

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMISULPRIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		233	6	167
- Occurrences of Medicine		241	6	167
- Reactions Related to Medicine		557	20	354
Blood and lymphatic system disorders	Agranulocytosis	1	0	0
	Coagulopathy	1	1	0
	Leukocytosis	3	0	1
	Leukopenia	1	0	0
	Neutropenia	2	0	0
	Thrombocythaemia	1	0	0
Cardiac disorders	Arrhythmia	1	1	0
	Atrial fibrillation	1	0	0
	Atrial flutter	1	0	0
	Atrioventricular block	1	0	1
	Bradycardia	1	0	1
	Bundle branch block left	1	0	0
	Cardiac arrest	1	1	1
	Cardiac failure	1	0	0
	Cardiomyopathy	1	0	0
	Extrasystoles	1	0	1
	Myocarditis	1	0	0
	Palpitations	3	0	1
	Sinoatrial block	1	0	0
	Sinus arrest	1	0	0
	Sinus bradycardia	1	0	0
	Supraventricular extrasystoles	1	0	0
	Tachycardia	6	0	3
	Ventricular extrasystoles	2	0	1
Congenital, familial and genetic disorders	Polydactyly	1	0	0
Ear and labyrinth disorders	Hearing impaired	1	0	1
Endocrine disorders	Hypercorticism	1	0	1
	Hyperprolactinaemia	7	0	5



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMISULPRIDE		Layer 1 of 1		
Eye disorders	Eyelid oedema	1	0	0
	Myopia	1	0	1
	Oculogyration	6	0	4
	Photophobia	1	0	1
	Vision blurred	2	0	2
	Visual disturbance	1	0	1
Gastrointestinal disorders	Abdominal pain	1	0	1
	Colitis ulcerative	2	0	1
	Constipation	2	0	2
	Diarrhoea	3	0	2
	Dry mouth	1	0	0
	Dysphagia	1	0	0
	Faecal incontinence	1	0	1
	Gastrointestinal haemorrhage	1	0	1
	Lip swelling	1	0	1
	Nausea	5	0	4
	Parotid gland enlargement	2	0	2
	Reflux oesophagitis	1	0	0
	Salivary hypersecretion	5	0	4
	Swollen tongue	4	0	4
	Tongue oedema	1	0	0
Vomiting	8	0	5	
General disorders and administration site conditions	Asthenia	1	0	0
	Chest discomfort	1	0	1
	Chest pain	1	0	0
	Chills	1	0	0
	Condition aggravated	1	0	0
	Death	1	1	0
	Drug ineffective	3	0	3
	Drug interaction	1	0	0
	Drug withdrawal syndrome	1	0	1
	Face oedema	1	0	0
	Fatigue	3	0	1
	Gait disturbance	2	0	1
	Hunger	1	0	0



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMISULPRIDE		Layer 1 of 1		
General disorders and administration site conditions	Influenza like illness	1	0	0
	Irritability	1	0	1
	Malaise	4	0	2
	Multi-organ failure	1	1	0
	Oedema peripheral	3	0	2
	Pain	1	0	1
	Pyrexia	11	0	4
	Sudden death	1	1	0
	Swelling	1	0	1
Hepatobiliary disorders	Hepatic function abnormal	1	1	0
	Jaundice	1	0	0
Immune system disorders	Hypersensitivity	1	0	1
Infections and infestations	Cellulitis	1	0	0
	Oesophageal candidiasis	1	0	0
	Sepsis	1	1	0
	Viral infection	1	0	1
Injury, poisoning and procedural complications	Contusion	1	0	1
	Fall	2	0	1
	Heat stroke	1	1	0
	Intentional overdose	3	0	2
	Overdose	1	1	1
Investigations	Blood creatine phosphokinase increased	8	1	4
	Blood prolactin increased	8	0	7
	Drug level increased	2	0	0
	Electrocardiogram abnormal	2	0	0
	Electrocardiogram QT prolonged	8	0	5
	International normalised ratio increased	1	0	1
	Platelet count increased	1	0	0
	QRS axis abnormal	1	0	0
	Respiratory rate increased	1	0	1
	Troponin increased	1	0	1
	Weight decreased	3	0	3
	Weight increased	5	1	4
	White blood cell count increased	1	0	1
Metabolism and nutrition disorders	Anorexia	1	0	1

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMISULPRIDE		Layer 1 of 1		
Metabolism and nutrition disorders	Dehydration	3	0	1
	Diabetes mellitus	2	0	1
	Hyperglycaemia	1	0	1
	Hypocalcaemia	1	0	0
	Hyponatraemia	2	0	0
	Increased appetite	1	0	1
	Polydipsia	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	1	0	1
	Joint stiffness	1	0	0
	Muscle rigidity	4	0	3
	Muscle spasms	8	0	6
	Muscle twitching	2	0	2
	Musculoskeletal stiffness	7	0	7
	Myalgia	2	0	2
	Neck pain	1	0	1
	Nuchal rigidity	1	0	1
	Pain in jaw	1	0	1
	Rhabdomyolysis	1	1	0
	Torticollis	1	0	0
	Trismus	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiocentric lymphoma	1	1	0
	Breast cancer female	2	0	2
	Pituitary tumour	1	0	1
	Pituitary tumour benign	1	0	1
	Prolactinoma	1	0	1
Nervous system disorders	Akathisia	5	0	3
	Aphasia	1	0	0
	Autonomic nervous system imbalance	1	0	1
	Brain oedema	1	0	0
	Clonus	1	0	1
	Cogwheel rigidity	2	0	1
	Coma	1	0	0
	Complex partial seizures	1	0	1
	Convulsion	9	0	3
	Convulsive threshold lowered	1	0	0

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMISULPRIDE		Layer 1 of 1		
Nervous system disorders	Coordination abnormal	4	0	3
	Disturbance in attention	1	0	1
	Dizziness	2	0	2
	Dysarthria	1	0	1
	Dysgeusia	1	1	1
	Dyskinesia	4	0	2
	Dystonia	17	0	14
	Extrapyramidal disorder	12	0	12
	Grand mal convulsion	2	0	2
	Headache	6	0	4
	Hemiparesis	1	0	0
	Hyperreflexia	2	0	1
	Hypertonia	4	0	3
	Hypoaesthesia	1	0	1
	Hyporeflexia	1	0	0
	Lethargy	2	0	1
	Loss of consciousness	1	1	0
	Myasthenia gravis	1	0	0
	Neuroleptic malignant syndrome	15	0	9
	Opisthotonus	1	0	1
	Parkinsonian gait	1	0	1
	Parkinsonism	6	0	5
	Parkinson's disease	1	0	1
	Somnolence	4	0	3
	Speech disorder	1	0	0
	Subarachnoid haemorrhage	1	0	1
	Syncope	1	0	0
	Tardive dyskinesia	9	0	7
	Tongue paralysis	1	0	0
	Tremor	13	1	12
Psychiatric disorders	Abnormal behaviour	1	0	1
	Agitation	6	0	3
	Anxiety	2	0	2
	Bipolar disorder	1	0	1
	Confusional state	3	0	0

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMISULPRIDE		Layer 1 of 1		
Psychiatric disorders	Delirium	3	0	1
	Depersonalisation	1	0	1
	Depression	3	0	3
	Depressive symptom	1	0	1
	Hypomania	2	0	2
	Insomnia	4	0	3
	Libido decreased	1	0	1
	Loss of libido	1	0	1
	Mania	1	0	1
	Nightmare	1	0	1
	Paranoia	3	0	3
	Psychotic disorder	3	0	2
	Restlessness	3	0	3
	Sleep disorder	2	0	2
	Suicidal ideation	1	0	1
	Suicide attempt	3	0	1
Renal and urinary disorders	Incontinence	1	0	0
	Micturition disorder	1	0	1
	Polyuria	1	0	1
	Renal failure acute	1	0	0
	Renal impairment	2	0	1
	Urinary incontinence	3	0	2
	Urinary retention	2	0	0
Reproductive system and breast disorders	Amenorrhoea	10	0	7
	Breast enlargement	1	0	0
	Breast pain	2	0	1
	Breast tenderness	1	0	0
	Dysmenorrhoea	1	0	0
	Erectile dysfunction	2	0	2
	Galactorrhoea	19	0	12
	Gynaecomastia	1	0	1
	Menorrhagia	1	0	1
	Metrorrhagia	1	0	0
	Nipple disorder	1	0	1
	Oligomenorrhoea	1	0	0

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMISULPRIDE		Layer 1 of 1		
Reproductive system and breast disorders	Priapism	1	0	1
Respiratory, thoracic and mediastinal disorders	Aspiration	1	1	1
	Bronchospasm	1	0	1
	Choking	1	0	1
	Dyspnoea	8	0	4
	Hyperventilation	1	0	1
	Laryngospasm	2	0	2
	Pneumonitis	1	0	1
	Respiratory disorder	1	0	0
	Wheezing	1	0	1
Skin and subcutaneous tissue disorders	Acne	2	0	2
	Alopecia	4	0	3
	Angioedema	2	0	2
	Cold sweat	1	0	0
	Dermatitis exfoliative	1	0	0
	Erythema	2	0	2
	Hyperhidrosis	10	0	4
	Pruritus	4	0	4
	Pruritus generalised	1	0	1
	Purpura	1	0	1
	Rash	6	0	5
	Rash erythematous	2	0	2
	Rash maculo-papular	2	0	1
	Rash pruritic	4	0	4
	Urticaria	2	0	2
	Vasculitic rash	1	0	1
Surgical and medical procedures	Therapy regimen changed	2	0	1
Vascular disorders	Circulatory collapse	2	1	1
	Hypertension	3	0	0
	Hypotension	4	1	1
	Orthostatic hypotension	1	0	0