



## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

MIANSERIN HYDROCHLORIDE		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		437	12	268
<b>- Occurrences of Medicine</b>		477	12	268
<b>- Reactions Related to Medicine</b>		902	23	539
Blood and lymphatic system disorders	Anaemia	8	0	4
	Bone marrow failure	4	0	2
	Pancytopenia	4	1	1
	Thrombocytopenia	12	0	6
	Lymphadenopathy	2	0	1
	Splenomegaly	1	0	1
	Eosinophilia	2	0	1
	Leukocytosis	1	0	0
	Lymphocytosis	1	0	1
	Leukopenia	13	1	9
	Lymphopenia	3	0	2
	Agranulocytosis	42	3	22
	Neutropenia	51	2	32
Cardiac disorders	Bradycardia	9	0	5
	Extrasystoles	2	0	0
	Tachycardia	5	0	1
	Atrial fibrillation	2	0	2
	Cardiac arrest	1	0	1
	Palpitations	5	0	2
	Coronary artery disease	1	1	0
	Angina pectoris	1	0	0
	Myocardial infarction	2	1	1
	Cardiac failure	1	1	1
	Left ventricular failure	1	0	1
	Pericarditis	1	0	0
	Congenital, familial and genetic disorders	Gastrointestinal malformation	1	0
Ear and labyrinth disorders	Deafness	1	0	0
	Tinnitus	2	0	1



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Ear and labyrinth disorders	Vertigo	1	0	1
Endocrine disorders	Hypothyroidism	2	0	0
Eye disorders	Lacrimal disorder	2	0	2
	Conjunctivitis	2	0	1
	Diplopia	4	0	3
	Vision blurred	1	0	0
	Visual disturbance	6	0	2
Gastrointestinal disorders	Gingivitis	2	0	2
	Gingival bleeding	1	0	0
	Gastrointestinal haemorrhage	1	1	0
	Haematemesis	1	1	0
	Melaena	1	1	0
	Diarrhoea	7	0	4
	Constipation	2	0	1
	Flatulence	2	0	1
	Abdominal pain	3	0	2
	Dysphagia	3	0	2
	Faecal incontinence	1	0	0
	Nausea	17	0	11
	Vomiting	3	0	1
	Mouth ulceration	4	0	4
	Stomatitis	2	0	2
Dry mouth	1	0	1	
Tongue oedema	1	0	1	
General disorders and administration site conditions	Chills	7	0	5
	Pyrexia	33	0	19
	Sudden death	3	3	0
	Asthenia	4	0	4
	Fatigue	15	0	7
	Malaise	11	0	8
	Gait disturbance	4	0	2
	Influenza like illness	1	0	1
	Face oedema	3	0	2
	Gravitational oedema	3	0	3
	Oedema	3	0	3

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General disorders and administration site conditions	Oedema peripheral	9	0	9
	Chest pain	1	0	1
	Pain	3	0	2
	Drug ineffective	2	0	1
	Drug withdrawal syndrome	1	0	0
Hepatobiliary disorders	Hepatitis cholestatic	2	0	1
	Jaundice	13	0	9
	Hepatic function abnormal	37	0	18
	Hepatic steatosis	1	0	1
	Hepatitis	4	0	3
	Hepatocellular damage	3	0	1
Infections and infestations	Cellulitis	1	0	1
	Candidiasis	1	0	0
	Abscess	1	0	1
	Infection	3	0	2
	Pneumonia	3	0	2
	Sepsis	9	1	5
	Furuncle	1	0	1
	Pharyngitis	8	0	2
	Rhinitis	2	0	2
	Lymphangitis	1	0	1
Injury, poisoning and procedural complications	Therapeutic agent toxicity	1	0	0
Investigations	Electrocardiogram abnormal	2	0	0
	Prothrombin level decreased	1	0	1
	Red blood cell sedimentation rate increased	3	0	1
	Liver function test abnormal	1	0	1
	Transaminases increased	1	0	1
	Weight decreased	3	0	2
	Weight increased	3	0	3
Metabolism and nutrition disorders	Anorexia	8	0	5
	Increased appetite	1	0	1
	Hypocalcaemia	1	0	0
	Polydipsia	1	0	0
	Hyponatraemia	4	0	1
	Dehydration	2	0	0

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Metabolism and nutrition disorders	Hyperglycaemia	4	0	3
	Hypercholesterolaemia	2	0	2
Musculoskeletal and connective tissue disorders	Arthritis	10	0	8
	Arthropathy	1	0	1
	Arthralgia	35	0	32
	Osteoarthritis	2	0	2
	Myalgia	19	0	14
	Muscle spasms	3	0	3
	Back pain	3	0	1
	Tenosynovitis	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	1	0	0
	Brain neoplasm benign	1	0	1
Nervous system disorders	Encephalopathy	2	0	2
	Headache	13	0	10
	Dementia	1	0	0
	Choreoathetosis	1	0	1
	Dyskinesia	1	0	1
	Extrapyramidal disorder	2	0	2
	Hyperkinesia	6	0	6
	Hypokinesia	1	0	0
	Psychomotor hyperactivity	1	0	0
	Tardive dyskinesia	1	0	1
	Dystonia	1	0	1
	Paresis	1	0	1
	Tremor	5	0	2
	Coordination abnormal	7	0	2
	Nystagmus	1	0	0
	Somnolence	19	0	17
	Syncope	13	0	8
	Dizziness	12	0	10
	Hypoaesthesia	2	0	0
	Paraesthesia	9	0	4
	Dysgeusia	2	0	2
	Restless legs syndrome	1	0	1
	Speech disorder	3	0	0

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Nervous system disorders	Hypertonia	4	0	1
	Neuroleptic malignant syndrome	1	0	0
	Serotonin syndrome	1	0	0
	Muscle contractions involuntary	1	0	0
	Neuropathy	1	0	0
	Neuropathy peripheral	1	0	0
	Grand mal convulsion	3	0	2
	Convulsion	6	0	3
	Epilepsy	1	0	0
Pregnancy, puerperium and perinatal condi	Neonatal disorder	1	0	1
Psychiatric disorders	Neurosis	2	0	2
	Agitation	10	1	3
	Anxiety	3	0	3
	Nervousness	1	0	1
	Panic attack	1	0	0
	Confusional state	16	1	9
	Delirium	2	0	0
	Depression	2	0	1
	Depersonalisation	1	0	1
	Hallucination	6	0	3
	Aggression	1	0	0
	Paranoia	2	0	1
	Libido decreased	2	0	1
	Insomnia	8	0	6
	Nightmare	14	0	11
	Sleep disorder	4	0	4
	Suicidal ideation	1	0	1
Renal and urinary disorders	Renal impairment	5	0	1
	Urinary incontinence	2	0	1
	Urinary retention	3	0	2
	Albuminuria	2	0	1
	Polyuria	1	0	0
Reproductive system and breast disorders	Menstrual disorder	1	0	1
	Erectile dysfunction	1	0	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	2	0	2

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Respiratory, thoracic and mediastinal disorders	Alveolitis allergic	1	0	1
	Eosinophilic pneumonia	1	0	0
	Pulmonary fibrosis	1	0	1
	Pleural effusion	1	0	1
	Pulmonary embolism	3	3	0
	Apnoea	1	0	1
	Dyspnoea	2	0	0
	Hyperventilation	1	0	0
	Cough	1	0	0
	Dysphonia	1	0	1
	Epistaxis	1	0	0
Skin and subcutaneous tissue disorders	Angioedema	1	0	1
	Periorbital oedema	3	0	2
	Urticaria	4	0	4
	Dermatitis bullous	1	0	1
	Skin necrosis	1	0	1
	Skin reaction	1	0	0
	Dermatitis	1	0	1
	Eczema	1	0	1
	Rash erythematous	2	0	2
	Skin exfoliation	1	0	0
	Photosensitivity reaction	3	0	3
	Pruritus	20	0	9
	Rash	18	0	10
	Rash maculo-papular	13	0	5
	Rash vesicular	1	0	0
	Alopecia	2	0	1
	Hyperhidrosis	9	0	6
	Hair colour changes	1	0	0
Purpura	5	1	1	
Vascular disorders	Hypotension	10	0	7
	Orthostatic hypotension	8	0	2
	Angiopathy	1	0	0
	Flushing	1	0	0
	Pallor	1	0	1



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Vascular disorders	Haematoma	1	0	1
	Hypertension	3	0	2
	Phlebitis	1	0	1