2	
			Alopecia	4	0	3	
			Cold sweat	1	0	1	
			Hyperhidrosis	12	0	8	
			Nail disorder	1	0	0	
			Petechiae	2	0	2	
			Skin and subcutaneous tissue disorders	89	0	72	
			Surgical and medical procedures	Drug therapy changed	3	0	3
		Therapy regimen changed		5	0	3	
		Surgical and medical procedures		8	0	6	
		Vascular disorders	Aneurysm	1	1	0	
			Circulatory collapse	2	0	0	
			Hypotension	6	1	2	
			Orthostatic hypotension	4	0	2	
			Thrombosis	1	0	1	
			Flushing	5	0	3	
			Hot flush	2	0	1	
			Haemorrhage	1	1	0	
			Hypertension	2	0	1	
			Vasculitis	1	0	1	
			Vascular disorders	25	3	11	
		Reaction			1614	25	1158