

## Medicine summary -doxepin (to date)

			Case Group	Death Outcomes	Sole	
Case Count			471	7	254	
Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	0	
		Aplastic anaemia	2	2	0	
		Bone marrow failure	1	0	1	
		Pancytopenia	4	0	1	
		Haemolytic anaemia	1	0	1	
		Coombs positive haemolytic anaemia	1	0	0	
		Thrombocytopenia	7	0	3	
		Eosinophilia	1	0	0	
		Leukocytosis	1	0	0	
		Leukopenia	6	0	2	
		Lymphopenia	3	0	2	
		Agranulocytosis	2	0	1	
		Neutropenia	8	0	2	
		<b>Blood and lymphatic system disorders</b>			<b>38</b>	<b>2</b>
	Cardiac disorders	Arrhythmia	1	1	0	
		Bradycardia	3	0	0	
		Extrasystoles	2	0	1	
		Tachycardia	10	0	5	
		Atrial fibrillation	2	0	1	
		Supraventricular tachycardia	1	0	0	
		Ventricular tachycardia	1	0	0	
		Palpitations	5	0	4	
		Coronary artery thrombosis	1	0	0	
		Myocardial infarction	1	1	0	
		Cardiomyopathy	1	0	1	
		<b>Cardiac disorders</b>			<b>28</b>	<b>2</b>
Congenital, familial and genetic disorders	Congenital hand malformation	1	0	0		
	<b>Congenital, familial and genetic disorders</b>			<b>1</b>	<b>0</b>	<b>0</b>
Ear and labyrinth disorders	Deafness	1	0	1		
	Hyperacusis	1	0	1		
	Tinnitus	7	0	5		
	Vertigo	3	0	1		
	<b>Ear and labyrinth disorders</b>			<b>12</b>	<b>0</b>	<b>8</b>
Endocrine disorders	Inappropriate antidiuretic hormone secretion	1	0	0		
	<b>Endocrine disorders</b>			<b>1</b>	<b>0</b>	<b>0</b>
Eye disorders	Cataract	1	0	0		
	Eye pain	1	0	1		
	Periorbital oedema	1	0	0		
	Glaucoma	3	0	3		
	Conjunctivitis	2	0	1		
	Oculogyric crisis	1	0	1		

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		Case Group	Death Outcomes	Sole	
Reaction Count	Eye disorders	Mydriasis	1	0	0
		Photophobia	2	0	1
		Blindness	1	0	0
		Chromatopsia	1	0	1
		Diplopia	2	0	1
		Visual impairment	12	0	8
		<b>Eye disorders</b>	<b>28</b>	<b>0</b>	<b>17</b>
	Gastrointestinal disorders	Dental caries	1	0	0
		Toothache	1	0	0
		Tooth discolouration	1	0	0
		Gingival atrophy	1	0	0
		Gingivitis	1	0	1
		Pancreatitis	1	0	0
		Haematemesis	1	0	0
		Melaena	3	0	0
		Gastritis	1	0	1
		Oesophagitis	4	0	2
		Diarrhoea	5	0	4
		Constipation	12	0	7
		Dyspepsia	6	0	4
		Eructation	1	0	1
		Flatulence	2	0	2
		Abdominal pain	7	0	3
		Breath odour	1	0	0
		Dysphagia	2	0	1
		Nausea	17	0	10
		Vomiting	9	0	2
		Ileus	1	0	1
		Duodenal ulcer	1	0	0
		Gastric ulcer	2	0	0
		Gastric ulcer haemorrhage	1	0	0
		Oesophagitis ulcerative	1	0	0
		Malabsorption	1	0	0
		Mouth ulceration	2	0	1
Retroperitoneal fibrosis		2	0	0	
Dry mouth	16	0	12		
Glossitis	1	0	1		
<b>Gastrointestinal disorders</b>	<b>105</b>	<b>0</b>	<b>53</b>		
General disorders and administration site conditions	Hyperthermia malignant	1	0	0	
	Hyperpyrexia	1	0	0	
	Pyrexia	9	0	1	
	Sudden death	1	1	0	

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			Case Group	Death Outcomes	Sole	
Reaction Count	General disorders and administration site conditions	Asthenia	4	0	2	
		Fatigue	7	0	3	
		Malaise	6	0	4	
		Gait disturbance	4	0	2	
		Mucosal inflammation	1	0	0	
		Face oedema	6	0	2	
		Generalised oedema	1	0	1	
		Gravitational oedema	2	0	1	
		Oedema	4	0	4	
		Oedema peripheral	6	0	6	
		Chest pain	2	0	1	
		Pain	3	0	2	
		Chills	3	0	0	
		Feeling hot	1	0	1	
		Drug ineffective	4	0	3	
		Therapeutic response decreased	1	0	0	
		Drug withdrawal syndrome neonatal	1	0	0	
			<b>General disorders and administration site conditions</b>	<b>68</b>	<b>1</b>	<b>33</b>
		Hepatobiliary disorders	Hepatitis cholestatic	2	0	1
			Jaundice	9	1	3
Liver disorder	1		0	1		
Hepatic function abnormal	14		0	2		
Hepatomegaly	2		0	0		
Hepatic steatosis	1		0	1		
Hepatitis	10		0	3		
Hepatocellular injury	1		0	1		
	<b>Hepatobiliary disorders</b>		<b>40</b>	<b>1</b>	<b>12</b>	
Infections and infestations	Sepsis	2	1	0		
	Nasopharyngitis	1	0	1		
	Pharyngitis	2	0	1		
	Rhinitis	1	0	1		
		<b>Infections and infestations</b>	<b>6</b>	<b>1</b>	<b>3</b>	
Injury, poisoning and procedural complications	Medication error	1	0	0		
		<b>Injury, poisoning and procedural complications</b>	<b>1</b>	<b>0</b>	<b>0</b>	
Investigations	Blood pressure increased	1	0	0		
	Blood creatine phosphokinase increased	2	0	0		
	Blood alkaline phosphatase increased	1	0	1		
	Prothrombin level decreased	1	0	0		
	Red blood cell sedimentation rate increased	1	0	0		
	Weight decreased	3	1	1		

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Reaction Count	Investigations	Weight increased	16	0	13
		<b>Investigations</b>	<b>25</b>	<b>1</b>	<b>15</b>
	Metabolism and nutrition disorders	Decreased appetite	7	0	4
		Increased appetite	4	0	3
		Feeding disorder neonatal	1	0	0
		Hyperkalaemia	2	0	0
		Hypokalaemia	3	0	0
		Hypernatraemia	1	0	0
		Hyponatraemia	13	0	6
		Dehydration	1	0	0
		Hyperglycaemia	3	0	1
		Hypoglycaemia	1	0	1
		Hyperuricaemia	2	0	1
		<b>Metabolism and nutrition disorders</b>	<b>38</b>	<b>0</b>	<b>16</b>
		Musculoskeletal and connective tissue disorders	Arthralgia	5	0
	Osteoarthritis		1	0	1
	Myalgia		8	0	5
	Muscle spasms		3	0	2
	Muscle twitching		4	0	3
	Muscle rigidity		1	0	0
	Musculoskeletal stiffness		1	0	0
	<b>Musculoskeletal and connective tissue disorders</b>		<b>23</b>	<b>0</b>	<b>16</b>
	Nervous system disorders	Encephalopathy	2	0	0
		Headache	17	0	15
		Dementia	1	0	0
		Amnesia	3	0	1
		Choreoathetosis	1	0	0
		Dyskinesia	2	0	0
		Extrapyramidal disorder	1	0	0
		Hyperkinesia	4	0	3
		Hypokinesia	2	0	0
		Tardive dyskinesia	1	0	0
		Dystonia	3	0	1
Hemiparesis		1	0	1	
Paresis		1	0	1	
Parkinsonian rest tremor		1	0	0	
Parkinsonism		1	0	0	
Tremor		19	0	10	
Hyperreflexia		1	0	0	
Ataxia	14	0	9		
Cerebellar syndrome	2	0	1		

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			Case Group	Death Outcomes	Sole		
Reaction Count	Nervous system disorders	Coordination abnormal	4	0	3		
		Coma	2	0	0		
		Aphasia	1	0	0		
		Consciousness fluctuating	1	0	0		
		Depressed level of consciousness	1	0	1		
		Somnolence	16	0	11		
		Stupor	3	0	2		
		Syncope	7	0	2		
		Clonus	2	0	0		
		Dizziness	16	0	12		
		Hyperaesthesia	1	0	1		
		Paraesthesia	8	0	6		
		Ageusia	1	0	1		
		Dysgeusia	5	0	1		
		Hypoaesthesia	2	0	2		
		Sensory disturbance	1	0	0		
		Speech disorder	3	0	1		
		Anticholinergic syndrome	1	0	0		
		Autonomic nervous system imbalance	1	0	0		
		Hypertonia	7	0	2		
		Neuroleptic malignant syndrome	1	0	0		
		Serotonin syndrome	4	1	0		
		Myasthenic syndrome	1	0	1		
		Neuritis	1	0	1		
		Neuropathy peripheral	1	0	1		
		Grand mal convulsion	4	0	2		
		Convulsion	10	0	2		
		Drug withdrawal convulsions	1	0	0		
			<b>Nervous system disorders</b>	<b>183</b>	<b>1</b>	<b>94</b>	
			Psychiatric disorders	Agitation	19	0	10
				Anxiety	8	0	4
				Nervousness	7	0	6
				Restlessness	1	0	0
				Bruxism	1	0	1
				Confusional state	21	0	7
				Disorientation	1	0	0
				Delirium	3	0	1
		Depression	6	1	2		
		Depressed mood	1	0	1		
		Depersonalisation	2	0	2		
		Delusion	1	0	0		
		Hallucination	12	0	6		

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			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Hallucination, visual	1	0	0
		Thinking abnormal	2	0	2
		Affect lability	2	0	1
		Aggression	4	0	2
		Paranoia	4	0	0
		Personality disorder	1	0	1
		Withdrawal syndrome	7	0	4
		Psychotic disorder	5	0	1
		Schizophreniform disorder	1	0	0
		Libido decreased	2	0	2
		Insomnia	18	0	15
		Nightmare	16	0	13
		Sleep disorder	1	0	0
		Conversion disorder	1	0	1
		Suicidal ideation	1	0	1
Suicide attempt	1	1	0		
	<b>Psychiatric disorders</b>		<b>150</b>	<b>2</b>	<b>83</b>
Renal and urinary disorders	Renal and urinary disorders	Tubulointerstitial nephritis	1	0	0
		Anuria	1	0	0
		Renal failure acute	3	0	0
		Renal impairment	4	0	0
		Micturition disorder	1	0	1
		Pollakiuria	2	0	1
		Urinary incontinence	1	0	1
		Urinary retention	4	0	1
		Renal pain	1	0	1
			<b>Renal and urinary disorders</b>		<b>18</b>
Reproductive system and breast disorders	Reproductive system and breast disorders	Breast enlargement	3	0	3
		Breast mass	1	0	0
		Gynaecomastia	3	0	2
		Breast pain	4	0	3
		Galactorrhoea	3	0	2
		Suppressed lactation	3	0	3
		Cervix disorder	1	0	0
		Menorrhagia	1	0	1
		Ejaculation failure	1	0	0
		Erectile dysfunction	5	0	3
		Testicular disorder	1	0	1
		Vulval disorder	1	0	1
			<b>Reproductive system and breast disorders</b>		<b>27</b>
Respiratory, thoracic and mediastinal disorders	Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0	1
		Pulmonary fibrosis	1	0	0

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		Case Group	Death Outcomes	Sole	
Reaction Count	Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	0	0
		Dyspnoea	2	0	1
		Respiratory depression	1	0	1
		Hypoxia	1	1	0
		Cough	2	0	1
		Haemoptysis	1	0	0
		Respiratory failure	1	0	0
		Respiratory disorder	2	0	1
		Epistaxis	2	0	2
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>15</b>	<b>1</b>	<b>7</b>
	Skin and subcutaneous tissue disorders	Angioedema	3	0	1
		Urticaria	13	0	5
		Skin hypertrophy	1	0	0
		Dermatitis bullous	2	0	0
		Erythema multiforme	5	0	3
		Pemphigoid	1	0	0
		Dermatitis	2	0	2
		Eczema	2	0	1
		Rash erythematous	9	0	4
		Skin exfoliation	1	0	0
		Photosensitivity reaction	13	0	7
		Pruritus	15	0	5
		Psoriasis	2	0	1
		Rash	18	0	5
		Rash maculo-papular	11	0	7
		Rash morbilliform	2	0	1
		Systemic lupus erythematosus rash	1	0	0
		Acne	2	0	0
		Alopecia	4	0	2
		Hyperhidrosis	20	0	9
		Hair texture abnormal	1	0	1
		Seborrhoea	1	0	1
		Purpura	8	0	4
		<b>Skin and subcutaneous tissue disorders</b>	<b>137</b>	<b>0</b>	<b>59</b>
Surgical and medical procedures	Off label use	1	0	1	
	<b>Surgical and medical procedures</b>	<b>1</b>	<b>0</b>	<b>1</b>	
Vascular disorders	Circulatory collapse	1	0	0	
	Hypotension	5	0	1	
	Orthostatic hypotension	10	0	5	
	Flushing	3	0	1	
	Hot flush	1	0	1	

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Reaction Count	Vascular disorders	Hypertension	3	0	3
		<b>Vascular disorders</b>	<b>23</b>	<b>0</b>	<b>11</b>
<b>Reaction</b>			<b>968</b>	<b>12</b>	<b>477</b>