

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		755	34	347
- Occurrences of Medicine		777	35	347
- Reactions Related to Medicine		1610	85	686
Blood and lymphatic system disorders	Anaemia	2	1	0
	Aplastic anaemia	2	2	0
	Bone marrow failure	2	0	0
	Pancytopenia	5	1	1
	Coagulopathy	1	1	0
	Coombs positive haemolytic anaemia	1	0	0
	Platelet disorder	1	0	1
	Thrombocytopenia	10	1	2
	Eosinophilia	4	1	0
	Leukopenia	7	2	2
	Agranulocytosis	2	1	0
Neutropenia	14	1	4	
Cardiac disorders	Atrioventricular block	2	0	0
	Brugada syndrome	1	1	0
	Arrhythmia	3	1	1
	Bradycardia	1	0	0
	Extrasystoles	1	0	0
	Tachycardia	23	0	12
	Atrial fibrillation	1	0	1
	Cardiac arrest	1	0	0
	Torsade de pointes	1	0	0
	Ventricular tachycardia	1	0	0
	Cardiac disorder	1	1	0
	Palpitations	9	0	6
	Myocardial infarction	4	1	3
	Cardiac failure	5	2	3
	Left ventricular failure	2	0	1
Cardiomyopathy	6	1	3	



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Cardiac disorders	Myocarditis	1	1	0
Congenital, familial and genetic disorders	Exomphalos	1	0	1
	Meningomyelocele	1	0	1
Ear and labyrinth disorders	Deafness	2	0	0
	Tinnitus	7	0	6
	Vertigo	3	0	3
Endocrine disorders	Inappropriate antidiuretic hormone secretion	3	0	1
	Hyperthyroidism	2	0	1
Eye disorders	Lacrimonal disorder	1	0	0
	Lacrimation increased	1	0	0
	Eye disorder	1	0	1
	Glaucoma	2	0	2
	Conjunctivitis	2	0	1
	Accommodation disorder	2	0	1
	Diplopia	2	0	1
	Vision blurred	2	0	0
	Visual disturbance	16	0	13
Gastrointestinal disorders	Dental caries	2	0	2
	Tooth discolouration	1	0	1
	Gingival hyperplasia	1	0	1
	Pancreatitis	1	0	0
	Gastrointestinal haemorrhage	2	0	1
	Haematemesis	2	1	0
	Colitis ulcerative	1	1	0
	Oesophagitis	1	0	0
	Diarrhoea	9	1	4
	Constipation	21	0	13
	Gastroesophageal reflux disease	1	0	0
	Oesophageal spasm	1	0	1
	Ileus paralytic	2	0	0
	Dyspepsia	2	0	2
	Faeces discoloured	2	0	2
	Flatulence	1	0	1
	Abdominal pain	11	0	2
Dysphagia	7	0	4	

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Gastrointestinal disorders	Faecal incontinence	1	0	0
	Nausea	20	0	8
	Vomiting	12	1	6
	Ileus	1	0	0
	Intestinal obstruction	5	1	2
	Duodenal ulcer	2	0	0
	Duodenal ulcer haemorrhage	1	0	0
	Duodenal ulcer perforation	2	1	0
	Oesophagitis ulcerative	1	0	0
	Peptic ulcer	1	1	0
	Peptic ulcer perforation	2	1	0
	Cheilitis	1	0	1
	Mouth ulceration	6	1	2
	Stomatitis	5	0	3
	Dry mouth	32	0	24
	Saliva altered	1	0	1
	Salivary hypersecretion	4	0	0
	Salivary gland enlargement	1	0	0
	Glossitis	1	0	0
	Tongue ulceration	1	0	0
Swollen tongue	1	0	1	
Tongue oedema	5	0	2	
General disorders and administration site conditions	Hypothermia	1	0	0
	Chills	3	0	0
	Pyrexia	13	2	2
	Sudden death	15	15	4
	Asthenia	4	0	1
	Fatigue	14	0	4
	Malaise	14	1	5
	Gait disturbance	3	0	0
	Chest discomfort	1	0	1
	Hangover	1	0	1
	Thirst	3	0	1
	Face oedema	8	0	6
	Gravitational oedema	2	0	1

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
General disorders and administration site conditions	Oedema	2	0	1
	Oedema peripheral	12	0	7
	Chest pain	9	0	4
	Pain	6	1	2
	Drug interaction	2	0	0
	Drug ineffective	11	1	5
	Drug withdrawal syndrome	8	0	6
Hepatobiliary disorders	Cholecystitis	1	0	0
	Hepatitis cholestatic	2	0	1
	Hyperbilirubinaemia	2	0	1
	Jaundice	8	1	4
	Hepatic function abnormal	23	1	5
	Hepatic failure	3	3	0
	Hepatitis	9	1	4
Infections and infestations	Hepatocellular damage	6	1	0
	Cellulitis	1	0	0
	Vaginal infection	1	0	1
	Pneumonia	2	1	0
	Sepsis	2	2	0
	Rash pustular	1	0	1
	Rhinitis	1	0	1
Injury, poisoning and procedural complications	Urinary tract infection	1	0	0
	Fall	7	0	2
Investigations	Medication error	1	0	1
	Electrocardiogram QT prolonged	4	1	0
	Electrocardiogram abnormal	2	1	1
	Heart rate decreased	1	0	0
	Blood creatine phosphokinase increased	3	1	0
	Blood amylase increased	1	0	0
	International normalised ratio increased	1	0	0
	Prothrombin level decreased	1	0	0
	Red blood cell sedimentation rate increased	2	0	0
	Platelet adhesiveness decreased	1	0	1
	Liver function test abnormal	4	0	1
Weight decreased	3	0	0	

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Investigations	Weight increased	1	0	1
	Urine analysis abnormal	2	0	1
	Serum ferritin increased	1	0	1
Metabolism and nutrition disorders	Acidosis	2	0	0
	Anorexia	9	0	3
	Increased appetite	1	0	1
	Hypomagnesaemia	1	1	0
	Hypochloraemia	1	1	0
	Polydipsia	1	0	1
	Hypokalaemia	2	0	0
	Hyponatraemia	14	1	2
	Dehydration	3	0	2
	Diabetes mellitus	2	0	0
	Hypoglycaemia	1	0	0
	Hypercholesterolaemia	1	0	0
	Hypertriglyceridaemia	1	0	0
	Gout	4	0	3
Musculoskeletal and connective tissue disorders	Bone pain	1	0	1
	Systemic lupus erythematosus	2	0	1
	Arthralgia	8	0	5
	Osteoarthritis	2	0	0
	Myositis	1	0	0
	Myalgia	6	0	1
	Muscle spasms	3	0	2
	Muscle twitching	6	0	2
	Muscle rigidity	1	0	0
	Muscular weakness	2	0	0
	Myopathy	1	0	0
	Rhabdomyolysis	2	0	0
	Back pain	1	0	0
	Musculoskeletal chest pain	1	0	0
	Musculoskeletal stiffness	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	1	0	1
	Breast cancer female	2	0	0
	Breast neoplasm	1	0	1



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Neoplasms benign, malignant and un	Metastases to bone marrow	1	1	0
Nervous system disorders	Cerebral haemorrhage	2	2	0
	Haemorrhage intracranial	1	0	0
	Cerebrovascular disorder	1	0	1
	Tongue paralysis	1	0	1
	Encephalopathy	4	1	1
	Headache	16	1	11
	Migraine	2	0	0
	Dementia	1	0	0
	Amnesia	5	0	4
	Cognitive disorder	1	0	0
	Dyskinesia	12	0	5
	Extrapyramidal disorder	6	1	4
	Hyperkinesia	3	0	2
	Hypokinesia	2	0	1
	Tardive dyskinesia	8	0	2
	Dystonia	1	0	1
	Hemiplegia	1	0	1
	Paralysis	2	0	2
	Paresis	2	0	0
	Tremor	31	1	17
	Hyperreflexia	1	0	0
	Balance disorder	2	0	1
	Cerebellar syndrome	1	0	0
	Coordination abnormal	16	1	8
	Nystagmus	1	0	0
	Coma	1	0	0
	Diabetic coma	1	0	0
	Aphasia	2	0	1
	Consciousness fluctuating	2	0	1
	Depressed level of consciousness	1	0	0
	Lethargy	1	0	1
	Loss of consciousness	1	0	1
Sedation	1	0	1	
Somnolence	30	0	12	

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Nervous system disorders	Stupor	2	0	2
	Syncope	12	0	4
	Clonus	1	0	0
	Dizziness	31	0	14
	Myoclonus	4	0	0
	Hypoaesthesia	2	0	2
	Paraesthesia	10	0	6
	Dysgeusia	6	0	5
	Sensory disturbance	1	0	0
	Dysarthria	8	0	5
	Incoherent	1	0	0
	Speech disorder	3	0	2
	Anticholinergic syndrome	1	0	1
	Autonomic nervous system imbalance	1	0	0
	Hypertonia	8	2	1
	Neuroleptic malignant syndrome	3	1	0
	Serotonin syndrome	21	0	1
	Muscle contractions involuntary	1	0	1
	Neuropathy	1	0	1
	Neuropathy peripheral	4	0	1
	Grand mal convulsion	5	0	0
	Convulsion	13	0	5
	Convulsions local	1	0	1
	Drug withdrawal convulsions	1	0	0
	Epilepsy	1	0	0
	Tonic convulsion	1	0	1
Hypersomnia	1	0	0	
Poor quality sleep	1	0	1	
Psychiatric disorders	Agitation	34	0	11
	Anxiety	8	0	5
	Nervousness	3	0	2
	Fear	1	0	0
	Panic attack	1	0	1
	Restlessness	2	0	0
	Communication disorder	1	0	1

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Psychiatric disorders	Confusional state	68	3	21
	Disorientation	2	0	0
	Delirium	13	0	3
	Depression	5	0	2
	Depersonalisation	2	0	0
	Delusion	6	0	1
	Hallucination	39	0	20
	Hallucination, auditory	1	0	1
	Hallucination, visual	3	0	2
	Illusion	1	0	1
	Thinking abnormal	1	0	0
	Hypomania	1	0	0
	Mania	1	0	0
	Inappropriate affect	1	0	0
	Anger	1	0	0
	Aggression	12	0	7
	Paranoia	3	0	1
	Personality disorder	2	0	2
	Abnormal behaviour	4	0	0
	Drug dependence	1	0	0
	Delusional disorder, unspecified type	1	0	0
	Psychotic disorder	4	0	2
	Libido decreased	7	0	6
	Libido increased	1	0	1
	Insomnia	15	0	11
	Abnormal dreams	1	0	1
	Nightmare	15	0	9
	Sleep terror	1	0	0
	Sleep walking	1	0	0
	Sleep disorder	3	0	3
	Suicidal ideation	1	0	1
	Suicide attempt	2	1	1
	Renal and urinary disorders	Oliguria	2	0
Renal failure acute		4	2	0
Renal impairment		3	1	0

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Renal and urinary disorders	Dysuria	2	0	2
	Micturition disorder	6	0	6
	Pollakiuria	4	0	3
	Urinary incontinence	5	0	2
	Urinary retention	20	0	13
	Chromaturia	1	0	1
	Haematuria	2	0	1
	Polyuria	2	0	2
Reproductive system and breast disorders	Breast enlargement	4	0	4
	Gynaecomastia	5	0	4
	Breast pain	3	0	3
	Suppressed lactation	1	0	0
	Amenorrhoea	2	0	2
	Scrotal oedema	1	0	0
	Ejaculation failure	1	0	1
	Erectile dysfunction	2	0	2
	Testicular disorder	1	0	1
	Vaginal haemorrhage	1	0	1
Respiratory, thoracic and mediastinal disorders	Bronchospasm	2	0	1
	Chronic obstructive pulmonary disease	1	0	0
	Pulmonary fibrosis	2	0	0
	Pulmonary oedema	1	0	1
	Pleural fibrosis	1	0	0
	Pulmonary embolism	3	1	2
	Dyspnoea	18	0	7
	Respiratory depression	1	0	0
	Asphyxia	1	0	0
	Cough	2	0	1
	Haemoptysis	1	0	1
	Productive cough	1	0	0
	Respiratory disorder	1	0	0
	Epistaxis	1	0	0
	Pharyngeal oedema	1	0	1
Skin and subcutaneous tissue disorders	Angioedema	2	0	0
	Periorbital oedema	2	0	1



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Skin and subcutaneous tissue disorders	Urticaria	8	0	5
	Lichenoid keratosis	4	0	1
	Dermatitis bullous	1	0	0
	Erythema multiforme	1	0	0
	Stevens-Johnson syndrome	1	0	0
	Toxic epidermal necrolysis	2	1	0
	Skin discolouration	1	0	0
	Skin disorder	1	0	1
	Dermatitis	1	0	0
	Eczema	1	0	1
	Drug eruption	1	0	0
	Rash erythematous	14	0	4
	Dermatitis exfoliative	3	0	1
	Skin exfoliation	4	0	3
	Photosensitivity allergic reaction	1	0	0
	Photosensitivity reaction	12	0	6
	Pruritus	42	0	25
	Dermatitis psoriasiform	1	0	0
	Fixed eruption	1	0	0
	Rash	31	1	13
	Rash macular	1	0	0
	Rash maculo-papular	15	0	5
	Rash morbilliform	3	0	0
	Chloasma	1	0	0
	Vitiligo	1	0	0
	Lipodystrophy acquired	2	0	0
	Alopecia	5	0	4
	Anhidrosis	1	0	1
	Cold sweat	1	0	0
	Hyperhidrosis	34	0	19
	Night sweats	1	0	0
	Hirsutism	1	0	0
	Nail disorder	1	0	1
Rosacea	1	0	0	
Petechiae	1	0	0	



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

AMITRIPTYLINE HYDROCHLORIDE		Layer 1 of 1		
Skin and subcutaneous tissue disorders	Purpura	9	0	5
Surgical and medical procedures	Therapy regimen changed	1	0	0
Vascular disorders	Circulatory collapse	2	0	0
	Shock	1	0	0
	Hypotension	7	0	1
	Orthostatic hypotension	23	0	12
	Flushing	7	0	1
	Hot flush	1	0	0
	Pallor	1	0	0
	Haemorrhage	4	0	0
	Hypertension	12	0	3