

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

RISPERIDONE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		849	27	554
- Occurrences of Medicine		887	30	554
- Reactions Related to Medicine		1935	60	1182
Blood and lymphatic system disorders	Agranulocytosis	4	0	2
	Anaemia	6	0	3
	Eosinophilia	3	0	1
	Febrile neutropenia	1	0	1
	Leukocytosis	8	0	5
	Leukopenia	6	1	2
	Lymphadenopathy	2	0	0
	Lymphopenia	1	0	0
	Neutropenia	15	0	11
	Pancytopenia	6	0	3
	Thrombocythaemia	1	0	0
Thrombocytopenia	5	0	3	
Cardiac disorders	Angina pectoris	1	0	1
	Arrhythmia	4	0	3
	Atrial fibrillation	1	1	0
	Atrioventricular block	1	0	0
	Bradycardia	4	0	1
	Cardiac arrest	3	2	2
	Cardiac failure	1	0	1
	Cardiac failure congestive	1	1	1
	Cardiomegaly	1	1	0
	Cardiomyopathy	2	0	0
	Left ventricular failure	1	1	0
	Myocardial infarction	3	1	3
	Myocarditis	3	0	0
	Palpitations	2	0	2
	Pericarditis	2	0	2
Supraventricular tachycardia	4	0	2	



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Cardiac disorders	Tachycardia	13	0	9
Congenital, familial and genetic disorders	Cleft palate	2	0	2
	Deafness congenital	1	0	0
	Tourette's disorder	1	0	1
Ear and labyrinth disorders	Hyperacusis	1	0	1
Endocrine disorders	Diabetes insipidus	1	0	0
	Goitre	1	0	0
	Hyperprolactinaemia	47	0	38
	Hyperthyroidism	1	0	1
	Hypothyroidism	1	0	0
	Inappropriate antidiuretic hormone secretior	1	0	1
Eye disorders	Blepharospasm	3	0	3
	Conjunctivitis	1	0	0
	Diplopia	1	0	0
	Eye oedema	1	0	1
	Eye pain	1	0	1
	Eyelid oedema	1	0	1
	Eyelid ptosis	1	0	1
	Lacrimation increased	1	0	1
	Macular degeneration	1	0	0
	Myopia	1	0	1
	Ocular hyperaemia	1	0	1
	Oculogyration	7	0	3
	Papilloedema	1	0	0
	Retinal disorder	1	0	0
	Retinal haemorrhage	1	0	0
	Retinopathy	1	0	1
	Vision blurred	7	0	6
	Visual acuity reduced	1	0	1
	Visual disturbance	3	0	3
	Gastrointestinal disorders	Abdominal pain	6	0
Abdominal pain upper		2	0	2
Breath odour		1	0	1
Constipation		8	0	5
Dry mouth		5	0	2

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Gastrointestinal disorders	Duodenal ulcer haemorrhage	1	0	0
	Dysphagia	14	0	8
	Faecal incontinence	3	0	2
	Flatulence	1	0	1
	Gastrointestinal disorder	2	0	2
	Gingivitis	1	0	1
	Haematemesis	1	0	0
	Intestinal obstruction	2	0	0
	Lip oedema	2	0	2
	Lip swelling	1	0	1
	Nausea	10	0	6
	Pancreatitis	2	0	1
	Retroperitoneal fibrosis	1	0	1
	Saliva altered	1	0	0
	Salivary hypersecretion	13	0	7
	Swollen tongue	4	0	4
	Thrombosis mesenteric vessel	1	0	1
	Tongue oedema	6	0	5
	Tongue spasm	2	0	2
	Vomiting	11	0	7
General disorders and administration site conditions	Asthenia	5	0	5
	Chest discomfort	2	0	2
	Chest pain	4	0	2
	Chills	3	0	2
	Condition aggravated	1	0	1
	Death	5	4	5
	Drug ineffective	10	0	8
	Drug interaction	2	0	0
	Drug withdrawal syndrome	6	0	6
	Drug withdrawal syndrome neonatal	3	0	0
	Face oedema	11	0	5
	Fatigue	11	0	9
	Feeling abnormal	4	0	3
	Feeling jittery	2	0	0
	Food interaction	1	0	1

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General disorders and administration site conditions	Gait disturbance	9	0	8
	Gravitational oedema	3	0	0
	Hyperthermia malignant	2	0	1
	Hypothermia	3	0	2
	Influenza like illness	6	0	2
	Injection site haemorrhage	1	0	1
	Irritability	1	0	1
	Malaise	7	0	3
	Mucosal inflammation	1	0	0
	Oedema	4	0	1
	Oedema peripheral	7	0	7
	Pain	1	0	1
	Pyrexia	35	1	11
	Sudden death	4	4	3
	Therapeutic response decreased	2	0	1
Thirst	3	0	2	
Hepatobiliary disorders	Bile duct obstruction	1	0	0
	Gallbladder disorder	1	0	1
	Hepatic function abnormal	25	1	11
	Hepatic steatosis	1	1	0
	Hepatitis	5	0	0
	Hepatitis cholestatic	1	0	1
	Hepatomegaly	1	0	0
	Jaundice	2	0	1
Immune system disorders	Anaphylactoid reaction	1	0	1
	Hypersensitivity	3	0	3
Infections and infestations	Abscess	2	0	0
	Cellulitis	1	0	1
	Herpes zoster	1	0	1
	Infection	3	0	3
	Lower respiratory tract infection	1	0	1
	Mastitis	1	0	1
	Pharyngitis	3	0	2
	Pneumonia	3	2	0
	Rhinitis	2	0	1

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Infections and infestations	Sepsis	3	1	0
Injury, poisoning and procedural complications	Drug administration error	1	0	1
	Drug exposure during pregnancy	4	0	4
	Drug toxicity	1	1	0
	Fall	9	1	7
	Incorrect dose administered	1	1	0
	Intentional drug misuse	1	0	1
	Intentional overdose	1	0	0
	Medication error	3	0	2
	Muscle injury	1	0	1
	Overdose	3	0	3
	Subdural haematoma	1	0	1
	Tendon injury	1	0	1
	Therapeutic agent toxicity	1	0	0
	Investigations	Alanine aminotransferase increased	2	0
Antiphospholipid antibodies positive		1	0	1
Aspartate aminotransferase increased		1	0	0
Blood creatine phosphokinase increased		42	2	22
Blood glucose fluctuation		1	0	1
Blood glucose increased		1	0	1
Blood lactate dehydrogenase increased		1	0	1
Blood pressure decreased		1	0	1
Blood prolactin increased		15	0	14
Blood testosterone decreased		1	0	1
Blood testosterone increased		1	0	0
Blood triglycerides increased		1	0	1
Drug level above therapeutic		1	0	0
Drug level increased		2	1	0
Ejection fraction decreased		1	0	0
Electrocardiogram QT prolonged		3	0	2
Electrocardiogram T wave inversion		1	0	1
Electroencephalogram abnormal		1	0	1
Heart rate abnormal		1	0	1
Hepatic enzyme increased		2	0	0
Liver function test abnormal	4	0	1	

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Investigations	Oxygen saturation decreased	1	0	0
	Prothrombin level increased	1	0	0
	Red blood cell sedimentation rate increased	2	0	0
	Troponin increased	1	0	0
	Weight decreased	4	0	0
	Weight increased	37	0	28
Metabolism and nutrition disorders	Anorexia	6	0	4
	Dehydration	2	0	1
	Diabetes mellitus	9	0	6
	Diabetes mellitus non-insulin-dependent	1	0	0
	Diabetic ketoacidosis	1	0	0
	Gestational diabetes	1	0	1
	Glucose tolerance impaired	1	0	1
	Hypercalcaemia	1	1	0
	Hyperglycaemia	3	0	0
	Hyperkalaemia	1	0	1
	Hypernatraemia	1	0	0
	Hyperproteinaemia	1	0	1
	Hypertriglyceridaemia	1	0	1
	Hypochloraemia	1	1	0
	Hypoglycaemia	2	0	0
	Hypokalaemia	1	0	0
	Hypomagnesaemia	1	1	0
	Hyponatraemia	11	1	4
	Hypoproteinaemia	2	0	1
	Increased appetite	7	0	6
Metabolic acidosis	1	0	0	
Obesity	1	0	1	
Polydipsia	4	0	2	
Vitamin B12 deficiency	1	0	1	
Musculoskeletal and connective tissue disorders	Arthralgia	1	0	0
	Arthritis	1	0	0
	Jaw disorder	1	0	1
	Joint stiffness	3	0	2
	Mobility decreased	5	0	3

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Musculoskeletal and connective tissue disorders	Muscle contracture	1	0	1
	Muscle disorder	1	0	1
	Muscle rigidity	11	0	7
	Muscle spasms	3	0	3
	Muscle twitching	4	0	3
	Muscular weakness	2	0	2
	Musculoskeletal stiffness	12	0	4
	Myalgia	6	0	1
	Myopathy	2	0	0
	Myositis	1	0	1
	Nuchal rigidity	1	0	1
	Pain in extremity	1	0	0
	Posture abnormal	1	0	1
	Rhabdomyolysis	2	0	1
	Rheumatoid arthritis	1	0	1
	Synostosis	1	0	1
	Torticollis	3	0	2
Trismus	1	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	6	0	6
	Breast cancer male	1	0	1
	Hairy cell leukaemia	1	0	0
	Lip neoplasm	1	0	0
	Metastases to lung	1	0	1
	Pituitary tumour	1	0	0
	Pituitary tumour benign	2	0	2
	Squamous cell carcinoma	1	0	0
Nervous system disorders	Ageusia	1	0	1
	Akathisia	23	0	14
	Amnesia	7	0	7
	Aphasia	2	0	1
	Balance disorder	3	0	3
	Bradykinesia	1	0	0
	Cerebrovascular accident	9	3	8
	Cerebrovascular disorder	2	0	1
	Choreoathetosis	1	0	1

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Nervous system disorders	Clonus	2	0	0
	Cogwheel rigidity	5	0	3
	Coma	2	0	0
	Consciousness fluctuating	11	1	8
	Convulsion	23	1	13
	Coordination abnormal	7	0	5
	Cranial nerve disorder	1	0	1
	Dementia	1	0	0
	Depressed level of consciousness	1	0	0
	Disturbance in attention	1	0	0
	Dizziness	20	0	12
	Drooling	3	0	2
	Drop attacks	1	0	1
	Dysarthria	11	0	6
	Dyskinesia	15	0	11
	Dysphasia	1	0	1
	Dystonia	45	0	26
	Encephalopathy	1	0	0
	Extrapyramidal disorder	39	0	29
	Grand mal convulsion	5	0	4
	Headache	18	0	11
	Hyperkinesia	13	0	9
	Hyperreflexia	2	0	0
	Hypertonia	33	2	13
	Hypoaesthesia	3	0	2
	Hypokinesia	3	0	2
	Hyporeflexia	1	0	0
	Hypotonia	1	0	1
	Intracranial pressure increased	2	0	1
	Lethargy	5	0	3
	Loss of consciousness	1	0	1
	Masked facies	1	0	1
	Mastication disorder	1	0	0
	Meningism	1	0	1
Migraine	2	0	2	

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Nervous system disorders	Migraine with aura	1	0	1
	Movement disorder	1	0	0
	Myoclonus	3	0	1
	Neuroleptic malignant syndrome	45	2	22
	Neuropathy peripheral	2	0	0
	Opisthotonus	3	0	2
	Paraesthesia	1	0	1
	Parkinsonism	7	1	3
	Partial seizures with secondary generalisati	1	0	1
	Restless legs syndrome	1	0	1
	Sedation	7	1	4
	Sensory disturbance	2	0	2
	Serotonin syndrome	1	0	0
	Simple partial seizures	1	0	1
	Sleep phase rhythm disturbance	1	0	0
	Somnolence	15	0	10
	Speech disorder	7	0	4
	Stupor	2	1	1
	Syncope	4	0	4
	Tardive dyskinesia	32	0	25
Tongue paralysis	2	0	2	
Tremor	25	0	12	
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	3	0	1
	Foetal movements decreased	1	0	0
	Neonatal disorder	1	0	0
	Premature baby	2	0	0
	Small for dates baby	1	0	0
Psychiatric disorders	Abnormal behaviour	2	1	0
	Affect lability	2	0	1
	Aggression	15	0	10
	Agitation	23	1	13
	Alcoholism	1	0	1
	Anger	2	0	1
	Anxiety	13	0	10
	Apathy	1	0	1

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Psychiatric disorders	Catatonia	3	0	2
	Completed suicide	5	5	3
	Confusional state	27	1	13
	Delirium	6	0	2
	Delusion	6	0	6
	Depersonalisation	3	0	2
	Depressed mood	2	0	1
	Depression	7	0	5
	Depressive symptom	1	0	0
	Disinhibition	1	0	0
	Dysphemia	1	0	1
	Elevated mood	1	0	0
	Euphoric mood	1	0	1
	Flat affect	2	0	2
	Frustration	1	0	0
	Hallucination	12	0	8
	Hallucination, visual	1	0	1
	Homicidal ideation	5	0	1
	Hypomania	1	0	0
	Insomnia	13	0	9
	Libido decreased	1	0	1
	Loss of libido	2	0	2
	Mania	2	0	0
	Mental disorder	2	0	0
	Mutism	1	0	0
	Nervousness	1	0	1
	Neurosis	1	0	1
	Obsessive-compulsive disorder	2	0	2
	Paranoia	2	0	2
	Psychotic disorder	10	0	6
	Restlessness	8	0	7
	Schizophrenia	1	0	1
	Self injurious behaviour	1	0	1
	Social avoidant behaviour	1	0	1
Staring	1	0	0	



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Psychiatric disorders	Suicidal ideation	14	0	8
	Suicide attempt	7	0	2
	Thinking abnormal	6	0	3
	Tic	2	0	2
	Violent ideation	1	0	0
Renal and urinary disorders	Dysuria	1	0	1
	Glycosuria	1	0	1
	Incontinence	1	0	0
	Ketonuria	1	0	1
	Micturition disorder	1	0	0
	Myoglobinuria	1	0	0
	Nephritis interstitial	1	0	0
	Nephrolithiasis	1	0	1
	Pollakiuria	1	0	0
	Polyuria	2	0	1
	Renal failure acute	4	0	1
	Renal impairment	5	1	3
	Urinary incontinence	13	0	8
	Urinary retention	3	0	2
Reproductive system and breast disorders	Amenorrhoea	22	0	18
	Breast discharge	1	0	1
	Breast engorgement	1	0	1
	Breast enlargement	4	0	2
	Breast mass	1	0	1
	Breast pain	5	0	3
	Breast tenderness	1	0	1
	Ejaculation failure	8	0	8
	Erectile dysfunction	4	0	4
	Galactorrhoea	34	0	27
	Genital ulceration	1	0	0
	Gynaecomastia	7	0	6
	Menorrhagia	1	0	1
	Menstrual disorder	4	0	4
	Menstruation irregular	2	0	1
	Metrorrhagia	1	0	1

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Reproductive system and breast disorders	Nipple exudate bloody	1	0	1
	Oedema genital	1	0	1
	Polycystic ovaries	1	0	0
	Priapism	8	0	8
	Sexual dysfunction	1	0	1
	Testicular disorder	2	0	1
Respiratory, thoracic and mediastinal disorders	Apnoea	1	0	0
	Bronchospasm	2	0	1
	Choking	2	0	1
	Dyspnoea	20	0	13
	Epistaxis	5	0	5
	Hyperventilation	1	0	1
	Hypoventilation	2	0	1
	Pharyngeal oedema	1	0	1
	Pharyngolaryngeal pain	2	0	1
	Pneumonia aspiration	1	0	0
	Pulmonary embolism	2	0	2
	Pulmonary oedema	2	2	1
	Respiratory arrest	1	0	0
	Respiratory depression	4	0	1
	Respiratory disorder	1	0	1
	Respiratory distress	1	0	0
	Respiratory failure	2	2	1
	Stridor	1	0	1
	Tachypnoea	1	0	1
	Throat tightness	2	0	2
Wheezing	1	0	1	
Skin and subcutaneous tissue disorders	Alopecia	5	0	4
	Angioedema	7	0	5
	Cold sweat	1	0	0
	Dermatitis	1	0	1
	Dermatitis bullous	1	0	1
	Dry skin	1	0	1
	Eczema	1	0	1
	Erythema	3	0	1

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Skin and subcutaneous tissue disorders	Erythema multiforme	1	0	0
	Hair texture abnormal	1	0	0
	Hirsutism	1	0	0
	Hyperhidrosis	6	0	2
	Hypertrichosis	1	0	0
	Lichenoid keratosis	1	0	1
	Livedo reticularis	1	0	1
	Periorbital oedema	6	0	4
	Photosensitivity reaction	1	0	0
	Pruritus	15	0	10
	Psoriasis	2	0	1
	Purpura	2	0	0
	Rash	23	0	14
	Rash erythematous	4	0	4
	Rash macular	1	0	0
	Rash maculo-papular	4	0	3
	Rash papular	1	0	1
	Rash pruritic	2	0	0
	Seborrhoea	1	0	1
	Skin discolouration	1	0	1
	Skin disorder	1	0	0
	Skin exfoliation	4	0	2
	Skin hyperpigmentation	1	0	0
	Skin hypopigmentation	1	0	1
	Skin odour abnormal	1	0	0
	Swelling face	4	0	3
Urticaria	11	0	8	
Social circumstances	Treatment noncompliance	1	0	0
Surgical and medical procedures	Prescribed overdose	2	1	1
	Therapy regimen changed	16	0	8
Vascular disorders	Blood pressure fluctuation	1	0	0
	Circulatory collapse	7	1	6
	Deep vein thrombosis	2	0	2
	Flushing	5	0	3
	Hot flush	2	0	2



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Vascular disorders	Hypertension	3	0	1
	Hypotension	16	0	8
	Infarction	1	0	1
	Orthostatic hypotension	15	1	12
	Pallor	1	0	1