

## Medicine summary -amitriptyline (to date)

			Case Group	Death Outcomes	Sole	
Case Count			830	40	383	
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	1	0	
		Aplastic anaemia	2	2	0	
		Bone marrow failure	2	0	0	
		Pancytopenia	6	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	
		<b>Blood and lymphatic system disorders</b>			<b>51</b>	<b>11</b>
	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	25	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	12	0	9	
Myocardial infarction		4	1	3		
Cardiac failure		5	2	3		
Left ventricular failure		2	0	1		
Cardiomyopathy		7	1	3		
Myocarditis		1	1	0		
<b>Cardiac disorders</b>			<b>71</b>	<b>8</b>	<b>34</b>	
Congenital, familial and genetic disorders	Exomphalos	1	0	1		
	Meningomyelocele	1	0	1		
	<b>Congenital, familial and genetic disorders</b>			<b>2</b>	<b>0</b>	<b>2</b>
Ear and labyrinth disorders	Deafness	2	0	0		
	Tinnitus	9	0	8		
	Vertigo	3	0	3		
	<b>Ear and labyrinth disorders</b>			<b>14</b>	<b>0</b>	<b>11</b>
Endocrine disorders	Inappropriate antidiuretic hormone secretion	4	0	2		
	Hyperthyroidism	2	0	1		
	<b>Endocrine disorders</b>			<b>6</b>	<b>0</b>	<b>3</b>

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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
		Periorbital oedema	2	0	1
		Glaucoma	2	0	2
		Open angle glaucoma	1	0	1
		Conjunctivitis	2	0	1
		Ocular hyperaemia	1	0	0
		Blindness	1	0	1
		Accommodation disorder	2	0	1
		Diplopia	2	0	1
		Vision blurred	4	0	2
		Visual impairment	16	0	13
		<b>Eye disorders</b>		<b>37</b>	<b>0</b>
	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	22	0	14
		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	
Abdominal pain upper		1	0	0	
Dysphagia		7	0	4	
Faecal incontinence		1	0	0	
Nausea		24	0	10	
Vomiting		14	1	7	
Ileus		1	0	0	
Intestinal obstruction		5	1	2	
Duodenal ulcer		2	0	0	

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			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	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	4	0	3
		Dry mouth	42	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
		<b>Gastrointestinal disorders</b>		<b>197</b>	<b>9</b>
	General disorders and administration site conditions	Hypothermia	1	0	0
		Pyrexia	16	2	3
		Death	2	2	1
		Sudden death	15	15	4
		Asthenia	5	0	1
		Fatigue	16	0	5
		Malaise	15	1	5
		Sluggishness	1	0	1
		Gait disturbance	6	0	2
		Condition aggravated	1	0	0
Irritability		1	0	1	
Face oedema		8	0	6	
Gravitational oedema		2	0	1	
Oedema		2	0	1	
Oedema peripheral		11	0	6	
Chest pain		9	0	4	
Pain		7	1	2	
Chest discomfort		1	0	1	
Chills		4	0	1	
Feeling abnormal		1	0	1	
Feeling cold	1	0	1		
Feeling hot	1	0	1		
Hangover	1	0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	Thirst	3	0	1
		Drug interaction	4	1	0
		Drug ineffective	12	1	5
		<b>General disorders and administration site conditions</b>	<b>146</b>	<b>23</b>	<b>55</b>
	Hepatobiliary disorders	Cholecystitis	1	0	0
		Hepatitis cholestatic	2	0	1
		Hyperbilirubinaemia	2	0	1
		Jaundice	8	1	4
		Hepatic function abnormal	24	1	5
		Hepatic failure	3	3	0
		Hepatic steatosis	1	1	0
		Hepatitis	9	1	4
		Hepatocellular injury	6	1	0
		<b>Hepatobiliary disorders</b>	<b>56</b>	<b>8</b>	<b>15</b>
	Immune system disorders	Hypersensitivity	1	0	1
		<b>Immune system disorders</b>	<b>1</b>	<b>0</b>	<b>1</b>
	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
		<b>Infections and infestations</b>	<b>9</b>	<b>3</b>	<b>3</b>
	Injury, poisoning and procedural complications	Drug toxicity	2	2	0
		Drug exposure during pregnancy	1	0	0
		Subdural haematoma	1	0	0
		Fall	10	0	3
		Medication error	1	0	1
		Accidental drug intake by child	1	0	1
		Overdose	2	1	0
		<b>Injury, poisoning and procedural complications</b>	<b>18</b>	<b>3</b>	<b>5</b>
	Investigations	Electrocardiogram QT prolonged	5	1	0
Electrocardiogram abnormal		2	1	1	
Heart rate decreased		1	0	0	
Heart rate increased		1	0	1	
Blood pressure decreased		1	0	0	
Blood creatine phosphokinase increased		4	1	0	
Blood amylase increased		1	0	0	
International normalised ratio increased		1	0	0	
Prothrombin level decreased	1	0	0		

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			Case Group	Death Outcomes	Sole
Reaction Count	Investigations	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	2	0	2
		Urine analysis abnormal	2	0	1
		Serum ferritin increased	1	0	1
		Blood electrolytes abnormal	1	0	1
		<b>Investigations</b>	<b>33</b>	<b>3</b>	<b>9</b>
Metabolism and nutrition disorders	Acidosis	2	0	0	
	Decreased appetite	11	0	4	
	Increased appetite	1	0	1	
	Hypomagnesaemia	1	1	0	
	Hypochloraemia	1	1	0	
	Polydipsia	1	0	1	
	Hyperkalaemia	2	0	0	
	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	3	0	2	
	<b>Metabolism and nutrition disorders</b>	<b>46</b>	<b>3</b>	<b>12</b>	
	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 tightness		1	0	1	
Muscle twitching		7	0	3	
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	

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			Case Group	Death Outcomes	Sole
Reaction Count	Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	1	0	0
		<b>Musculoskeletal and connective tissue disorders</b>	<b>41</b>	<b>0</b>	<b>16</b>
	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
		<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>5</b>	<b>1</b>	<b>2</b>
	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	11	0	4
		Extrapyramidal disorder	6	1	4
		Hyperkinesia	3	0	2
		Hypokinesia	2	0	1
		Tardive dyskinesia	9	0	2
		Dystonia	2	0	1
		Hemiplegia	1	0	1
		Paralysis	2	0	2
		Paresis	2	0	0
		Tremor	35	1	21
		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		

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			Case Group	Death Outcomes	Sole		
Reaction Count	Nervous system disorders	Loss of consciousness	3	0	1		
		Sedation	2	0	2		
		Somnolence	31	0	13		
		Stupor	1	0	1		
		Syncope	14	0	5		
		Clonus	1	0	0		
		Dizziness	32	0	14		
		Myoclonus	8	0	1		
		Paraesthesia	11	0	7		
		Dysgeusia	8	0	6		
		Hypoaesthesia	2	0	2		
		Sensory disturbance	1	0	0		
		Dysarthria	9	0	5		
		Incoherent	2	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	27	1	1		
		Muscle contractions involuntary	1	0	1		
		Mononeuropathy	1	0	0		
		Neuropathy peripheral	5	0	2		
		Brachial plexopathy	1	0	0		
		Grand mal convulsion	5	0	0		
		Convulsion	18	1	7		
		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		
			<b>Nervous system disorders</b>		<b>346</b>	<b>11</b>	<b>145</b>
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous		1	0	0
			<b>Pregnancy, puerperium and perinatal conditions</b>		<b>1</b>	<b>0</b>	<b>0</b>
Psychiatric disorders	Agitation		37	0	14		
	Anxiety		10	0	6		
	Nervousness		4	0	3		
	Stress		1	0	0		
	Fear		1	0	0		
	Panic attack		1	0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Restlessness	3	0	1
		Bruxism	1	0	1
		Communication disorder	1	0	1
		Confusional state	71	3	23
		Disorientation	5	0	3
		Delirium	15	0	3
		Depression	6	0	3
		Tearfulness	2	0	2
		Depersonalisation	2	0	0
		Delusion	7	0	2
		Persecutory delusion	1	0	0
		Hallucination	48	0	27
		Hallucination, auditory	3	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	2	0	1
		Aggression	13	0	8
		Paranoia	5	0	2
		Personality disorder	2	0	2
		Abnormal behaviour	6	0	1
		Mental disorder	1	0	0
		Drug dependence	1	0	0
		Withdrawal syndrome	9	0	7
		Delusional disorder, unspecified type	1	0	0
		Psychotic disorder	4	0	2
		Libido decreased	5	0	4
		Libido increased	1	0	1
		Insomnia	16	0	12
		Abnormal dreams	2	0	2
		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	4	0	3
		Suicide attempt	3	1	1
	<b>Psychiatric disorders</b>	<b>324</b>	<b>4</b>	<b>155</b>	



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			Case Group	Death Outcomes	Sole
Reaction Count	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	22	0	14
		Chromaturia	1	0	1
		Haematuria	2	0	1
		Polyuria	2	0	2
		<b>Renal and urinary disorders</b>	<b>54</b>	<b>3</b>	<b>34</b>
		Reproductive system and breast disorders	Breast enlargement	4	0
	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
	<b>Reproductive system and breast disorders</b>		<b>20</b>	<b>0</b>	<b>17</b>
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	2	0	1
		Chronic obstructive pulmonary disease	1	0	0
		Pulmonary fibrosis	2	0	0
		Pulmonary oedema	3	1	1
		Pleural fibrosis	1	0	0
		Pulmonary embolism	4	1	3
		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
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>41</b>	<b>2</b>	<b>15</b>
		Skin and subcutaneous tissue disorders	Angioedema	2	0
	Urticaria		7	0	5
	Lichenoid keratosis		3	0	1

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			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	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	16	0	5
		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
		Rash pruritic	1	0	1
		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	6	0	5
		Anhidrosis	1	0	1
		Cold sweat	2	0	0
		Hyperhidrosis	36	0	19
		Night sweats	2	0	0
		Hirsutism	1	0	0
		Nail disorder	1	0	1
		Rosacea	1	0	0
		Petechiae	1	0	0
		Purpura	9	0	5
			<b>Skin and subcutaneous tissue disorders</b>	<b>213</b>	<b>2</b>
Surgical and medical procedures	Off label use	3	0	2	
	Therapy regimen changed	1	0	0	
	<b>Surgical and medical procedures</b>	<b>4</b>	<b>0</b>	<b>2</b>	
Vascular disorders	Circulatory collapse	3	0	0	
	Hypotension	10	0	1	
	Orthostatic hypotension	23	0	12	

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Reaction Count	Vascular disorders	Arterial thrombosis limb	1	0	0
		Flushing	7	0	1
		Hot flush	1	0	0
		Pallor	1	0	0
		Haemorrhage	3	0	0
		Hypertension	14	0	3
		<b>Vascular disorders</b>	<b>63</b>	<b>0</b>	<b>17</b>
	<b>Reaction</b>	<b>1799</b>	<b>94</b>	<b>783</b>	