

Medicine summary - thioridazine (to end January 2009)

			Case Group	Death Outcomes	Sole	
Case Count			542	23	236	
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	1	0	
		Aplastic anaemia	3	0	0	
		Bone marrow failure	2	0	0	
		Pancytopenia	2	0	0	
		Haemolytic anaemia	1	0	0	
		Thrombocytopenia	6	1	1	
		Lymphadenopathy	1	0	0	
		Leukocytosis	6	0	1	
		Leukopenia	5	0	2	
		Lymphopenia	2	0	0	
		Agranulocytosis	6	0	3	
		Neutropenia	15	2	3	
		Blood and lymphatic system disorders		51	4	10
		Cardiac disorders	Atrioventricular block	1	0	0
	Arrhythmia		4	2	2	
	Bradycardia		4	0	1	
	Extrasystoles		1	0	0	
	Tachycardia		6	0	4	
	Cardiac arrest		5	3	1	
	Torsade de pointes		4	0	1	
	Ventricular arrhythmia		1	1	1	
	Ventricular fibrillation		2	1	1	
	Ventricular tachycardia		3	0	2	
	Cyanosis		2	0	2	
	Myocardial infarction		2	1	0	
	Cardiac failure		1	1	0	
	Right ventricular failure		1	0	0	
	Cardiomyopathy		1	1	0	
	Cardiac disorders		38	10	15	
	Congenital, familial and genetic disorders		Multiple congenital abnormalities	1	0	0
		Ear malformation	1	0	1	
		Anal atresia	1	0	0	
		Gastrointestinal malformation	1	0	1	
		Oesophageal atresia	1	0	0	
		Congenital foot malformation	1	0	0	
		Syndactyly	1	0	0	
		Talipes	2	0	1	
		Skull malformation	1	0	0	
		Congenital musculoskeletal anomaly	1	0	0	
		Congenital genitourinary abnormality	1	0	1	
	Congenital, familial and genetic disorders		12	0	4	

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			Case Group	Death Outcomes	Sole
Reaction Count	Ear and labyrinth disorders	Vertigo	1	0	1
		Ear and labyrinth disorders	1	0	1
	Endocrine disorders	Hyperprolactinaemia	2	0	1
		Hyperthyroidism	1	0	0
		Hypothyroidism	1	0	0
		Endocrine disorders	4	0	1
	Eye disorders	Cataract	3	0	1
		Cataract subcapsular	1	0	0
		Lens disorder	1	0	1
		Retinal disorder	1	0	0
		Oculogyric crisis	2	0	2
		Ophthalmoplegia	1	0	1
		Mydriasis	1	0	0
		Pupillary reflex impaired	1	0	1
		Photophobia	1	0	0
		Chorioretinal atrophy	1	0	1
		Myodesopsia	1	0	1
		Retinal depigmentation	1	0	1
		Retinal pigmentation	5	0	3
		Retinopathy	1	0	1
		Night blindness	1	0	1
		Visual acuity reduced	1	0	1
		Accommodation disorder	1	0	1
		Diplopia	1	0	1
		Visual impairment	7	0	4
		Eye disorders	32	0	21
		Gastrointestinal disorders	Gastrointestinal haemorrhage	1	0
	Haematemesis		2	0	0
	Melaena		2	0	0
	Gastritis		1	1	0
	Diarrhoea		3	0	1
	Constipation		9	0	1
	Ileus paralytic		2	1	1
Dyspepsia	4		0	2	
Abdominal pain	5		1	3	
Dysphagia	5		0	2	
Faecal incontinence	1		0	1	
Nausea	13		0	4	
Vomiting	6		0	1	
Intestinal obstruction	1		0	0	
Duodenal ulcer	1		0	0	
Gastric ulcer haemorrhage	1	0	0		

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Reaction Count	Gastrointestinal disorders	Oesophagitis ulcerative	1	0	0		
		Cheilitis	1	0	0		
		Mouth ulceration	2	0	0		
		Stomatitis	1	0	1		
		Dry mouth	13	0	9		
		Saliva altered	1	0	0		
		Salivary hypersecretion	1	0	1		
		Salivary gland enlargement	1	0	0		
		Tongue ulceration	1	0	0		
		Tongue oedema	3	0	0		
Gastrointestinal disorders			82	3	28		
Reaction Count	General disorders and administration site conditions	Application site reaction	1	0	1		
		Hypothermia	1	0	1		
		Hyperpyrexia	1	0	0		
		Pyrexia	20	1	8		
		Death	1	1	1		
		Sudden death	9	9	2		
		Sudden infant death syndrome	1	1	1		
		Asthenia	3	0	1		
		Fatigue	5	0	2		
		Malaise	5	0	1		
		Gait disturbance	4	0	0		
		Generalised oedema	1	0	1		
		Gravitational oedema	1	0	1		
		Oedema	2	0	1		
		Oedema peripheral	2	0	1		
		Chest pain	3	0	0		
		Pain	2	0	2		
		Chills	4	1	1		
		Thirst	1	0	1		
		Drug ineffective	4	0	2		
		Therapeutic response decreased	2	0	2		
		General disorders and administration site conditions			73	13	30
		Reaction Count	Hepatobiliary disorders	Hepatitis cholestatic	1	0	1
Jaundice	6			0	1		
Hepatic function abnormal	8			0	2		
Hepatic cirrhosis	1			0	0		
Hepatitis	5			1	0		
Hepatobiliary disorders	21			1	4		
Reaction Count	Immune system disorders	Hypersensitivity	1	0	0		
		Immune system disorders	1	0	0		

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		Case Group	Death Outcomes	Sole	
Reaction Count	Infections and infestations	Infection	2	0	1
		Bronchitis	1	0	1
		Bronchopneumonia	1	0	1
		Pneumonia	1	0	1
		Sepsis	1	0	0
		Pharyngitis	1	0	1
		Rhinitis	10	0	8
		Urinary tract infection	2	0	0
		Herpes zoster	1	0	0
		Infections and infestations	20	0	13
	Injury, poisoning and procedural complications	Drug toxicity	1	1	0
		Drug exposure during pregnancy	1	1	1
		Medication error	1	0	1
		Overdose	1	1	0
		Injury, poisoning and procedural complications	4	3	2
	Investigations	Electrocardiogram QT prolonged	3	1	1
		Electrocardiogram abnormal	6	1	1
		Blood creatine phosphokinase increased	11	0	6
		Blood alkaline phosphatase increased	2	0	1
		Prothrombin level decreased	2	0	0
		Red blood cell sedimentation rate increased	1	0	1
		Weight decreased	2	0	1
		Weight increased	12	0	8
		Urine analysis abnormal	1	0	0
		Semen analysis abnormal	1	0	0
		Drug level increased	4	0	0
		Investigations	45	2	19
	Metabolism and nutrition disorders	Ketoacidosis	1	0	1
		Metabolic acidosis	1	0	1
		Anorexia	1	0	0
		Polydipsia	2	0	1
		Hyperkalaemia	1	0	1
		Hypokalaemia	4	1	1
		Hyponatraemia	12	0	3
		Diabetes mellitus	1	0	0
		Hyperglycaemia	3	0	3
		Metabolism and nutrition disorders	26	1	11
	Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	1	1	0
		Arthralgia	1	0	0
		Joint stiffness	1	0	1
		Myalgia	3	0	0
		Muscle spasms	1	0	0

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Reaction Count	Musculoskeletal and connective tissue disorders	Muscle twitching	2	0	1
		Muscle rigidity	1	0	1
		Musculoskeletal stiffness	3	0	1
		Musculoskeletal and connective tissue disorders	13	1	4
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pseudolymphoma	1	0	0
		Benign hepatic neoplasm	1	0	0
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0	0
	Nervous system disorders	Cerebrovascular disorder	1	0	0
		Tongue paralysis	1	0	1
		Optic neuritis	1	0	1
		Encephalopathy	2	0	0
		Headache	10	1	2
		Dementia	2	0	0
		Disturbance in attention	3	0	1
		Choreoathetosis	2	0	0
		Akathisia	2	0	1
		Dyskinesia	16	0	9
		Extrapyramidal disorder	27	0	10
		Hyperkinesia	13	0	6
		Hypokinesia	2	1	0
		Tardive dyskinesia	18	0	10
		Dystonia	28	0	12
		Tremor	25	1	7
		Hyperreflexia	2	0	0
		Ataxia	7	1	1
		Coordination abnormal	3	0	2
		Coma	5	1	1
		Aphasia	2	0	1
		Consciousness fluctuating	3	0	2
		Somnolence	18	1	7
		Stupor	1	0	0
		Syncope	11	0	5
		Nervous system disorder	1	0	0
Clonus		1	0	0	
Dizziness		15	0	3	
Drooling		1	0	1	
Hyperaesthesia		1	0	1	
Paraesthesia	5	0	1		
Dysgeusia	1	0	0		
Hypoaesthesia	1	0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Neuralgia	1	0	1
		Dysarthria	7	0	4
		Incoherent	1	0	0
		Speech disorder	11	0	5
		Visual field defect	1	0	1
		Hypertonia	23	0	11
		Hypotonia	1	0	0
		Neuroleptic malignant syndrome	25	1	9
		Serotonin syndrome	2	0	0
		Grand mal convulsion	3	0	1
		Convulsion	5	0	3
		Nervous system disorders	311	7	121
		Pregnancy, puerperium and perinatal conditions	Stillbirth	1	0
	Premature baby		1	0	0
	Neonatal disorder		1	0	0
	Pregnancy, puerperium and perinatal conditions		3	0	1
	Psychiatric disorders	Agitation	17	0	3
		Anxiety	8	0	4
		Nervousness	2	0	0
		Neurosis	2	0	2
		Catatonia	2	0	0
		Bruxism	1	0	0
		Confusional state	30	0	4
		Delirium	5	0	0
		Depression	2	0	0
		Depersonalisation	1	0	0
		Delusion	1	0	0
		Hallucination	16	0	4
		Thinking abnormal	6	0	3
		Mania	2	0	0
		Euphoric mood	1	0	1
		Aggression	6	0	1
		Paranoia	1	0	0
		Abnormal behaviour	1	0	0
Regressive behaviour		1	0	1	
Withdrawal syndrome		7	0	7	
Psychotic disorder		4	0	1	
Libido decreased		5	0	1	
Insomnia		6	0	3	
Nightmare	1	0	1		
Completed suicide	1	1	0		

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Reaction Count	Psychiatric disorders	Suicide attempt	1	0	1
		Psychiatric disorders	130	1	37
	Renal and urinary disorders	Renal failure acute	2	0	0
		Renal impairment	3	0	1
		Dysuria	1	0	1
		Micturition disorder	3	0	2
		Pollakiuria	1	0	0
		Urinary incontinence	7	0	6
		Urinary retention	6	0	0
		Nocturia	1	0	1
		Polyuria	3	0	2
		Renal and urinary disorders	27	0	13
		Reproductive system and breast disorders	Breast cyst	1	0
	Breast enlargement		1	0	1
	Gynaecomastia		2	0	1
	Breast pain		3	0	2
	Galactorrhoea		14	0	10
	Menstrual disorder		1	0	1
	Amenorrhoea		5	0	4
	Ejaculation failure		14	0	8
	Erectile dysfunction		5	0	2
	Priapism		3	0	2
	Reproductive system and breast disorders		49	0	31
	Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	1	0	0
		Pulmonary oedema	1	1	0
		Pulmonary embolism	2	1	0
		Pulmonary thrombosis	1	1	0
		Dyspnoea	4	0	1
		Hypoventilation	1	0	1
		Hypoxia	1	0	1
		Cough	2	1	0
		Respiratory failure	1	0	0
		Respiratory disorder	1	0	0
		Epistaxis	2	0	0
		Respiratory, thoracic and mediastinal disorders	17	4	3
		Skin and subcutaneous tissue disorders	Angioedema	1	0
	Periorbital oedema		1	0	0
	Urticaria		2	0	1
	Dermatitis bullous		3	0	1
	Erythema multiforme		1	0	0
	Dry skin		1	0	0
	Skin disorder		2	0	0

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Reaction Count	Skin and subcutaneous tissue disorders	Rash erythematous	7	0	3
		Dermatitis exfoliative	1	0	0
		Skin exfoliation	3	0	3
		Photosensitivity reaction	7	1	2
		Pruritus	18	0	8
		Rash pruritic	1	0	1
		Dermatitis psoriasiform	1	0	1
		Rash	13	0	5
		Rash maculo-papular	14	1	5
		Systemic lupus erythematosus rash	2	1	1
		Skin ulcer	3	0	0
		Alopecia	3	0	2
		Cold sweat	1	0	1
		Hyperhidrosis	7	0	2
		Hirsutism	1	0	1
		Purpura	3	1	0
		Leukocytoclastic vasculitis	1	0	1
	Skin and subcutaneous tissue disorders		97	4	39
	Surgical and medical procedures	Therapy regimen changed	1	0	0
		Vascular graft	1	0	0
		Surgical and medical procedures	2	0	0
	Vascular disorders	Aneurysm	1	1	0
		Blood pressure fluctuation	1	0	0
		Shock	1	0	1
		Hypotension	24	0	14
		Orthostatic hypotension	20	0	10
		Deep vein thrombosis	1	0	0
		Flushing	1	0	1
		Pallor	1	0	0
Hypertension		6	0	2	
Vasculitis		3	0	2	
Vascular disorders		59	1	30	
Reaction		1120	55	438	