

## THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

THIORIDAZINE HYDROCHLORIDE		Layer 1 of 1		
		<b>ALL REPORT DATES</b>		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
<b>- Cases Including Medicine</b>		538	23	236
<b>- Occurrences of Medicine</b>		569	26	236
<b>- Reactions Related to Medicine</b>		1136	56	444
Blood and lymphatic system disorders	Agranulocytosis	6	0	3
	Anaemia	2	1	0
	Aplastic anaemia	3	0	0
	Bone marrow failure	2	0	0
	Haemolytic anaemia	1	0	0
	Leukocytosis	6	0	1
	Leukopenia	5	0	2
	Lymphadenopathy	1	0	0
	Lymphopenia	2	0	0
	Neutropenia	15	2	3
	Pancytopenia	2	0	0
Thrombocytopenia	6	1	1	
Cardiac disorders	Arrhythmia	3	2	2
	Atrioventricular block	1	0	0
	Bradycardia	4	0	1
	Cardiac arrest	5	3	1
	Cardiac failure	1	1	0
	Cardiomyopathy	1	1	0
	Cyanosis	2	0	2
	Extrasystoles	1	0	0
	Myocardial infarction	1	1	0
	Right ventricular failure	1	0	0
	Tachycardia	6	0	4
	Torsade de pointes	3	0	1
	Ventricular arrhythmia	1	1	1
	Ventricular fibrillation	2	1	1
Ventricular tachycardia	3	0	2	
Congenital, familial and genetic disorders	Anal atresia	1	0	0

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Congenital, familial and genetic disorders	Congenital foot malformation	1	0	0
	Congenital genitourinary abnormality	1	0	1
	Congenital musculoskeletal anomaly	1	0	0
	Ear malformation	1	0	1
	Gastrointestinal malformation	1	0	1
	Multiple congenital abnormalities	2	0	0
	Oesophageal atresia	1	0	0
	Skull malformation	1	0	0
	Syndactyly	1	0	0
	Talipes	2	0	1
Ear and labyrinth disorders	Vertigo	1	0	1
Endocrine disorders	Hyperprolactinaemia	2	0	1
	Hyperthyroidism	1	0	0
	Hypothyroidism	1	0	0
Eye disorders	Accommodation disorder	1	0	1
	Cataract	3	0	1
	Cataract subcapsular	1	0	0
	Chorioretinal atrophy	1	0	1
	Diplopia	1	0	1
	Lens disorder	1	0	1
	Mydriasis	1	0	0
	Night blindness	1	0	1
	Oculogyration	2	0	2
	Ophthalmoplegia	1	0	1
	Photophobia	1	0	0
	Pupillary reflex impaired	1	0	1
	Retinal depigmentation	1	0	1
	Retinal disorder	1	0	0
	Retinal pigmentation	5	0	3
	Retinopathy	1	0	1
	Visual acuity reduced	1	0	1
Visual disturbance	7	0	4	
Vitreous floaters	1	0	1	
Gastrointestinal disorders	Abdominal pain	5	1	3
	Cheilitis	1	0	0

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Gastrointestinal disorders	Constipation	10	0	1
	Diarrhoea	3	0	1
	Dry mouth	13	0	9
	Duodenal ulcer	1	0	0
	Dyspepsia	4	0	2
	Dysphagia	5	0	2
	Faecal incontinence	1	0	1
	Gastric ulcer haemorrhage	1	0	0
	Gastritis	1	1	0
	Gastrointestinal haemorrhage	1	0	1
	Haematemesis	2	0	0
	Ileus paralytic	2	1	1
	Intestinal obstruction	1	0	0
	Melaena	2	0	0
	Mouth ulceration	2	0	0
	Nausea	13	0	4
	Oesophagitis ulcerative	1	0	0
	Saliva altered	1	0	0
	Salivary gland enlargement	1	0	0
	Salivary hypersecretion	1	0	1
	Stomatitis	1	0	1
	Tongue oedema	3	0	0
	Tongue ulceration	1	0	0
Vomiting	6	0	1	
General disorders and administration site conditions	Application site reaction	1	0	1
	Asthenia	3	0	1
	Chest pain	3	0	0
	Chills	4	1	1
	Death	1	1	1
	Drug ineffective	4	0	2
	Drug withdrawal syndrome	7	0	7
	Fatigue	5	0	2
	Gait disturbance	4	0	0
	Generalised oedema	1	0	1
	Gravitational oedema	1	0	1

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General disorders and administration site conditions	Hyperpyrexia	1	0	0
	Hypothermia	1	0	1
	Malaise	5	0	1
	Oedema	2	0	1
	Oedema peripheral	2	0	1
	Pain	2	0	2
	Pyrexia	20	1	8
	Sudden death	9	9	2
	Sudden infant death syndrome	1	1	1
	Therapeutic response decreased	2	0	2
	Thirst	1	0	1
Hepatobiliary disorders	Hepatic cirrhosis	1	0	0
	Hepatic function abnormal	8	0	2
	Hepatitis	5	1	0
	Hepatitis cholestatic	1	0	1
	Jaundice	6	0	1
Immune system disorders	Hypersensitivity	1	0	0
Infections and infestations	Bronchitis	1	0	1
	Bronchopneumonia	1	0	1
	Herpes zoster	1	0	0
	Infection	2	0	1
	Pharyngitis	1	0	1
	Pneumonia	1	0	1
	Rhinitis	11	0	8
	Sepsis	1	0	0
	Urinary tract infection	2	0	0
Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	1	1
	Drug toxicity	1	1	0
	Medication error	1	0	1
	Overdose	1	1	0
Investigations	Blood alkaline phosphatase increased	2	0	1
	Blood creatine phosphokinase increased	11	0	6
	Drug level increased	4	0	0
	Electrocardiogram abnormal	6	1	1
	Electrocardiogram QT prolonged	3	1	1

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Investigations	Prothrombin level decreased	2	0	0
	Red blood cell sedimentation rate increased	1	0	1
	Semen abnormal	1	0	0
	Urine analysis abnormal	1	0	0
	Weight decreased	2	0	1
	Weight increased	12	0	8
Metabolism and nutrition disorders	Anorexia	1	0	0
	Diabetes mellitus	1	0	0
	Hyperglycaemia	3	0	3
	Hyperkalaemia	1	0	1
	Hypokalaemia	4	1	1
	Hyponatraemia	12	0	3
	Ketoacidosis	1	0	1
	Metabolic acidosis	1	0	1
	Polydipsia	2	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	1	0	0
	Joint stiffness	1	0	1
	Muscle rigidity	1	0	1
	Muscle spasms	1	0	0
	Muscle twitching	2	0	1
	Musculoskeletal stiffness	3	0	1
	Myalgia	3	0	0
	Systemic lupus erythematosus	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign hepatic neoplasm	1	0	0
	Pseudolymphoma	1	0	0
Nervous system disorders	Akathisia	2	0	1
	Aphasia	2	0	1
	Cerebrovascular disorder	1	0	0
	Choreoathetosis	2	0	0
	Clonus	1	0	0
	Coma	5	1	1
	Consciousness fluctuating	3	0	2
	Convulsion	5	0	3
	Coordination abnormal	10	1	3
	Dementia	2	0	0

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Nervous system disorders	Disturbance in attention	3	0	1
	Dizziness	15	0	3
	Drooling	1	0	1
	Dysarthria	7	0	4
	Dysgeusia	1	0	0
	Dyskinesia	16	0	9
	Dystonia	30	0	13
	Encephalopathy	2	0	0
	Extrapyramidal disorder	32	0	13
	Grand mal convulsion	3	0	1
	Headache	10	1	2
	Hyperaesthesia	1	0	1
	Hyperkinesia	13	0	6
	Hyperreflexia	2	0	0
	Hypertonia	24	0	11
	Hypoaesthesia	1	0	1
	Hypokinesia	2	1	0
	Hypotonia	1	0	0
	Incoherent	1	0	0
	Nervous system disorder	1	0	0
	Neuralgia	1	0	1
	Neuroleptic malignant syndrome	23	1	9
	Optic neuritis	1	0	1
	Paraesthesia	6	0	1
	Serotonin syndrome	2	0	0
	Somnolence	18	1	7
	Speech disorder	11	0	5
	Stupor	1	0	0
	Syncope	11	0	5
	Tardive dyskinesia	18	0	10
	Tongue paralysis	1	0	1
Tremor	25	1	7	
Visual field defect	1	0	1	
Pregnancy, puerperium and perinatal conditions	Neonatal disorder	1	0	0
	Premature baby	1	0	0

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Pregnancy, puerperium and perinatal condi	Stillbirth	1	0	1
Psychiatric disorders	Abnormal behaviour	1	0	0
	Aggression	6	0	1
	Agitation	18	0	3
	Anxiety	8	0	4
	Bruxism	1	0	0
	Catatonia	2	0	0
	Completed suicide	1	1	0
	Confusional state	33	0	4
	Delirium	5	0	0
	Delusion	1	0	0
	Depersonalisation	1	0	0
	Depression	2	0	0
	Euphoric mood	1	0	1
	Hallucination	18	0	4
	Insomnia	6	0	3
	Libido decreased	5	0	1
	Mania	2	0	0
	Nervousness	2	0	0
	Neurosis	2	0	2
	Nightmare	1	0	1
Paranoia	1	0	0	
Psychotic disorder	4	0	1	
Regressive behaviour	1	0	1	
Suicide attempt	1	0	1	
Thinking abnormal	6	0	3	
Renal and urinary disorders	Dysuria	1	0	1
	Micturition disorder	5	0	3
	Nocturia	1	0	1
	Pollakiuria	1	0	0
	Polyuria	3	0	2
	Renal failure acute	2	0	0
	Renal impairment	3	0	1
	Urinary incontinence	7	0	6
Urinary retention	6	0	0	

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Reproductive system and breast disorders	Amenorrhoea	5	0	4
	Breast cyst	1	0	0
	Breast enlargement	1	0	1
	Breast pain	3	0	2
	Ejaculation failure	14	0	8
	Erectile dysfunction	5	0	2
	Galactorrhoea	14	0	10
	Gynaecomastia	2	0	1
	Menstrual disorder	1	0	1
	Priapism	3	0	2
Respiratory, thoracic and mediastinal disorders	Cough	2	1	0
	Dyspnoea	4	0	1
	Epistaxis	2	0	0
	Hypoventilation	1	0	1
	Hypoxia	1	0	1
	Pulmonary embolism	3	2	0
	Pulmonary fibrosis	1	0	0
	Pulmonary oedema	1	1	0
	Pulmonary thrombosis	1	1	0
	Respiratory disorder	1	0	0
	Respiratory failure	1	0	0
	Skin and subcutaneous tissue disorders	Alopecia	3	0
Angioedema		1	0	1
Cold sweat		1	0	1
Dermatitis bullous		3	0	1
Dermatitis exfoliative		1	0	0
Dermatitis psoriasiform		1	0	1
Dry skin		1	0	0
Erythema multiforme		1	0	0
Hirsutism		1	0	1
Hyperhidrosis		7	0	2
Leukocytoclastic vasculitis		1	0	1
Periorbital oedema		1	0	0
Photosensitivity reaction		7	1	2
Pruritus		18	0	8





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Skin and subcutaneous tissue disorders	Purpura	3	1	0
	Rash	13	0	5
	Rash erythematous	7	0	3
	Rash maculo-papular	14	1	5
	Rash pruritic	1	0	1
	Skin disorder	2	0	0
	Skin exfoliation	3	0	3
	Skin ulcer	3	0	0
	Systemic lupus erythematosus rash	2	1	1
	Urticaria	2	0	1
Surgical and medical procedures	Therapy regimen changed	1	0	0
Vascular disorders	Aneurysm	1	1	0
	Blood pressure fluctuation	1	0	0
	Deep vein thrombosis	1	0	0
	Flushing	1	0	1
	Hypertension	6	0	2
	Hypotension	24	0	14
	Orthostatic hypotension	21	0	11
	Pallor	1	0	0
	Shock	1	0	1
	Vasculitis	3	0	2