

## Medicine summary -imipramine (to date)

			Case Group	Death Outcomes	Sole
Case Count			410	6	232
Reaction Count	Blood and lymphatic system disorders	Anaemia	3	0	1
		Aplastic anaemia	2	1	0
		Bone marrow failure	1	0	0
		Hypoplastic anaemia	1	0	0
		Thrombocytopenia	6	0	2
		Lymphadenopathy	1	0	1
		Leukopenia	5	0	3
		Lymphopenia	1	0	1
		Agranulocytosis	5	0	3
		Neutropenia	6	0	4
		<b>Blood and lymphatic system disorders</b>		<b>31</b>	<b>1</b>
	Cardiac disorders	Atrioventricular block	1	0	1
		Bundle branch block	1	0	0
		Arrhythmia	4	0	2
		Extrasystoles	4	0	1
		Tachycardia	6	1	2
		Torsade de pointes	1	0	0
		Palpitations	7	0	4
		<b>Cardiac disorders</b>		<b>24</b>	<b>1</b>
	Congenital, familial and genetic disorders	Cleft lip	1	0	1
		Dysmorphism	1	0	1
		Congenital brain damage	3	0	3
		<b>Congenital, familial and genetic disorders</b>		<b>5</b>	<b>0</b>
	Ear and labyrinth disorders	Tinnitus	4	0	3
		Vertigo	3	0	1
		<b>Ear and labyrinth disorders</b>		<b>7</b>	<b>0</b>
	Endocrine disorders	Adrenal insufficiency	1	1	0
Inappropriate antidiuretic hormone secretion		4	0	2	
<b>Endocrine disorders</b>		<b>5</b>	<b>1</b>	<b>2</b>	
Eye disorders	Eye pain	1	0	0	
	Periorbital oedema	2	0	2	
	Glaucoma	1	0	1	
	Conjunctivitis	1	0	1	
	Mydriasis	2	0	1	
	Pupillary reflex impaired	1	0	0	
	Diplopia	1	0	1	
	Vision blurred	1	0	0	
	Visual impairment	8	0	5	
	Scotoma	1	0	1	
	<b>Eye disorders</b>		<b>19</b>	<b>0</b>	<b>12</b>
Gastrointestinal disorders	Pancreatitis	1	0	1	

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Reaction Count	Gastrointestinal disorders	Reflux oesophagitis	1	0	0		
		Diarrhoea	3	0	2		
		Constipation	11	0	8		
		Dyspepsia	2	0	2		
		Flatulence	1	0	1		
		Abdominal pain	9	0	7		
		Dysphagia	1	0	0		
		Nausea	25	0	14		
		Vomiting	18	1	9		
		Duodenal ulcer haemorrhage	2	0	0		
		Duodenal ulcer perforation	1	1	0		
		Peptic ulcer perforation	1	1	0		
		Cheilitis	2	0	1		
		Mouth ulceration	5	0	4		
		Stomatitis	2	0	2		
		Peritonitis	1	1	0		
		Dry mouth	11	0	8		
		Salivary hypersecretion	1	0	0		
		Glossitis	3	0	2		
		Tongue ulceration	2	0	1		
		<b>Gastrointestinal disorders</b>			<b>103</b>	<b>4</b>	<b>62</b>
Reaction Count	General disorders and administration site conditions	Pyrexia	7	0	3		
		Sudden death	1	1	0		
		Asthenia	1	0	0		
		Fatigue	8	0	4		
		Malaise	2	0	0		
		Gait disturbance	2	0	1		
		Influenza like illness	1	0	1		
		Irritability	1	0	1		
		Face oedema	5	0	4		
		Oedema	2	0	2		
		Oedema peripheral	2	0	1		
		Chest pain	2	0	1		
		Pain	1	0	1		
		Drug interaction	1	0	0		
		Drug ineffective	4	0	2		
		<b>General disorders and administration site conditions</b>			<b>40</b>	<b>1</b>	<b>21</b>
		Reaction Count	Hepatobiliary disorders	Hepatitis cholestatic	4	0	3
Jaundice	8			0	6		
Hepatic function abnormal	14			0	5		
Hepatitis	11			0	6		

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Reaction Count	Hepatobiliary disorders	<b>Hepatobiliary disorders</b>	<b>37</b>	<b>0</b>	<b>20</b>
	Infections and infestations	Candidiasis	2	0	0
		Oesophageal candidiasis	1	0	0
		Otitis externa	1	0	0
		Pneumonia	1	1	0
		Rash pustular	1	0	1
		Pharyngitis	3	0	1
		Rhinitis	1	0	1
		<b>Infections and infestations</b>	<b>10</b>	<b>1</b>	<b>3</b>
		Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	0
	Medication error		1	0	1
	Accidental overdose		1	0	1
	<b>Injury, poisoning and procedural complications</b>		<b>3</b>	<b>0</b>	<b>2</b>
	Investigations	Electrocardiogram QT interval	1	0	1
		Electrocardiogram ST segment abnormal	1	0	1
		Electrocardiogram abnormal	2	0	2
		Heart rate increased	1	0	0
		Weight decreased	3	0	2
		Weight increased	2	0	1
		Urine analysis abnormal	1	0	0
		Drug level decreased	1	0	0
		<b>Investigations</b>	<b>12</b>	<b>0</b>	<b>7</b>
	Metabolism and nutrition disorders	Decreased appetite	7	0	5
		Increased appetite	2	0	2
		Hyperkalaemia	2	1	0
		Hyponatraemia	10	0	3
		Dehydration	4	0	2
		<b>Metabolism and nutrition disorders</b>	<b>25</b>	<b>1</b>	<b>12</b>
	Musculoskeletal and connective tissue disorders	Bone pain	1	0	0
		Osteoporosis	1	0	0
		Systemic lupus erythematosus	1	0	0
		Pathological fracture	1	0	0
		Arthralgia	2	0	2
		Myalgia	4	0	3
		Muscle spasms	2	0	1
		Muscle tightness	1	0	1
		Muscle twitching	3	0	2
		Muscular weakness	1	0	1
		<b>Musculoskeletal and connective tissue disorders</b>	<b>17</b>	<b>0</b>	<b>10</b>
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia granulocytic	1	0	0

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Reaction Count	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	1	0	0
	Nervous system disorders	VIIth nerve paralysis	1	0	1
		Parosmia	1	0	1
		Encephalopathy	1	0	0
		Headache	14	0	6
		Amnesia	1	0	1
		Memory impairment	1	0	0
		Dyskinesia	1	0	1
		Extrapyramidal disorder	5	0	1
		Hyperkinesia	2	0	0
		Hypokinesia	1	0	0
		Tardive dyskinesia	5	0	1
		Dystonia	4	0	1
		Tremor	9	0	6
		Ataxia	6	0	3
		Coordination abnormal	2	0	0
		Coma	1	0	0
		Aphasia	1	0	1
		Sedation	1	0	0
		Somnolence	8	0	6
		Stupor	1	0	0
		Syncope	6	1	4
		Dizziness	22	0	8
		Hyperaesthesia	1	0	1
		Paraesthesia	8	0	5
		Dysgeusia	1	0	0
		Neuralgia	1	0	1
		Restless legs syndrome	1	0	1
		Dysarthria	2	0	1
		Speech disorder	3	0	1
		Anticholinergic syndrome	1	0	1
		Autonomic neuropathy	1	0	0
		Hypertonia	2	0	0
		Serotonin syndrome	2	0	0
		Neuritis	1	0	0
		Neuropathy peripheral	2	0	1
		Grand mal convulsion	2	0	0
		Convulsion	1	0	1
		<b>Nervous system disorders</b>	<b>123</b>	<b>1</b>	<b>54</b>
	Psychiatric disorders	Agitation	10	0	4
		Anxiety	4	0	2

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Reaction Count	Psychiatric disorders	Nervousness	2	0	2	
		Neurosis	1	0	1	
		Confusional state	19	1	3	
		Disorientation	1	0	0	
		Delirium	4	0	1	
		Depression	6	0	5	
		Depersonalisation	6	0	6	
		Delusion	2	0	0	
		Hallucination	15	0	4	
		Thinking abnormal	2	0	2	
		Affect lability	3	0	3	
		Emotional distress	1	0	0	
		Euphoric mood	1	0	1	
		Apathy	1	0	0	
		Aggression	7	0	6	
		Personality disorder	4	0	4	
		Drug dependence	1	0	0	
		Withdrawal syndrome	5	0	4	
		Psychotic disorder	1	0	0	
		Libido decreased	2	0	2	
		Insomnia	8	0	8	
		Nightmare	7	0	5	
		Somnambulism	1	0	0	
	Sleep disorder	2	0	1		
	<b>Psychiatric disorders</b>			<b>116</b>	<b>1</b>	<b>64</b>
	Renal and urinary disorders	Oliguria	1	1	0	
		Renal failure acute	2	1	1	
		Urethral disorder	1	0	0	
		Dysuria	5	1	3	
		Micturition disorder	4	0	4	
		Pollakiuria	1	0	1	
		Urinary incontinence	2	0	0	
		Urinary retention	7	0	4	
		<b>Renal and urinary disorders</b>			<b>23</b>	<b>3</b>
	Reproductive system and breast disorders	Gynaecomastia	3	0	2	
		Breast pain	2	0	2	
Galactorrhoea		4	0	2		
Suppressed lactation		1	0	1		
Menstrual disorder		1	0	1		
Genital ulceration		1	0	0		
Genital discharge		1	0	1		
Oedema genital		1	0	1		

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Reaction Count	Reproductive system and breast disorders	Erectile dysfunction	1	0	1
		Infertility male	1	0	1
		Testicular disorder	2	0	2
		<b>Reproductive system and breast disorders</b>	<b>18</b>	<b>0</b>	<b>14</b>
	Respiratory, thoracic and mediastinal disorders	Dyspnoea	3	0	0
		Respiratory distress	1	0	0
		Cough	3	0	1
		Respiratory failure	1	1	0
		Respiratory disorder	1	0	0
		Dysphonia	1	0	1
		Epistaxis	2	0	1
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>12</b>	<b>1</b>	<b>3</b>
		Skin and subcutaneous tissue disorders	Angioedema	2	0
	Urticaria		8	0	6
	Skin discolouration		1	0	1
	Dermatitis		1	0	1
	Rash erythematous		9	0	5
	Dermatitis exfoliative		2	0	2
	Skin exfoliation		1	0	1
	Photosensitivity reaction		6	0	4
	Pruritus		25	0	19
	Psoriasis		1	0	0
	Rash		21	0	10
	Rash maculo-papular		21	0	19
	Rash morbilliform		3	0	2
	Vitiligo		1	0	1
	Alopecia		3	0	2
	Cold sweat		2	0	1
	Hyperhidrosis		29	0	17
	Nail disorder		1	0	0
	Purpura		5	0	3
	<b>Skin and subcutaneous tissue disorders</b>		<b>142</b>	<b>0</b>	<b>94</b>
	Surgical and medical procedures	Therapy regimen changed	2	0	0
		<b>Surgical and medical procedures</b>	<b>2</b>	<b>0</b>	<b>0</b>
	Vascular disorders	Peripheral ischaemia	2	0	1
		Hypotension	12	0	4
		Orthostatic hypotension	21	0	10
		Thrombosis	1	1	0
		Thrombophlebitis	1	0	0
		Vein pain	1	0	1
Hot flush		5	0	5	
Hypertension		3	1	1	

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			<b>Case Group</b>	<b>Death Outcomes</b>	<b>Sole</b>
Reaction Count	Vascular disorders	<b>Vascular disorders</b>	<b>46</b>	<b>2</b>	<b>22</b>
	<b>Reaction</b>		<b>821</b>	<b>18</b>	<b>449</b>