



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		591	11	452
<b>- Occurrences of Medicine</b>		593	11	452
<b>- Reactions Related to Medicine</b>		1447	24	1040
Blood and lymphatic system disorders	Anaemia	2	0	2
	Bone marrow failure	2	0	2
	Pancytopenia	5	0	2
	Haemolytic anaemia	1	0	1
	Thrombocytopenia	6	1	1
	Lymphadenopathy	1	0	1
	Leukopenia	5	0	3
	Lymphopenia	1	0	1
	Agranulocytosis	5	1	3
	Febrile neutropenia	1	0	1
	Neutropenia	18	1	14
Cardiac disorders	Arrhythmia	1	0	1
	Bradycardia	1	0	0
	Extrasystoles	1	0	1
	Tachycardia	3	0	3
	Atrial fibrillation	3	0	3
	Sinus tachycardia	1	0	1
	Palpitations	8	0	5
	Cardiac valve disease	1	0	1
	Angina pectoris	1	0	1
	Myocardial infarction	3	1	1
	Cardiac failure	2	0	2
	Myocarditis	2	0	0
Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	1
	Syndactyly	1	0	1
Ear and labyrinth disorders	Hearing impaired	1	0	1
	Hyperacusis	1	0	1
	Tinnitus	6	0	4



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Ear and labyrinth disorders	Vertigo	4	0	3
Endocrine disorders	Inappropriate antidiuretic hormone secretior	6	0	4
Eye disorders	Dry eye	1	0	1
	Eye pain	1	0	1
	Eye swelling	2	0	2
	Ocular discomfort	1	0	1
	Glaucoma	1	0	1
	Conjunctivitis	1	0	1
	Ocular hyperaemia	2	0	1
	Oculogyration	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	4	0	4
	Visual disturbance	3	0	2
	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		2	0	2
Irritable bowel syndrome		1	0	1
Ileus paralytic		1	0	1
Eructation		1	0	0
Abdominal distension		6	0	5
Flatulence		3	0	3
Abdominal pain		5	0	4
Dysphagia		2	0	2

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Gastrointestinal disorders	Faecal incontinence	2	0	2
	Nausea	18	0	11
	Vomiting	7	0	3
	Intestinal obstruction	2	0	2
	Intestinal perforation	1	0	1
	Lip swelling	1	0	1
	Hypoaesthesia oral	1	0	1
	Palatal oedema	1	0	1
	Mouth ulceration	4	0	4
	Ascites	2	0	1
	Dry mouth	7	0	5
	Glossitis	1	0	1
	Swollen tongue	1	0	1
	General disorders and administration site conditions	Hypothermia	2	1
Chills		2	0	0
Feeling cold		1	0	0
Pyrexia		9	0	6
Death		1	1	0
Sudden death		1	1	1
Asthenia		5	0	3
Fatigue		10	0	8
Malaise		10	0	4
Gait disturbance		4	0	4
Chest discomfort		1	0	1
Condition aggravated		1	0	1
Developmental delay		1	0	1
Feeling abnormal		5	0	5
Hunger		1	0	1
Influenza like illness		1	0	1
Irritability		13	0	10
Swelling		1	0	1
Thirst		3	0	2
Face oedema		3	0	3
Generalised oedema		5	0	4
Gravitational oedema	8	0	6	

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
General disorders and administration site conditions	Oedema	11	0	11
	Oedema peripheral	28	0	26
	Pitting oedema	1	0	0
	Chest pain	4	0	4
	Pain	7	0	7
	Drug interaction	3	0	0
	Drug ineffective	2	0	1
	Drug withdrawal syndrome	8	0	6
	Paradoxical drug reaction	2	0	1
Hepatobiliary disorders	Biliary colic	1	0	1
	Cholecystitis	1	0	1
	Cholestasis	1	0	0
	Hepatitis cholestatic	2	0	2
	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
Immune system disorders	Hypersensitivity	3	0	3
	Anaphylactoid reaction	1	0	0
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
Injury, poisoning and procedural complications	Drug toxicity	1	1	0
	Fall	4	0	2
	Contusion	2	0	2
	Medication error	1	0	1
	Overdose	2	0	2
Investigations	Ejection fraction decreased	1	0	0
	Electrocardiogram QT corrected interval	1	0	1
	Blood pressure systolic decreased	1	0	1

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1			
Investigations	Blood prolactin increased	1	0	0	
	Blood creatine phosphokinase increased	1	0	1	
	Troponin increased	1	0	0	
	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	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	
	Serum ferritin increased	1	0	1	
	Metabolism and nutrition disorders	Acidosis	1	1	0
		Anorexia	6	0	4
Increased appetite		13	0	13	
Hyperkalaemia		1	0	1	
Hypokalaemia		3	0	0	
Hyponatraemia		19	0	10	
Dehydration		1	0	1	

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Metabolism and nutrition disorders	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
	Hypoglycaemia	1	0	1
	Hyperlipidaemia	3	0	2
Musculoskeletal and connective tissue disorders	Bone pain	1	0	1
	Arthritis	3	0	3
	Polyarthritis	2	0	2
	Temporomandibular joint syndrome	1	0	1
	Arthralgia	29	0	27
	Joint swelling	5	0	5
	Osteoarthritis	6	0	6
	Myalgia	27	0	24
	Muscle disorder	1	0	1
	Muscle fatigue	1	0	1
	Muscle spasms	6	0	5
	Muscle twitching	2	0	1
	Muscular weakness	4	0	3
	Myopathy	1	0	1
	Rhabdomyolysis	2	0	1
	Back pain	3	0	2
	Musculoskeletal stiffness	1	0	0
Pain in extremity	4	0	4	
Bursitis	1	0	1	
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	15	0	10
	Migraine	1	0	0



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Nervous system disorders	Brain oedema	1	0	0
	Amnesia	6	0	4
	Memory impairment	2	0	2
	Disturbance in attention	5	0	4
	Akathisia	11	0	7
	Akinesia	1	0	1
	Bradykinesia	1	0	0
	Clumsiness	2	0	2
	Dyskinesia	4	0	2
	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
	Paralysis	1	0	1
	Parkinsonian gait	1	0	0
	Parkinsonism	1	0	1
	Asterixis	1	0	0
	Tremor	18	0	10
	Hyperreflexia	1	0	0
	Balance disorder	2	0	1
	Coordination abnormal	10	0	5
	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	2	0	1
	Sedation	9	0	7
	Somnolence	39	1	31
	Syncope	7	0	2
	Dizziness	27	0	23
Myoclonus	1	0	1	

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Nervous system disorders	Hyperaesthesia	1	0	1
	Hypoaesthesia	6	0	5
	Paraesthesia	18	0	14
	Ageusia	1	0	1
	Dysgeusia	3	0	3
	Restless legs syndrome	17	0	17
	Sensory disturbance	2	0	1
	Sensory loss	2	0	2
	Dysarthria	5	0	3
	Dysphasia	1	0	0
	Repetitive speech	1	0	0
	Speech disorder	1	0	1
	Hemianopia	2	0	1
	Visual field defect	1	0	1
	Gait spastic	1	0	1
	Hypertonia	4	0	1
	Neuroleptic malignant syndrome	2	0	1
	Serotonin syndrome	13	0	3
	Muscle contractions involuntary	1	0	0
	Eaton-Lambert syndrome	1	0	1
	Neuropathy	1	0	1
	Grand mal convulsion	11	0	7
	Convulsion	24	0	16
Sleep paralysis	2	0	1	
Hypersomnia	1	0	1	
Psychiatric disorders	Neurosis	1	0	1
	Obsessive-compulsive disorder	2	0	2
	Agitation	40	1	25
	Anxiety	8	0	6
	Nervousness	4	0	4
	Tension	1	0	1
	Panic attack	5	0	1
	Restlessness	12	0	7
	Tic	1	0	0
	Verbigeration	1	0	0



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Psychiatric disorders	Confusional state	29	0	17
	Disorientation	8	0	5
	Delirium	9	0	6
	Depression	12	0	10
	Depressed mood	1	0	1
	Depersonalisation	5	0	4
	Delusion	1	0	1
	Hallucination	17	0	14
	Hallucination, auditory	2	0	1
	Hallucination, tactile	1	0	1
	Hallucination, visual	2	0	2
	Jamais vu	1	0	0
	Thinking abnormal	4	0	3
	Hypomania	1	0	1
	Mania	6	0	5
	Affect lability	2	0	2
	Inappropriate affect	1	0	0
	Anger	7	0	7
	Dysphoria	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	17	0	14
	Homicidal ideation	3	0	1
	Paranoia	8	0	6
	Personality change	1	0	1
	Social avoidant behaviour	1	0	1
	Violent ideation	2	0	1
	Abnormal behaviour	3	0	2
	Drug dependence	2	0	2
	Psychotic disorder	3	0	3
	Premature ejaculation	1	0	0
Libido decreased	2	0	2	

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Psychiatric disorders	Loss of libido	1	0	1
	Insomnia	17	0	11
	Abnormal dreams	4	0	3
	Nightmare	23	0	21
	Sleep walking	1	0	0
	Sleep disorder	3	0	2
	Completed suicide	1	1	1
	Intentional self-injury	3	0	2
	Self injurious behaviour	1	0	0
	Suicidal ideation	20	0	13
	Suicide attempt	10	1	3
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	8	0	7
	Polyuria	1	0	1
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	2	0	2
	Ejaculation failure	1	0	1
	Erectile dysfunction	1	0	0
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	5	0	3
	Respiratory distress	1	0	1
	Sleep apnoea syndrome	1	0	1
	Cough	1	0	1
	Hiccups	1	0	0
	Respiratory failure	1	1	0



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Respiratory, thoracic and mediastinal disorders	Pharyngolaryngeal 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
Skin and subcutaneous tissue disorders	Angioedema	1	0	1
	Periorbital oedema	2	0	2
	Urticaria	6	0	6
	Lichenoid keratosis	1	0	1
	Dermatitis bullous	1	0	1
	Swelling face	3	0	2
	Eczema	1	0	1
	Erythema	2	0	2
	Rash erythematous	3	0	3
	Rash papular	2	0	2
	Photosensitivity reaction	1	0	1
	Pruritus	7	0	5
	Pruritus generalised	1	0	1
	Dermatitis psoriasiform	1	0	1
	Rash	14	0	11
	Rash macular	1	0	0
	Rash maculo-papular	7	0	5
	Skin hyperpigmentation	1	0	1
	Acne	2	0	2
	Alopecia	4	0	3
	Cold sweat	1	0	1
Hyperhidrosis	9	0	7	
Nail disorder	1	0	0	
Petechiae	2	0	2	
Surgical and medical procedures	Drug therapy changed	3	0	3
	Therapy regimen changed	5	0	3
Vascular disorders	Aneurysm	1	1	0
	Circulatory collapse	2	0	0



# THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIRTAZAPINE		Layer 1 of 1		
Vascular disorders	Hypotension	4	1	1
	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