

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

DOXEPIN HYDROCHLORIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		462	6	249
- Occurrences of Medicine		477	6	249
- Reactions Related to Medicine		973	11	487
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
Cardiac disorders	Arrhythmia	1	1	0
	Bradycardia	3	0	0
	Extrasystoles	2	0	1
	Tachycardia	9	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
	Congenital, familial and genetic disorders	Congenital hand malformation	2	0
Ear and labyrinth disorders	Deafness	2	0	2
	Hyperacusis	1	0	1
	Tinnitus	7	0	5

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Ear and labyrinth disorders	Vertigo	3	0	1
Endocrine disorders	Inappropriate antidiuretic hormone secretior	1	0	0
Eye disorders	Cataract	1	0	0
	Glaucoma	3	0	3
	Conjunctivitis	2	0	1
	Oculogyration	1	0	1
	Mydriasis	1	0	0
	Photophobia	1	0	0
	Blindness	1	0	0
	Chromatopsia	1	0	1
	Diplopia	2	0	1
	Visual disturbance	12	0	8
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	6	0	5
	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	16	0	10
	Vomiting	8	0	2
	Ileus	1	0	1
	Duodenal ulcer	1	0	0
	Gastric ulcer	2	0	0

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Gastrointestinal disorders	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
General disorders and administration site conditions	Hyperthermia malignant	1	0	0
	Chills	4	0	0
	Feeling hot	1	0	1
	Hyperpyrexia	1	0	0
	Pyrexia	9	0	1
	Sudden death	1	1	0
	Asthenia	4	0	2
	Fatigue	6	0	2
	Malaise	6	0	4
	Prostration	1	0	1
	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
	Drug ineffective	4	0	3
Drug withdrawal syndrome	6	0	4	
Drug withdrawal syndrome neonatal	1	0	0	
Therapeutic response decreased	1	0	0	
Hepatobiliary disorders	Hepatitis cholestatic	2	0	1
	Jaundice	9	1	3
	Hepatic function abnormal	14	0	2
	Hepatomegaly	2	0	0
	Hepatic steatosis	1	0	1

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Hepatobiliary disorders	Hepatitis	11	0	4
	Hepatocellular damage	1	0	1
Infections and infestations	Sepsis	2	1	0
	Nasopharyngitis	1	0	1
	Pharyngitis	3	0	2
	Rhinitis	1	0	1
Injury, poisoning and procedural complicatic	Medication error	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 increasec	1	0	0
	Weight decreased	2	1	0
	Weight increased	16	0	13
Metabolism and nutrition disorders	Anorexia	6	0	3
	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
	Musculoskeletal and connective tissue disorders	Arthralgia	5	0
Osteoarthritis		1	0	1
Myalgia		9	0	6
Muscle spasms		3	0	2
Muscle twitching		4	0	3
Muscle rigidity		1	0	0
Musculoskeletal stiffness		1	0	0
Nervous system disorders	Encephalopathy	2	0	0
	Headache	19	0	17
	Dementia	1	0	0

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Nervous system disorders	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	20	0	11
	Hyperreflexia	1	0	0
	Cerebellar syndrome	2	0	1
	Coordination abnormal	18	0	12
	Coma	2	0	0
	Aphasia	1	0	0
	Consciousness fluctuating	1	0	0
	Depressed level of consciousness	1	0	1
	Somnolence	17	0	12
	Stupor	3	0	2
	Syncope	7	0	2
	Clonus	2	0	0
	Dizziness	15	0	11
	Hyperaesthesia	1	0	1
	Hypoaesthesia	2	0	2
	Paraesthesia	9	0	7
	Ageusia	1	0	1
	Dysgeusia	5	0	1
	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

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Nervous system disorders	Neuroleptic malignant syndrome	1	0	0
	Serotonin syndrome	3	0	0
	Eaton-Lambert syndrome	1	0	1
	Neuritis	1	0	1
	Neuropathy	2	0	2
	Grand mal convulsion	4	0	2
	Convulsion	8	0	2
	Drug withdrawal convulsions	1	0	0
Psychiatric disorders	Agitation	19	0	10
	Anxiety	7	0	3
	Nervousness	7	0	6
	Restlessness	1	0	0
	Bruxism	1	0	1
	Confusional state	22	0	7
	Disorientation	1	0	0
	Delirium	3	0	1
	Depression	6	1	2
	Depersonalisation	2	0	2
	Delusion	1	0	0
	Hallucination	12	0	6
	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
	Psychotic disorder	5	0	1
	Schizophreniform disorder	1	0	0
	Libido decreased	2	0	2
	Insomnia	18	0	15
	Nightmare	18	0	15
	Sleep disorder	1	0	0
Conversion disorder	1	0	1	
Suicide attempt	1	1	0	
Renal and urinary disorders	Nephritis interstitial	1	0	0

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Renal and urinary disorders	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
Reproductive system and breast disorders	Breast enlargement	4	0	4
	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	6	0	4
	Testicular disorder	1	0	1
	Vulval disorder	1	0	1
Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0	1
	Pulmonary fibrosis	1	0	0
	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
Skin and subcutaneous tissue disorders	Angioedema	3	0	1
	Periorbital oedema	1	0	0
	Urticaria	13	0	5
	Skin hypertrophy	1	0	0

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Skin and subcutaneous tissue disorders	Dermatitis bullous	2	0	0
	Erythema multiforme	6	0	4
	Pemphigoid	1	0	0
	Systemic lupus erythematosus rash	1	0	0
	Dermatitis	2	0	2
	Eczema	2	0	1
	Rash erythematous	11	0	6
	Skin exfoliation	1	0	0
	Photosensitivity reaction	14	0	8
	Pruritus	15	0	5
	Psoriasis	2	0	1
	Rash	19	0	6
	Rash maculo-papular	11	0	7
	Rash morbilliform	2	0	1
	Acne	2	0	0
	Alopecia	4	0	2
	Hyperhidrosis	19	0	9
	Hair texture abnormal	1	0	1
	Seborrhoea	1	0	1
	Purpura	8	0	4
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
	Hypertension	3	0	3