



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

HALOPERIDOL + HALOPERIDOL DECANOATE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		733	20	326
- Occurrences of Medicine		789	22	326
- Reactions Related to Medicine		1607	86	642
Blood and lymphatic system disorders	Anaemia	2	0	0
	Bone marrow failure	1	0	0
	Pancytopenia	4	0	1
	Haemolytic anaemia	1	0	0
	Thrombocytopenia	2	0	0
	Lymphadenopathy	1	0	0
	Splenomegaly	2	0	0
	Eosinophilia	1	0	0
	Leukocytosis	10	1	3
	Leukopenia	3	0	0
	Lymphopenia	2	0	1
	Agranulocytosis	4	0	0
	Neutropenia	6	0	0
Cardiac disorders	Brugada syndrome	1	1	0
	Arrhythmia	2	1	0
	Bradycardia	3	0	0
	Extrasystoles	3	0	1
	Tachycardia	22	0	1
	Cardiac arrest	6	4	1
	Torsade de pointes	1	0	0
	Ventricular arrhythmia	1	0	1
	Ventricular fibrillation	2	0	1
	Ventricular tachycardia	1	0	0
	Cyanosis	8	0	5
	Coronary artery disease	1	1	0
	Cardiac failure	3	1	0
	Cardiomyopathy	4	0	0
	Myocarditis	5	0	0

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Congenital, familial and genetic disorders	Vascular malformation peripheral	1	0	0
	Congenital hand malformation	1	0	0
	Polydactyly	1	0	0
	Congenital brain damage	1	0	0
Ear and labyrinth disorders	Hyperacusis	1	0	0
	Tinnitus	2	0	1
Endocrine disorders	Diabetes insipidus	2	1	0
Eye disorders	Cataract	1	0	0
	Glaucoma	1	0	1
	Conjunctivitis	3	0	2
	Uveitis	1	0	0
	Blepharospasm	1	0	1
	Oculogyration	44	0	23
	Miosis	1	0	1
	Mydriasis	1	0	0
	Pupillary reflex impaired	1	0	0
	Eye rolling	1	0	1
	Diplopia	1	0	0
	Vision blurred	1	0	1
	Visual disturbance	8	0	5
	Gastrointestinal disorders	Rectal tenesmus	1	0
Tooth discolouration		1	0	0
Gingival hyperplasia		1	0	1
Gingivitis		2	0	2
Haematemesis		2	0	1
Oesophagitis		1	0	0
Diarrhoea		2	0	0
Constipation		5	1	2
Dyspepsia		1	0	1
Abdominal pain		2	0	0
Dysphagia		6	0	4
Faecal incontinence		2	0	1
Nausea		11	0	5
Retching		1	0	1
Vomiting		11	0	4

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Gastrointestinal disorders	Oesophagitis ulcerative	1	0	0
	Cheilitis	1	1	0
	Mouth ulceration	3	0	1
	Stomatitis	1	0	0
	Dry mouth	2	1	0
	Salivary hypersecretion	12	0	4
	Salivary gland enlargement	1	0	0
	Glossitis	1	0	0
	Swollen tongue	3	0	2
	Tongue oedema	8	1	5
General disorders and administration site conditions	Injection site reaction	3	0	3
	Hypothermia	1	0	0
	Chills	6	0	3
	Pyrexia	53	6	12
	Sudden death	7	7	1
	Asthenia	2	0	2
	Fatigue	5	1	1
	Malaise	3	1	1
	Gait disturbance	13	0	8
	Condition aggravated	3	0	1
	Feeling abnormal	1	0	0
	Face oedema	7	0	1
	Generalised oedema	1	0	0
	Gravitational oedema	1	0	0
	Oedema	2	0	0
	Oedema peripheral	2	0	0
	Chest pain	1	0	0
	Pain	6	0	5
	Drug ineffective	2	0	0
	Drug withdrawal syndrome	2	0	1
Hepatobiliary disorders	Hepatitis cholestatic	1	0	1
	Jaundice	12	1	3
	Hepatic function abnormal	14	2	1
	Hepatomegaly	2	0	0
	Hepatic steatosis	1	0	0

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Hepatobiliary disorders	Hepatitis	2	0	1
Infections and infestations	Abscess	2	0	0
	Pneumonia	5	1	1
	Sepsis	2	1	0
	Pharyngitis	5	0	2
	Upper respiratory tract infection	1	0	0
	Urinary tract infection	1	0	0
	Injury, poisoning and procedural complications	Fall	2	0
Contusion		1	0	1
Sunburn		1	0	1
Medication error		1	0	0
Overdose		2	0	0
Investigations	Ejection fraction decreased	1	0	0
	Electrocardiogram QT prolonged	2	1	0
	Electrocardiogram abnormal	1	0	1
	Blood prolactin increased	1	0	1
	Blood creatine phosphokinase increased	25	1	9
	Troponin increased	1	0	0
	Blood alkaline phosphatase increased	1	0	0
	Activated partial thromboplastin time prolonged	1	0	1
	Prothrombin level decreased	1	0	0
	Red blood cell sedimentation rate increased	2	0	0
	Platelet aggregation abnormal	1	0	0
	Alanine aminotransferase increased	1	0	0
	Liver function test abnormal	2	0	0
	Antiphospholipid antibodies positive	1	0	1
	Weight decreased	4	0	0
	Weight increased	3	0	2
	Metabolism and nutrition disorders	Anorexia	6	3
Tetany		1	0	0
Hypomagnesaemia		1	1	0
Hypochloraemia		1	1	0
Hypokalaemia		1	0	0
Hypernatraemia		2	0	0
Hyponatraemia		11	1	3

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Metabolism and nutrition disorders	Dehydration	7	2	0
	Hyperglycaemia	1	1	0
	Hypoglycaemia	2	0	1
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	1	0	1
	Myalgia	2	0	2
	Muscle spasms	2	0	1
	Muscle twitching	8	0	6
	Muscle rigidity	4	0	2
	Torticollis	8	0	5
	Trismus	1	0	0
	Myopathy	1	0	1
	Rhabdomyolysis	1	0	0
	Back pain	3	0	3
	Musculoskeletal stiffness	6	0	4
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	1	0
Hepatic neoplasm malignant		1	0	0
Malignant melanoma		1	0	0
Nervous system disorders	Cerebral infarction	1	0	1
	Tongue paralysis	1	0	0
	Encephalopathy	1	0	0
	Headache	10	0	6
	Dementia	2	0	1
	Amnesia	1	0	1
	Choreoathetosis	6	0	5
	Akathisia	2	0	1
	Bradykinesia	4	0	1
	Dyskinesia	23	0	11
	Extrapyramidal disorder	90	1	55
	Hyperkinesia	18	0	9
	Hypokinesia	5	0	3
	Movement disorder	1	0	1
	Tardive dyskinesia	18	0	4
	Dystonia	154	0	101
	Opisthotonus	8	0	5
Paresis	1	0	0	

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Nervous system disorders	Cogwheel rigidity	3	0	2
	Parkinsonism	4	0	4
	Tremor	39	0	19
	Hyperreflexia	5	1	1
	Hyporeflexia	2	0	2
	Coordination abnormal	7	0	3
	Nystagmus	1	0	0
	Coma	13	1	6
	Aphasia	2	0	1
	Altered state of consciousness	1	0	0
	Consciousness fluctuating	8	2	1
	Depressed level of consciousness	2	0	1
	Lethargy	1	0	0
	Sedation	2	0	1
	Somnolence	30	2	10
	Stupor	1	0	0
	Syncope	9	1	1
	Dizziness	10	0	6
	Drooling	1	0	1
	Myoclonus	1	0	0
	Unresponsive to stimuli	1	0	1
	Formication	1	0	1
	Hypoaesthesia	1	0	1
	Paraesthesia	3	0	1
	Dysarthria	5	0	1
	Speech disorder	13	0	7
	Upper motor neurone lesion	1	1	0
	Hypertonia	59	5	29
	Hypotonia	3	1	1
	Neuroleptic malignant syndrome	65	4	22
	Serotonin syndrome	1	0	0
	Muscle contractions involuntary	1	0	1
	Neuritis	1	0	1
	Neuropathy peripheral	1	0	0
	Grand mal convulsion	9	0	1



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Nervous system disorders	Convulsion	20	2	7
	Convulsions local	1	0	0
	Sleep talking	1	0	0
	Brain damage	1	1	1
Pregnancy, puerperium and perinatal conditions	Small for dates baby	1	0	0
	Jaundice neonatal	1	0	0
Psychiatric disorders	Agitation	27	3	13
	Anxiety	10	0	7
	Nervousness	1	0	0
	Tension	1	0	0
	Catatonia	5	0	3
	Restlessness	1	0	1
	Bruxism	1	0	0
	Mutism	1	0	0
	Confusional state	48	2	18
	Disorientation	1	0	0
	Delirium	7	0	0
	Depression	1	0	0
	Depressive symptom	1	0	0
	Delusion	2	0	0
	Hallucination	8	0	2
	Thinking abnormal	5	0	1
	Mania	3	0	0
	Euphoric mood	1	0	0
	Frustration	1	0	0
	Apathy	1	0	0
	Aggression	5	0	2
	Homicidal ideation	1	0	0
	Paranoia	3	0	1
	Personality disorder	1	0	0
	Psychotic disorder	2	0	0
	Insomnia	9	0	2
	Sleep disorder	2	0	2
	Suicidal ideation	2	0	0
Suicide attempt	2	0	0	

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Renal and urinary disorders	Anuria	1	0	0
	Renal failure acute	2	1	0
	Renal impairment	2	0	0
	Dysuria	2	1	0
	Incontinence	1	0	0
	Urinary incontinence	8	1	5
	Urinary retention	5	0	2
Reproductive system and breast disorders	Galactorrhoea	3	0	2
	Ejaculation failure	2	0	1
	Priapism	1	0	1
	Infertility female	2	0	2
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	1	0
	Apnoea	1	1	1
	Dyspnoea	13	2	7
	Hyperventilation	4	1	2
	Respiratory arrest	3	0	0
	Respiratory depression	3	0	1
	Respiratory distress	1	0	0
	Hypoxia	1	0	0
	Productive cough	4	1	0
	Respiratory failure	1	0	0
	Respiratory disorder	5	0	1
	Choking	1	0	1
	Dysphonia	1	0	1
	Laryngospasm	7	1	7
	Stridor	2	0	1
	Epistaxis	1	0	0
	Skin and subcutaneous tissue disorders	Angioedema	5	0
Periorbital oedema		1	1	0
Urticaria		6	1	1
Dermatitis bullous		1	0	0
Stevens-Johnson syndrome		1	0	0
Toxic epidermal necrolysis		2	0	0
Rash erythematous		8	0	0
Skin exfoliation		2	0	1

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Skin and subcutaneous tissue disorders	Photosensitivity reaction	3	0	1
	Pruritus	7	0	5
	Psoriasis	1	0	0
	Rash	15	0	6
	Rash maculo-papular	15	0	2
	Rash morbilliform	1	0	0
	Melanodermia	1	0	0
	Acne	1	0	0
	Alopecia	4	0	2
	Cold sweat	2	0	1
	Hyperhidrosis	17	0	5
	Hair colour changes	1	0	1
	Purpura	2	0	0
	Social circumstances	Treatment noncompliance	1	0
Surgical and medical procedures	Therapy regimen changed	4	0	2
Vascular disorders	Peripheral ischaemia	1	0	0
	Blood pressure fluctuation	2	0	0
	Hypotension	21	2	0
	Orthostatic hypotension	5	0	0
	Embolism	1	0	0
	Vasodilatation	1	0	0
	Flushing	1	0	0
	Pallor	2	0	1
	Hypertension	8	0	3