

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole		
Case Count			753	21	559		
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			
Lymphadenopathy mediastinal		1	0	1			
Leukopenia		5	0	3			
Lymphopenia		1	0	1			
Agranulocytosis		5	1	3			
Febrile neutropenia		1	0	1			
Neutropenia		23	1	16			
Blood and lymphatic system disorders			55	3	36		
Reaction Count	Cardiac disorders	Arrhythmia	1	0	1		
		Bradycardia	1	0	0		
		Extrasystoles	1	0	1		
		Tachycardia	5	0	4		
		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		
		Stress cardiomyopathy	1	0	0		
		Cardiac failure	3	0	3		
		Cardiomyopathy	2	0	2		
		Myocarditis	2	0	0		
		Cardiac disorders			36	1	25
		Reaction Count	Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	1
Syndactyly	1			0	1		
Congenital, familial and genetic disorders	2			0	2		
Reaction Count	Ear and labyrinth disorders	Hearing impaired	1	0	1		
		Hyperacusis	2	0	2		
		Tinnitus	7	0	4		
		Vertigo	4	0	3		
		Ear and labyrinth disorders	14	0	10		
Reaction Count	Endocrine disorders	Inappropriate antidiuretic hormone secretion	8	0	7		
		Endocrine disorders	8	0	7		
Reaction Count	Eye disorders	Dry eye	2	0	2		
		Eye disorder	1	0	1		

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole		
Reaction Count	Eye disorders	Eye pain	1	0	1		
		Eye swelling	2	0	2		
		Ocular discomfort	1	0	1		
		Periorbital oedema	3	0	3		
		Glaucoma	1	0	1		
		Conjunctivitis	1	0	1		
		Ocular hyperaemia	3	0	1		
		Blepharospasm	1	0	1		
		Oculogyric crisis	1	0	0		
		Ophthalmoplegia	1	0	1		
		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	6	0	6		
		Visual impairment	4	0	3		
			Eye disorders	38	0	33	
			Gastrointestinal disorders	Gingivitis	1	0	1
				Pancreatitis	2	0	1
				Haematemesis	1	0	0
Melaena	1			0	0		
Reflux oesophagitis	1			0	0		
Diarrhoea	13			0	9		
Constipation	3			0	3		
Gastrooesophageal reflux disease	1			0	1		
Irritable bowel syndrome	1			0	1		
Ileus paralytic	1			0	1		
Eructation	1			0	0		
Abdominal distension	8			0	7		
Flatulence	3			0	3		
Abdominal pain	6			0	4		
Dysphagia	2			0	2		
Faecal incontinence	2			0	2		
Nausea	20			0	12		
Vomiting	7			0	3		
Intestinal obstruction	2			0	2		
Intestinal perforation	1			0	1		

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Lip swelling	1	0	1
		Hypoaesthesia oral	2	0	2
		Burning mouth syndrome	1	0	0
		Palatal oedema	1	0	1
		Mouth ulceration	5	0	5
		Ascites	2	0	1
		Dry mouth	8	0	6
		Glossitis	1	0	1
		Tongue ulceration	1	0	1
		Swollen tongue	1	0	1
		Tongue oedema	1	0	1
		Gastrointestinal disorders	101	0	73
		General disorders and administration site conditions	Hypothermia	2	1
	Pyrexia		14	1	8
	Death		4	4	0
	Sudden death		1	1	1
	Asthenia		5	0	3
	Fatigue		13	0	9
	Malaise		11	0	4
	Gait disturbance		4	0	4
	Loss of control of legs		1	0	1
	Condition aggravated		1	0	1
	Developmental delay		1	0	1
	Influenza like illness		1	0	1
	Irritability		13	0	10
	Swelling		1	0	1
	General symptom		1	0	1
	Face oedema		4	0	4
	Generalised oedema		6	0	5
	Gravitational oedema		9	0	7
	Oedema		17	0	15
	Oedema peripheral		32	0	30
	Chest pain	6	0	6	
Pain	7	0	7		
Chest discomfort	1	0	1		
Chills	4	0	0		
Feeling abnormal	7	0	7		
Feeling cold	1	0	0		
Hunger	1	0	1		
Thirst	3	0	2		
Drug interaction	5	1	0		
Drug ineffective	4	0	2		

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	Paradoxical drug reaction	2	0	1
		Therapeutic response decreased	1	0	1
		Therapeutic response unexpected with drug substitution	5	0	5
		Drug withdrawal syndrome	3	0	3
		General disorders and administration site conditions	191	8	142
	Hepatobiliary disorders	Biliary colic	1	0	1
		Cholecystitis	1	0	1
		Cholestasis	1	0	0
		Hepatitis cholestatic	2	0	2
		Jaundice	5	0	4
		Hepatic function abnormal	10	0	7
		Hepatic failure	1	1	0
		Portal vein thrombosis	1	0	1
		Autoimmune hepatitis	1	0	0
		Hepatic steatosis	1	1	0
		Hepatitis	2	0	1
		Hepatitis acute	1	0	1
		Hepatotoxicity	1	0	0
		Hepatobiliary disorders	28	2	18
	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	3	1	1
		Sepsis	3	2	0
		Urinary tract infection	1	0	1
		Herpes zoster	1	0	1
		Infections and infestations	11	3	4
	Injury, poisoning and procedural complications	Drug toxicity	4	4	0
		Drug exposure during pregnancy	2	0	2
		Fall	4	0	2
Road traffic accident		1	0	0	
Contusion		2	0	2	
Medication error		2	0	1	
Intentional overdose		1	0	0	
Overdose		3	0	2	
Injury, poisoning and procedural complications	19	4	9		
Investigations	Ejection fraction decreased	1	0	0	

Medicine summary -mirtazapine (to date)

Reaction Count	Investigations	Case Group	Death Outcomes	Sole
	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	2	1	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
	Red blood cell sedimentation rate increased	1	0	1
	Platelet count decreased	3	0	3
	CD4 lymphocytes decreased	1	0	1
	Lymphocyte count decreased	1	0	1
	Neutrophil count decreased	1	0	1
	Neutrophil count increased	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	13	0	9
	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	2	0	2
	Weight increased	30	0	26
	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

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Investigations	Investigations	95	1	70
	Metabolism and nutrition disorders	Acidosis	1	1	0
		Decreased appetite	6	0	4
		Hyperphagia	1	0	1
		Increased appetite	17	0	15
		Abnormal weight gain	1	0	1
		Electrolyte imbalance	1	0	1
		Polydipsia	2	0	0
		Hyperkalaemia	1	0	1
		Hypokalaemia	3	0	0
		Hyponatraemia	30	0	16
		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	2	0	2
		Hypoglycaemia	1	0	1
		Hyperlipidaemia	4	0	3
		Metabolism and nutrition disorders	80	1	54
	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	7	0	7
		Osteoarthritis	5	0	5
		Myalgia	28	0	25
		Muscle disorder	1	0	1
		Muscle fatigue	1	0	1
		Muscle spasms	5	0	4
		Muscle twitching	3	0	1
		Muscle rigidity	1	1	0
		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

Medicine summary -mirtazapine (to date)

Reaction Count			Case Group	Death Outcomes	Sole
	Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	111	1	97
	Nervous system disorders	Cerebellar infarction	1	0	0
		Cerebral haemorrhage	2	1	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	22	1	14
		Migraine	1	0	0
		Brain oedema	1	0	0
		Dementia with Lewy bodies	1	1	0
		Amnesia	6	0	4
		Memory impairment	5	0	4
		Cognitive disorder	2	0	0
		Disturbance in attention	6	0	5
		Akathisia	11	0	7
		Akinesia	1	0	1
		Bradykinesia	2	1	0
		Clumsiness	2	0	2
		Dyskinesia	6	0	3
		Extrapyramidal disorder	1	0	0
		Hyperkinesia	14	0	13
		Movement disorder	1	0	0
		Psychomotor hyperactivity	1	0	1
		Tardive dyskinesia	2	0	2
		Dystonia	1	0	1
		Gait spastic	1	0	1
		Paralysis	1	0	1
		Parkinsonian gait	1	0	0
		Parkinsonism	3	2	1
		Asterixis	1	0	0
		Tremor	23	0	13
		Hyperreflexia	1	0	0
		Ataxia	9	0	5
		Balance disorder	2	0	1
		Coordination abnormal	1	0	0
		Coma	1	0	0
		Aphasia	3	0	2
		Altered state of consciousness	1	1	0
		Consciousness fluctuating	1	0	0

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Depressed level of consciousness	1	0	0	
		Lethargy	8	0	7	
		Loss of consciousness	5	0	2	
		Sedation	12	0	8	
		Somnolence	47	2	37	
		Syncope	10	0	4	
		Nervous system disorder	1	0	1	
		Dizziness	30	0	24	
		Myoclonus	3	0	3	
		Hyperaesthesia	1	0	1	
		Paraesthesia	21	0	17	
		Ageusia	1	0	1	
		Dysgeusia	3	0	3	
		Hypoaesthesia	6	0	5	
		Restless legs syndrome	19	0	19	
		Sensory disturbance	2	0	1	
		Sensory loss	2	0	2	
		Dysarthria	5	0	3	
		Repetitive speech	1	0	0	
		Speech disorder	4	0	1	
		Hemianopia	2	0	1	
		Tunnel vision	1	0	1	
		Visual field defect	1	0	1	
		Hypertonia	5	1	1	
		Hypotonia	1	0	1	
		Neuroleptic malignant syndrome	4	1	1	
		Serotonin syndrome	26	3	5	
		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	
		Status epilepticus	1	0	1	
		Tonic convulsion	1	0	0	
		Sleep paralysis	2	0	1	
		Hypersomnia	2	0	2	
			Nervous system disorders	413	14	265
		Pregnancy, puerperium and perinatal conditions	Hyperemesis gravidarum	1	0	1
			Pregnancy, puerperium and perinatal conditions	1	0	1
		Psychiatric disorders	Agitation	52	2	31
			Anxiety	11	0	7

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Nervousness	4	0	4
		Tension	1	0	1
		Panic attack	5	0	1
		Neurosis	1	0	1
		Obsessive-compulsive disorder	3	0	3
		Restlessness	13	0	7
		Tic	1	0	0
		Verbigeration	1	0	0
		Dysphemia	1	0	1
		Confusional state	37	2	21
		Disorientation	11	0	7
		Delirium	9	0	6
		Depression	13	0	11
		Postpartum depression	1	0	1
		Depressed mood	3	0	2
		Depersonalisation	7	0	6
		Delusion	1	0	1
		Hallucination	24	1	17
		Hallucination, auditory	3	0	2
		Hallucination, tactile	1	0	1
		Hallucination, visual	4	0	4
		Jamais vu	1	0	0
		Thinking abnormal	5	0	4
		Eating disorder	1	0	0
		Impulsive behaviour	1	0	0
		Hypomania	1	0	1
		Mania	6	0	5
		Affect lability	3	0	3
		Inappropriate affect	1	0	0
		Anger	9	0	9
		Dysphoria	1	0	0
		Emotional disorder	1	0	0
		Euphoric mood	4	0	2
		Frustration	2	0	1
		Mood altered	2	0	2
		Mood swings	4	0	4
		Apathy	2	0	2
		Aggression	22	0	18
		Homicidal ideation	4	0	2
		Paranoia	10	0	6
Personality change	1	0	1		
Social avoidant behaviour	2	0	2		

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Violence-related symptom	2	0	1
		Abnormal behaviour	4	0	2
		Mental disorder	1	0	0
		Drug dependence	2	0	2
		Withdrawal syndrome	8	0	6
		Psychotic disorder	4	0	4
		Premature ejaculation	1	0	0
		Libido decreased	2	0	2
		Loss of libido	2	0	1
		Insomnia	22	0	14
		Middle insomnia	1	0	0
		Abnormal dreams	5	0	3
		Nightmare	29	0	26
		Sleep talking	1	0	1
		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	28	0	19
Suicide attempt	11	1	3		
	Psychiatric disorders	423	8	286	
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
			Renal and urinary disorders	23	0
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
Respiratory, thoracic and mediastinal disorders		Asthma	1	0	1
		Pleural effusion	1	0	0

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	2	1	1
		Pulmonary embolism	3	1	2
		Dyspnoea	7	0	5
		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	4	0	4
		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	31	3	22
	Skin and subcutaneous tissue disorders	Angioedema	1	0	1
		Urticaria	6	0	6
		Lichenoid keratosis	1	0	1
		Dermatitis bullous	2	0	2
		Swelling face	6	0	4
		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
		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		5	0	4	
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		

Medicine summary -mirtazapine (to date)

			Case Group	Death Outcomes	Sole	
Reaction Count	Surgical and medical procedures	Drug therapy changed	3	0	3	
		Off label use	1	0	1	
		Therapy regimen changed	5	0	3	
		Surgical and medical procedures	9	0	7	
	Vascular disorders	Aneurysm	1	1	0	
		Circulatory collapse	2	0	0	
		Hypotension	6	1	2	
		Orthostatic hypotension	5	0	3	
		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	26	3	12	
	Reaction			1817	52	1274