

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
		Blood and lymphatic system disorders	38	2	13
	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
		Cardiac disorders	28	2	12
	Congenital, familial and genetic disorders	Congenital hand malformation	1	0	0
		Congenital, familial and genetic disorders	1	0	0
	Ear and labyrinth disorders	Deafness	1	0	1
		Hyperacusis	1	0	1
		Tinnitus	7	0	5
		Vertigo	3	0	1
		Ear and labyrinth disorders	12	0	8
	Endocrine disorders	Inappropriate antidiuretic hormone secretion	1	0	0
		Endocrine disorders	1	0	0
	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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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
		Eye disorders	28	0 17
	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
		Eruption	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
		Gastrointestinal disorders	105	0 53
	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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Reaction Count		Case Group	Death Outcomes	Sole
	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
		General disorders and administration site conditions	68	1 33
	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
		Hepatobiliary disorders	40	1 12
	Infections and infestations	Sepsis	2	1 0
		Nasopharyngitis	1	0 1
		Pharyngitis	2	0 1
		Rhinitis	1	0 1
		Infections and infestations	6	1 3
	Injury, poisoning and procedural complications	Medication error	1	0 0
		Injury, poisoning and procedural complications	1	0 0
	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		Case Group	Death Outcomes	Sole
		Weight increased	16	0	13
	Investigations		25	1	15
	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
	Metabolism and nutrition disorders		38	0	16
	Musculoskeletal and connective tissue disorders	Arthralgia	5	0	5
		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
	Musculoskeletal and connective tissue disorders		23	0	16
	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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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
		Hypoesthesia	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
		Nervous system disorders	183	1 94
	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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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
		Psychiatric disorders	150	2 83
	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
		Renal and urinary disorders	18	0 5
	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
		Reproductive system and breast disorders	27	0 19
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0 1
		Pulmonary fibrosis	1	0 0

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	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
		Respiratory, thoracic and mediastinal disorders	15	1	7
	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
		Skin and subcutaneous tissue disorders	137	0	59
	Surgical and medical procedures	Off label use	1	0	1
		Surgical and medical procedures	1	0	1
	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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			Case Group	Death Outcomes	Sole
Reaction Count	Vascular disorders	Hypertension	3	0	3
		Vascular disorders	23	0	11
	Reaction		968	12	477