

Medicine summary - amitriptyline (to end January 2009)

			Case Group	Death Outcomes	Sole	
Case Count			786	34	366	
Reaction Count	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	9	1	2	
		Eosinophilia	4	1	0	
		Leukopenia	7	2	2	
		Agranulocytosis	2	1	0	
		Neutropenia	14	1	4	
		Blood and lymphatic system disorders		50	11	10
		Cardiac disorders	Atrioventricular block	2	0	0
	Brugada syndrome		1	1	0	
	Arrhythmia		3	1	1	
	Bradycardia		2	0	0	
	Extrasystoles		1	0	0	
	Tachycardia		24	0	13	
	Atrial fibrillation		1	0	1	
	Cardiac arrest		2	0	0	
	Torsade de pointes		1	0	0	
	Ventricular tachycardia		1	0	0	
	Cardiac disorder		1	1	0	
	Palpitations		10	0	7	
	Myocardial infarction		4	1	3	
Cardiac failure	5		2	3		
Left ventricular failure	2		0	1		
Cardiomyopathy	6		1	3		
Myocarditis	1		1	0		
Cardiac disorders			67	8	32	
Congenital, familial and genetic disorders	Exomphalos	1	0	1		
	Meningomyelocele	1	0	1		
	Congenital, familial and genetic disorders		2	0	2	
Ear and labyrinth disorders	Deafness	2	0	0		
	Tinnitus	8	0	7		
	Vertigo	3	0	3		
	Ear and labyrinth disorders		13	0	10	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	4	0	2		
	Hyperthyroidism	2	0	1		
	Endocrine disorders		6	0	3	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Eye disorders	Lacrimal disorder	1	0	0	
		Lacrimation increased	1	0	0	
		Eye disorder	1	0	1	
		Eye pain	1	0	1	
		Glaucoma	2	0	2	
		Open angle glaucoma	1	0	1	
		Conjunctivitis	2	0	1	
		Blindness	1	0	1	
		Accommodation disorder	2	0	1	
		Diplopia	2	0	1	
		Vision blurred	4	0	2	
		Visual impairment	16	0	13	
		Eye disorders		34	0	24
		Gastrointestinal disorders	Dental caries	3	0	3
	Sensitivity of teeth		1	0	1	
	Tooth discolouration		1	0	1	
	Gingival hyperplasia		1	0	1	
	Gingivitis		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		10	1	5	
	Constipation		21	0	13	
	Gastrooesophageal 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	
	Faecal incontinence	1	0	0		
Nausea	23	0	10			
Vomiting	14	1	7			
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			

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			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Peptic ulcer	1	1	0
		Peptic ulcer perforation	2	1	0
		Cheilitis	1	0	1
		Mouth ulceration	6	1	2
		Stomatitis	4	0	3
		Dry mouth	41	0	32
		Lip dry	1	0	1
		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 blistering	1	0	0
		Tongue oedema	5	0	2
		Gastrointestinal disorders	193	9	100
		General disorders and administration site conditions	Hypothermia	1	0
	Pyrexia		14	2	3
	Sudden death		15	15	4
	Asthenia		5	0	1
	Fatigue		15	0	5
	Malaise		14	1	5
	Gait disturbance		4	0	1
	Face oedema		8	0	6
	Gravitational oedema		2	0	1
	Oedema		2	0	1
	Oedema peripheral		11	0	6
	Chest pain		8	0	3
	Pain		7	1	2
	Chest discomfort		1	0	1
	Chills		4	0	1
	Feeling hot		1	0	1
	Hangover		1	0	1
	Thirst		3	0	1
Drug interaction	2		0	0	
Drug ineffective	11		1	5	
General disorders and administration site conditions	129	20	48		
Hepatobiliary disorders	Cholecystitis	1	0	0	
	Hepatitis cholestatic	2	0	1	
	Hyperbilirubinaemia	2	0	1	
	Jaundice	8	1	4	

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Reaction Count	Hepatobiliary disorders	Hepatic function abnormal	23	1	5
		Hepatic failure	3	3	0
		Hepatitis	9	1	4
		Hepatocellular injury	6	1	0
		Hepatobiliary disorders	54	7	15
	Infections and infestations	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
		Urinary tract infection	1	0	0
		Infections and infestations	9	3	3
	Injury, poisoning and procedural complications	Fall	9	0	3
		Medication error	1	0	1
		Injury, poisoning and procedural complications	10	0	4
	Investigations	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
		Weight increased	1	0	1
		Urine analysis abnormal	2	0	1
		Serum ferritin increased	1	0	1
		Blood electrolytes abnormal	1	0	1
		Investigations	28	3	7
		Metabolism and nutrition disorders	Acidosis	2	0
	Decreased appetite		10	0	4
	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

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Reaction Count	Metabolism and nutrition disorders	Hypoglycaemia	1	0	0	
		Hypercholesterolaemia	1	0	0	
		Hypertriglyceridaemia	1	0	0	
		Gout	3	0	2	
		Metabolism and nutrition disorders	43	3	12	
	Musculoskeletal and connective tissue disorders	Bone pain	1	0	1	
		Systemic lupus erythematosus	2	0	1	
		Arthralgia	7	0	4	
		Osteoarthritis	1	0	0	
		Myositis	1	0	0	
		Myalgia	7	0	2	
		Muscle spasms	3	0	2	
		Muscle twitching	6	0	2	
		Muscle rigidity	1	0	0	
		Trismus	1	0	1	
		Muscular weakness	2	0	0	
		Myopathy	1	0	0	
		Rhabdomyolysis	2	0	0	
		Musculoskeletal stiffness	1	0	0	
		Sensation of heaviness	1	0	1	
		Back pain	1	0	0	
		Musculoskeletal chest pain	1	0	0	
		Musculoskeletal and connective tissue disorders	39	0	14	
		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	
	Metastases to bone marrow		1	1	0	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		5	1	2	
	Nervous system disorders	Cerebral haemorrhage	1	1	0	
		Haemorrhage intracranial	1	0	0	
		Cerebrovascular disorder	1	0	1	
		Tongue paralysis	1	0	1	
		Encephalopathy	4	1	1	
		Headache	18	1	11	
		Migraine	2	0	0	
		Dementia	1	0	0	
		Amnesia	6	0	5	
		Cognitive disorder	1	0	0	
		Mental impairment	1	0	1	
		Dyskinesia	10	0	4	

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Reaction Count	Nervous system disorders	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	32	1	18
		Hyperreflexia	1	0	0
		Ataxia	14	1	8
		Balance disorder	2	0	1
		Cerebellar syndrome	1	0	0
		Coordination abnormal	2	0	0
		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	2	0	1
		Loss of consciousness	3	0	1
		Sedation	1	0	1
		Somnolence	31	0	13
		Stupor	1	0	1
		Syncope	13	0	5
		Clonus	1	0	0
		Dizziness	30	0	13
		Myoclonus	5	0	1
		Paraesthesia	11	0	7
		Dysgeusia	8	0	6
		Hypoaesthesia	2	0	2
		Sensory disturbance	1	0	0
		Dysarthria	9	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	22	0	1		
Muscle contractions involuntary	1	0	1		

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Reaction Count	Nervous system disorders	Neuropathy peripheral	5	0	2
		Grand mal convulsion	5	0	0
		Convulsion	16	0	6
		Convulsions local	1	0	1
		Drug withdrawal convulsions	1	0	0
		Epilepsy	2	0	0
		Tonic convulsion	1	0	1
		Hypersomnia	1	0	0
		Poor quality sleep	1	0	1
		Nervous system disorders	323	9	139
	Psychiatric disorders	Agitation	35	0	12
		Anxiety	10	0	6
		Nervousness	4	0	3
		Stress	1	0	0
		Fear	1	0	0
		Panic attack	1	0	1
		Restlessness	2	0	0
		Communication disorder	1	0	1
		Confusional state	69	3	22
		Disorientation	4	0	2
		Delirium	15	0	3
		Depression	6	0	3
		Tearfulness	2	0	2
		Depersonalisation	2	0	0
		Delusion	7	0	2
		Hallucination	45	0	24
		Hallucination, auditory	2	0	2
		Hallucination, visual	3	0	2
		Illusion	1	0	1
		Thinking abnormal	1	0	0
		Hypomania	1	0	0
		Mania	1	0	0
		Affect lability	1	0	1
Inappropriate affect		1	0	0	
Anger		1	0	0	
Aggression		13	0	8	
Paranoia		4	0	2	
Personality disorder		2	0	2	
Abnormal behaviour		5	0	0	
Drug dependence	1	0	0		
Withdrawal syndrome	8	0	6		
Delusional disorder, unspecified type	1	0	0		

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Reaction Count	Psychiatric disorders	Psychotic disorder	4	0	2
		Libido decreased	5	0	4
		Libido increased	1	0	1
		Insomnia	16	0	12
		Abnormal dreams	1	0	1
		Nightmare	15	0	9
		Sleep terror	1	0	0
		Somnambulism	1	0	0
		Sleep disorder	3	0	3
		Self-injurious ideation	1	0	1
		Suicidal ideation	3	0	2
		Suicide attempt	2	1	1
			Psychiatric disorders	304	4
Renal and urinary disorders	Oliguria	2	0	2	
	Renal failure acute	4	2	0	
	Renal impairment	3	1	0	
	Dysuria	4	0	4	
	Micturition disorder	5	0	5	
	Pollakiuria	4	0	3	
	Urinary incontinence	5	0	2	
	Urinary retention	21	0	14	
	Chromaturia	1	0	1	
	Haematuria	2	0	1	
	Polyuria	2	0	2	
		Renal and urinary disorders	53	3	34
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	1	0	1	
	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	
		Reproductive system and breast disorders	20	0	17
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	

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Reaction Count	Respiratory, thoracic and mediastinal disorders	Dyspnoea	19	0	7
		Respiratory depression	1	0	0
		Asphyxia	1	0	0
		Cough	2	0	1
		Haemoptysis	1	0	1
		Sputum increased	1	0	0
		Respiratory disorder	1	0	0
		Epistaxis	1	0	0
		Pharyngeal oedema	1	0	1
		Respiratory, thoracic and mediastinal disorders	38	1	14
	Skin and subcutaneous tissue disorders	Angioedema	2	0	0
		Periorbital oedema	2	0	1
		Urticaria	6	0	4
		Lichenoid keratosis	3	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	3	0	2
		Photosensitivity allergic reaction	1	0	0
		Photosensitivity reaction	12	0	6
		Pruritus	41	0	24
		Dermatitis psoriasiform	1	0	0
		Fixed eruption	1	0	0
		Rash	30	1	12
		Rash macular	1	0	0
Rash maculo-papular	14	0	4		
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	2	0	0		
Hyperhidrosis	36	0	19		

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Reaction Count	Skin and subcutaneous tissue disorders	Night sweats	1	0	0	
		Hirsutism	1	0	0	
		Nail disorder	1	0	1	
		Rosacea	1	0	0	
		Petechiae	1	0	0	
		Purpura	9	0	5	
		Skin and subcutaneous tissue disorders	209	2	91	
	Surgical and medical procedures	Therapy regimen changed	1	0	0	
		Surgical and medical procedures	1	0	0	
	Vascular disorders	Circulatory collapse	3	0	0	
		Hypotension	9	0	1	
		Orthostatic hypotension	23	0	12	
		Flushing	7	0	1	
		Hot flush	1	0	0	
		Pallor	1	0	0	
		Haemorrhage	3	0	0	
		Hypertension	12	0	3	
		Vascular disorders	59	0	17	
	Reaction			1689	84	739