



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CITALOPRAM HYDROBROMIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		691	11	464
- Occurrences of Medicine		702	11	464
- Reactions Related to Medicine		1851	30	1222
Blood and lymphatic system disorders	Iron deficiency anaemia	1	0	1
	Anaemia	1	0	1
	Pancytopenia	2	0	0
	Thrombocytopenia	3	0	2
	Lymphadenopathy	1	0	1
	Eosinophilia	2	0	1
	Leukocytosis	1	0	0
	Leukopenia	3	0	1
	Neutropenia	3	0	0
Cardiac disorders	Atrioventricular block	1	0	0
	Arrhythmia	1	0	0
	Bradycardia	3	0	3
	Extrasystoles	1	0	1
	Tachycardia	15	0	8
	Arrhythmia supraventricular	1	0	1
	Sick sinus syndrome	1	0	1
	Sinus bradycardia	1	0	1
	Supraventricular tachycardia	1	0	0
	Cardiac arrest	3	2	1
	Torsade de pointes	3	1	1
	Ventricular tachycardia	1	0	0
	Cyanosis	1	1	0
	Palpitations	23	0	18
	Myocardial infarction	1	0	0
	Myocardial ischaemia	1	1	1
	Cardiomyopathy	1	1	0
Congenital, familial and genetic disorders	Ventricular septal defect	1	0	0
	Falot's tetralogy	1	0	0

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Ear and labyrinth disorders	Ear pain	1	0	1
	Hearing impaired	1	0	1
	Hyperacusis	1	0	1
	Tinnitus	3	0	3
	Vertigo	1	0	1
Endocrine disorders	Hyperprolactinaemia	2	0	1
	Inappropriate antidiuretic hormone secretior	12	0	11
Eye disorders	Eye pain	2	0	1
	Eye swelling	2	0	2
	Glaucoma	3	0	2
	Conjunctival haemorrhage	1	0	1
	Keratitis	1	0	1
	Blepharospasm	1	0	1
	Strabismus	1	0	1
	Mydriasis	6	0	4
	Photophobia	1	0	1
	Visual acuity reduced	1	0	1
	Accommodation disorder	2	0	1
	Diplopia	3	0	2
	Photopsia	1	0	1
	Vision blurred	7	0	6
	Visual disturbance	16	0	14
Gastrointestinal disorders	Abdominal hernia	1	0	1
	Anorectal disorder	1	0	1
	Tooth disorder	1	0	0
	Toothache	1	0	1
	Tooth discolouration	1	0	0
	Gingivitis	1	0	1
	Pancreatitis	1	0	0
	Rectal haemorrhage	1	0	0
	Gastrointestinal haemorrhage	2	1	0
	Haematemesis	4	0	3
	Melaena	2	1	0
	Colitis	1	0	0
	Gastritis	3	1	1

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Gastrointestinal disorders	Crohn's disease	1	0	1
	Diarrhoea	34	0	24
	Constipation	3	0	2
	Gastrointestinal motility disorder	1	0	1
	Ileus paralytic	2	0	0
	Dyspepsia	6	0	6
	Eructation	1	0	1
	Abdominal distension	3	0	3
	Flatulence	7	0	6
	Abdominal pain	14	0	9
	Abdominal pain upper	3	0	3
	Abdominal discomfort	1	0	1
	Breath odour	2	0	1
	Dysphagia	3	0	2
	Nausea	93	0	68
	Vomiting	33	0	22
	Intestinal obstruction	2	0	0
	Lip oedema	1	0	1
	Lip swelling	3	0	2
	Hypoaesthesia oral	2	0	2
	Oral discomfort	1	0	1
	Mouth ulceration	2	0	2
	Dry mouth	15	0	12
	Salivary hypersecretion	1	0	0
	Glossitis	1	0	1
	Swollen tongue	2	0	1
General disorders and administration site conditions	Hypothermia	1	0	1
	Chills	2	0	1
	Feeling cold	1	0	0
	Pyrexia	12	0	6
	Death	1	1	0
	Sudden death	3	3	0
	Asthenia	6	0	5
	Fatigue	25	0	18
	Malaise	12	0	9

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General disorders and administration site conditions	Gait disturbance	6	0	2
	Chest discomfort	2	0	2
	Condition aggravated	1	0	0
	Feeling abnormal	1	0	1
	Feeling jittery	1	0	0
	Influenza like illness	2	0	2
	Irritability	4	0	3
	Swelling	1	0	1
	Thirst	3	0	2
	Face oedema	4	0	4
	Generalised oedema	3	0	2
	Oedema	3	0	1
	Oedema peripheral	2	0	2
	Chest pain	10	0	8
	Pain	4	0	4
	Drug interaction	3	0	0
	Drug ineffective	13	0	13
	Drug tolerance increased	1	1	0
	Drug withdrawal syndrome	13	0	9
	Drug withdrawal syndrome neonatal	3	0	3
Therapeutic response decreased	1	0	1	
Therapeutic response unexpected	1	0	1	
Hepatobiliary disorders	Hepatitis cholestatic	4	0	3
	Jaundice	2	0	1
	Hepatic function abnormal	1	0	1
	Hepatic failure	1	0	1
	Hepatomegaly	1	0	0
	Hepatitis	3	0	0
Immune system disorders	Hypersensitivity	1	0	1
Infections and infestations	Vaginal infection	1	0	1
	Infection	1	0	1
	Bronchitis	1	0	1
	Pneumonia	2	0	1
	Rash pustular	1	0	1
	Pharyngitis	2	0	2



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Infections and infestations	Rhinitis	3	0	3
	Sinusitis	1	0	1
	Upper respiratory tract infection	2	0	2
	Herpes simplex	1	0	1
	Influenza	1	0	1
Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	0	0
	Fall	3	0	1
	Self mutilation	1	0	1
	Contusion	3	0	2
	Intentional overdose	2	0	2
	Overdose	3	0	2
Investigations	Electrocardiogram QT prolonged	3	0	1
	Electrocardiogram T wave inversion	1	0	0
	Electrocardiogram abnormal	2	0	0
	Blood pressure increased	1	0	1
	Blood creatine phosphokinase increased	5	0	1
	Prothrombin time prolonged	1	0	0
	Gamma-glutamyltransferase increased	1	0	1
	Liver function test abnormal	4	0	0
	Blood glucose decreased	1	0	0
	Blood glucose increased	1	0	1
	Electroencephalogram abnormal	1	0	0
	Apgar score low	1	0	1
	Weight decreased	10	0	8
	Weight increased	4	0	3
	C-reactive protein increased	1	0	1
	Blood creatinine increased	1	0	1
	Drug level decreased	1	0	0
	Drug level increased	4	2	0
Metabolism and nutrition disorders	Anorexia	8	0	6
	Decreased appetite	1	0	1
	Tetany	2	0	0
	Hypomagnesaemia	1	0	0
	Electrolyte imbalance	1	0	0
	Polydipsia	1	0	1

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Metabolism and nutrition disorders	Hyperkalaemia	3	0	2
	Hypokalaemia	3	0	1
	Hypernatraemia	2	0	2
	Hyponatraemia	63	0	33
	Dehydration	2	0	1
	Alcohol intolerance	1	0	0
	Diabetes mellitus	1	0	0
	Hyperinsulinaemia	1	0	1
	Hypoglycaemia	1	0	1
	Hypoglycaemia neonatal	1	0	1
Musculoskeletal and connective tissue disorders	Exostosis	1	0	1
	Bone pain	1	0	1
	Sjogren's syndrome	1	0	1
	Arthralgia	2	0	2
	Myalgia	13	0	11
	Muscle spasms	4	0	4
	Muscle twitching	6	0	4
	Muscle rigidity	2	0	0
	Trismus	2	0	2
	Muscular weakness	1	0	1
	Rhabdomyolysis	1	0	0
	Back pain	3	0	2
	Musculoskeletal stiffness	1	0	0
	Pain in extremity	1	0	1
Neoplasms benign, malignant and unspecified	Lymphoma	1	0	0
Nervous system disorders	Cerebral haemorrhage	1	0	0
	Cerebrovascular disorder	1	0	1
	Drug withdrawal headache	1	0	1
	Headache	43	0	31
	Migraine	3	0	2
	Brain oedema	1	0	1
	Dementia	1	0	0
	Amnesia	6	0	5
	Memory impairment	2	0	2
	Cognitive disorder	1	0	0

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Nervous system disorders	Disturbance in attention	8	0	7
	Chorea	1	0	0
	Akathisia	5	0	3
	Bradykinesia	1	0	1
	Clumsiness	1	0	1
	Dyskinesia	3	0	1
	Extrapyramidal disorder	5	0	5
	Hyperkinesia	5	0	4
	Hypokinesia	3	0	0
	Tardive dyskinesia	3	0	1
	Dystonia	8	0	5
	Opisthotonus	1	0	1
	Paresis	1	0	0
	Tremor	49	0	30
	Hyperreflexia	6	0	2
	Balance disorder	1	0	0
	Coordination abnormal	10	0	7
	Nystagmus	2	0	0
	Coma	4	0	3
	Coma hepatic	1	0	1
	Aphasia	1	0	0
	Consciousness fluctuating	3	0	1
	Depressed level of consciousness	3	0	1
	Lethargy	3	0	3
	Loss of consciousness	4	0	2
	Sedation	1	0	0
	Somnolence	18	0	11
	Syncope	10	1	4
	Dizziness	35	0	25
	Myoclonus	6	0	1
	Burning sensation	1	0	1
	Formication	2	0	2
	Hypoaesthesia	7	0	6
	Paraesthesia	22	0	19
Ageusia	2	0	2	

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Nervous system disorders	Dysgeusia	2	0	2
	Restless legs syndrome	1	0	1
	Sensory disturbance	1	0	1
	Dysarthria	7	0	4
	Speech disorder	1	0	1
	Hypertonia	15	0	6
	Neuroleptic malignant syndrome	3	0	0
	Serotonin syndrome	32	0	9
	Muscle contractions involuntary	1	0	1
	Eaton-Lambert syndrome	2	0	2
	Neuropathy peripheral	1	0	1
	Grand mal convulsion	5	0	4
	Convulsion	21	0	11
	Epilepsy	1	0	0
Pregnancy, puerperium and perinatal conditions	Foetal distress syndrome	1	0	1
	Pre-eclampsia	1	0	1
	Neonatal disorder	2	0	2
	Meconium stain	1	0	1
Psychiatric disorders	Neurosis	4	0	4
	Agitation	44	0	29
	Agitation neonatal	1	0	1
	Anxiety	26	0	18
	Nervousness	6	0	3
	Tension	1	0	1
	Fear	1	0	0
	Panic disorder	1	0	0
	Panic attack	4	0	4
	Restlessness	4	0	4
	Automatism	1	0	0
	Bruxism	8	0	6
	Screaming	1	0	1
	Confusional state	50	0	28
	Disorientation	2	0	2
	Delirium	7	0	2
	Depression	8	0	5

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Psychiatric disorders	Depersonalisation	9	0	9
	Dissociation	1	0	0
	Delusion	2	0	2
	Hallucination	22	0	12
	Hallucination, auditory	3	0	2
	Hallucination, visual	2	0	2
	Thinking abnormal	2	0	2
	Eating disorder	1	0	0
	Hypomania	1	0	1
	Mania	8	0	6
	Affect lability	3	0	2
	Anger	2	0	1
	Crying	2	0	2
	Euphoric mood	1	0	1
	Mood altered	2	0	1
	Mood swings	2	0	2
	Aggression	12	0	6
	Homicidal ideation	4	0	1
	Indifference	1	0	1
	Paranoia	2	0	2
	Violent ideation	1	0	0
	Abnormal behaviour	4	0	1
	Hypervigilance	1	0	1
	Mental disorder	1	0	1
	Psychotic disorder	2	0	2
	Anorgasmia	4	0	4
	Libido decreased	7	0	7
	Insomnia	16	0	11
	Sleep attacks	1	0	1
	Abnormal dreams	1	0	1
	Abnormal sleep-related event	1	1	0
	Nightmare	16	0	12
	Sleep disorder	6	0	5
	Completed suicide	3	3	1
Self injurious behaviour	1	0	1	

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Psychiatric disorders	Self-injurious ideation	1	0	0
	Suicidal ideation	12	0	7
	Suicide attempt	16	0	9
Renal and urinary disorders	Nephritis interstitial	4	0	2
	Anuria	1	0	0
	Renal failure	2	0	2
	Renal failure acute	5	0	1
	Renal impairment	1	0	0
	Renal tubular necrosis	1	0	1
	Urethral disorder	1	0	0
	Dysuria	3	0	2
	Pollakiuria	3	0	2
	Urethral pain	1	0	1
	Urinary hesitation	2	0	1
	Urinary incontinence	3	0	2
	Urinary retention	5	0	4
	Chromaturia	1	0	0
	Haematuria	1	0	1
	Nocturia	1	0	1
	Polyuria	2	0	2
	Renal pain	1	0	0
Reproductive system and breast disorders	Breast enlargement	1	0	1
	Gynaecomastia	1	0	1
	Breast pain	1	0	1
	Galactorrhoea	6	0	6
	Suppressed lactation	1	0	1
	Premenstrual syndrome	1	0	1
	Amenorrhoea	1	0	0
	Penile size reduced	1	0	1
	Penis disorder	1	0	1
	Genital ulceration	1	0	1
	Perineal pain	1	0	1
	Ejaculation delayed	1	0	1
	Ejaculation disorder	1	0	1
	Ejaculation failure	3	0	3

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Reproductive system and breast disorders	Erectile dysfunction	9	0	6
	Priapism	1	0	0
	Sexual dysfunction	2	0	2
	Uterine haemorrhage	1	0	1
	Vulval leukoplakia	1	0	0
	Vulval ulceration	1	0	1
	Vulval erythema	1	0	1
Respiratory, thoracic and mediastinal disorders	Asthma	2	0	1
	Interstitial lung disease	1	0	1
	Pulmonary fibrosis	1	0	1
	Pulmonary hypertension	1	0	0
	Pulmonary embolism	1	1	0
	Apnoea	1	0	1
	Dyspnoea	18	1	11
	Hyperventilation	3	0	3
	Hypoventilation	1	0	1
	Respiratory depression	1	1	0
	Hypoxia	2	1	0
	Cough	9	0	8
	Productive cough	1	0	1
	Hiccups	1	0	1
	Respiratory failure	1	1	0
	Aspiration	1	0	1
	Respiratory disorder	2	0	2
	Dysphonia	1	0	1
	Sneezing	1	0	1
	Snoring	1	0	1
	Throat irritation	1	0	1
	Yawning	3	0	3
	Stridor	1	0	0
	Nasal congestion	1	0	0
	Epistaxis	1	0	1
	Nasal dryness	1	0	1
Pharyngeal oedema	1	0	1	
Skin and subcutaneous tissue disorders	Angioedema	5	0	5

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Skin and subcutaneous tissue disorders	Periorbital oedema	5	0	5
	Dermographism	1	0	1
	Urticaria	15	0	15
	Blister	2	0	0
	Dry skin	3	0	3
	Skin burning sensation	1	0	1
	Skin discolouration	1	0	1
	Dermatitis	1	0	1
	Erythema	2	0	1
	Rash erythematous	5	0	5
	Skin exfoliation	1	0	1
	Rash papular	1	0	1
	Photosensitivity reaction	1	0	1
	Pruritus	21	0	15
	Rash pruritic	2	0	2
	Psoriasis	1	0	1
	Fixed eruption	1	0	1
	Rash	25	0	18
	Rash generalised	1	0	0
	Rash macular	1	0	0
	Rash maculo-papular	5	0	2
	Erythema nodosum	1	0	1
	Acne	1	0	0
	Alopecia	6	0	3
	Cold sweat	1	0	0
	Hyperhidrosis	42	1	27
	Nail disorder	1	0	1
	Henoch-Schonlein purpura	1	0	1
	Purpura	3	0	3
	Social circumstances	Walking disability	1	0
Surgical and medical procedures	Drug therapy changed	12	0	10
	Therapy regimen changed	6	0	3
Vascular disorders	Peripheral ischaemia	2	0	1
	Circulatory collapse	4	0	1
	Hypotension	4	1	2



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Vascular disorders	Orthostatic hypotension	2	0	1
	Deep vein thrombosis	1	1	0
	Flushing	6	0	4
	Hot flush	5	0	4
	Pallor	1	1	0
	Hypertension	9	0	6
	Arteritis	1	0	0
	Vasculitis	1	0	0