

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		5087	36	4320
- Occurrences of Medicine		5194	36	4320
- Reactions Related to Medicine		9764	95	7864
Blood and lymphatic system disorders	Anaemia	6	0	5
	Hypochromic anaemia	1	0	1
	Microcytic anaemia	1	0	1
	Normochromic normocytic anaemia	1	0	0
	Aplastic anaemia	1	0	1
	Pancytopenia	3	0	0
	Coagulopathy	1	0	0
	Haemolytic anaemia	1	0	0
	Platelet disorder	3	0	3
	Thrombocythaemia	2	0	0
	Thrombocytopenia	9	0	7
	Lymphadenopathy	2	0	2
	Eosinophilia	4	0	0
	Leukocytosis	8	1	4
	Neutrophilia	1	0	0
	Leukopenia	7	1	4
	Lymphopenia	1	0	0
Agranulocytosis	2	0	1	
Neutropenia	9	0	4	
Cardiac disorders	Atrioventricular block	3	0	2
	Arrhythmia	7	1	4
	Bradycardia	8	0	3
	Extrasystoles	4	0	3
	Tachycardia	48	0	29
	Atrial fibrillation	7	0	4
	Sinus tachycardia	1	0	0
	Supraventricular tachycardia	1	0	0
	Cardiac arrest	4	2	1



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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Cardiac disorders	Ventricular tachycardia	3	1	2
	Cardiac disorder	1	0	0
	Cyanosis	2	0	2
	Palpitations	102	0	85
	Mitral valve incompetence	2	0	1
	Coronary artery occlusion	1	0	1
	Angina pectoris	1	0	1
	Myocardial infarction	2	0	0
	Cardiac failure	1	0	0
	Cardiac failure congestive	1	0	1
	Left ventricular failure	1	0	0
	Cardiomyopathy	3	0	1
	Cardiomegaly	1	1	0
	Dilatation ventricular	2	0	0
	Myocarditis	2	0	0
Congenital, familial and genetic disorders	Heart disease congenital	3	0	2
	Chromosome abnormality	1	0	1
	Multiple congenital abnormalities	5	1	3
	Cleft palate	1	0	1
	Congenital foot malformation	1	0	0
	Congenital hand malformation	1	0	0
	Limb reduction defect	1	0	1
	Polydactyly	1	0	1
	Congenital hydrocephalus	1	0	1
	Tourette's disorder	2	0	2
	Hypospadias	1	0	0
	Pulmonary malformation	1	0	1
Ear and labyrinth disorders	Ear pain	3	0	3
	Deafness	13	0	10
	Deafness neurosensory	1	0	1
	Hypoacusis	1	0	0
	Hyperacusis	4	0	3
	Inner ear disorder	3	0	3
	Motion sickness	1	0	1
	Tinnitus	25	0	22



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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Ear and labyrinth disorders	Vertigo	18	0	17
	Vertigo positional	1	0	1
	Otosclerosis	1	0	1
	Tympanic membrane hyperaemia	1	0	0
Endocrine disorders	Cushing's syndrome	1	0	0
	Hyperprolactinaemia	14	0	11
	Inappropriate antidiuretic hormone secretior	26	0	20
	Hyperparathyroidism	1	0	1
	Goitre	1	0	1
	Thyroid disorder	1	0	1
	Hypothyroidism	5	0	2
Eye disorders	Cataract	3	0	2
	Xerophthalmia	4	0	4
	Lacrimonal disorder	2	0	2
	Lacrimation increased	1	0	1
	Eye disorder	3	0	3
	Eye pain	7	0	5
	Ocular discomfort	1	0	1
	Retinal disorder	2	0	2
	Angle closure glaucoma	1	0	1
	Glaucoma	9	0	7
	Hyphaema	1	0	1
	Conjunctival haemorrhage	1	0	1
	Optic ischaemic neuropathy	1	0	1
	Conjunctivitis	5	0	4
	Blepharospasm	1	0	0
	Eye movement disorder	1	0	1
	Oculogyration	3	0	3
	Miosis	1	0	0
	Mydriasis	11	0	8
	Eye rolling	1	0	0
	Photophobia	8	0	6
	Macular degeneration	1	0	0
	Exophthalmos	1	0	1
	Retinal haemorrhage	1	0	1

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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Eye disorders	Blindness	2	0	2
	Night blindness	1	0	1
	Visual acuity reduced	3	0	2
	Accommodation disorder	7	0	7
	Diplopia	6	0	4
	Scintillating scotoma	1	0	1
	Vision blurred	9	1	8
	Visual disturbance	66	1	58
Gastrointestinal disorders	Hiatus hernia	1	0	1
	Proctalgia	1	0	1
	Anal inflammation	1	0	1
	Rectal tenesmus	1	0	1
	Dental caries	2	0	2
	Sensitivity of teeth	1	0	1
	Toothache	1	0	1
	Gingival atrophy	1	0	1
	Gingival hyperplasia	2	0	2
	Gingivitis	1	0	1
	Gingival bleeding	2	0	2
	Pancreatitis	5	0	3
	Pancreatitis acute	2	0	0
	Gastrointestinal disorder	3	0	3
	Hyperchlorhydria	1	0	1
	Rectal haemorrhage	5	0	5
	Gastrointestinal haemorrhage	1	1	0
	Haematemesis	1	0	1
	Melaena	3	0	0
	Upper gastrointestinal haemorrhage	1	0	1
	Colitis	7	0	7
	Gastritis	3	0	2
	Oesophagitis	5	0	4
	Reflux oesophagitis	2	0	2
	Diarrhoea	317	1	284
	Diarrhoea neonatal	1	0	1
	Constipation	16	0	13

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Gastrointestinal disorders	Gastrooesophageal reflux disease	4	0	4
	Impaired gastric emptying	1	0	0
	Oesophageal spasm	4	0	4
	Dyspepsia	44	1	40
	Eructation	3	0	3
	Abdominal distension	1	0	0
	Flatulence	11	0	10
	Abdominal pain	92	0	71
	Abdominal pain upper	6	0	5
	Oesophageal pain	1	0	1
	Dysphagia	18	0	16
	Faecal incontinence	4	0	4
	Stomach discomfort	1	0	1
	Nausea	555	0	501
	Retching	2	0	2
	Vomiting	170	1	143
	Vomiting neonatal	2	0	2
	Intestinal obstruction	1	0	1
	Oesophageal stenosis	1	0	0
	Duodenal ulcer	3	0	0
	Duodenal ulcer haemorrhage	3	0	1
	Gastric ulcer	1	0	0
	Oesophagitis ulcerative	1	0	0
	Peptic ulcer haemorrhage	1	0	1
	Coeliac disease	1	0	1
	Cheilitis	2	0	2
	Lip swelling	1	0	0
	Palatal disorder	1	0	1
	Aphthous stomatitis	1	0	1
	Mouth ulceration	14	0	14
	Stomatitis	1	0	1
	Ascites	1	1	0
	Dry mouth	47	1	41
Salivary hypersecretion	15	1	12	
Glossitis	7	0	7	

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Gastrointestinal disorders	Tongue disorder	3	0	2
	Tongue ulceration	2	0	2
	Swollen tongue	2	0	1
	Tongue discolouration	1	0	1
	Tongue oedema	3	0	3
General disorders and administration site conditions	Chills	27	0	16
	Feeling cold	1	0	1
	Peripheral coldness	1	0	1
	Fever neonatal	1	0	1
	Hyperpyrexia	1	0	0
	Pyrexia	39	0	21
	Death	2	2	1
	Death neonatal	1	0	1
	Sudden death	9	9	2
	Asthenia	41	0	29
	Chronic fatigue syndrome	1	0	1
	Fatigue	115	1	101
	Malaise	72	0	54
	Gait disturbance	16	0	14
	Chest discomfort	1	0	0
	Condition aggravated	1	0	0
	Feeling abnormal	5	1	5
	Influenza like illness	8	0	7
	Irritability	6	0	6
	Thirst	5	0	4
	Face oedema	22	0	17
	Gravitational oedema	4	0	2
	Oedema	9	1	5
	Oedema peripheral	4	0	4
	Chest pain	48	0	35
	Pain	32	0	28
	Drug interaction	4	1	0
Drug ineffective	80	5	66	
Drug tolerance increased	1	0	1	
Drug withdrawal syndrome	208	0	191	



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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
General disorders and administration site conditions	Drug withdrawal syndrome neonatal	8	0	6
	Therapeutic response decreased	3	0	1
	Therapeutic response unexpected	11	0	11
	Therapeutic response unexpected with drug	1	0	1
Hepatobiliary disorders	Biliary colic	1	0	1
	Cholangitis	1	0	1
	Cholelithiasis	3	0	3
	Cholestasis	1	0	1
	Hepatitis cholestatic	5	0	4
	Hyperbilirubinaemia	1	0	0
	Jaundice	18	2	12
	Hepatic function abnormal	57	1	33
	Hepatic failure	2	1	1
	Hepatic cirrhosis	2	1	0
	Hepatomegaly	2	0	0
	Hepatosplenomegaly	2	0	0
	Hepatic necrosis	1	1	0
	Hepatitis	16	0	8
	Hepatocellular damage	2	0	1
Immune system disorders	Hypersensitivity	3	0	3
	Serum sickness	1	0	1
	Drug hypersensitivity	1	0	1
	Anaphylactic reaction	2	0	1
	Anaphylactoid reaction	2	0	2
Infections and infestations	Folliculitis	1	0	1
	Pyomyositis	1	0	1
	Candidiasis	2	0	2
	Fungal infection	1	0	0
	Diverticulitis	1	0	1
	Meningitis	2	0	2
	Meningitis aseptic	1	0	0
	Labyrinthitis	1	0	0
	Otitis media	2	0	1
	Lower respiratory tract infection	2	0	2
	Pneumonia	4	2	1

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Infections and infestations	Sepsis	1	1	0
	Rash pustular	3	0	3
	Laryngitis	1	0	1
	Pharyngitis	6	0	5
	Rhinitis	6	0	5
	Sinusitis	3	0	3
	Cystitis	1	0	1
	Urinary tract infection	7	0	5
	Herpes simplex	2	0	2
	Viral infection	1	0	0
Injury, poisoning and procedural complications	Drug toxicity	1	1	0
	Therapeutic agent toxicity	1	0	0
	Drug exposure during pregnancy	8	0	8
	Fall	11	0	6
	Self mutilation	1	0	1
	Contusion	4	0	4
	Drug administration error	1	0	1
	Medication error	2	0	2
	Accidental overdose	1	0	1
	Intentional overdose	5	1	3
	Overdose	7	0	3
	Post procedural haemorrhage	1	0	1
Investigations	Electrocardiogram abnormal	6	0	1
	Heart rate increased	1	0	1
	Blood pressure decreased	4	0	2
	Blood pressure increased	2	0	2
	Glucocorticoids increased	1	0	0
	Blood prolactin increased	1	0	0
	Blood thyroid stimulating hormone decrease	1	0	1
	Thyroid function test abnormal	1	0	1
	Blood creatine phosphokinase increased	14	1	5
	Blood alkaline phosphatase increased	1	0	1
	Blood amylase increased	2	0	0
	Lipase increased	1	0	0
	Bleeding time prolonged	3	0	3

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Investigations	Prothrombin level decreased	8	0	1
	Red blood cell sedimentation rate increased	1	0	1
	Alanine aminotransferase increased	1	0	0
	Aspartate aminotransferase increased	1	0	0
	Gamma-glutamyltransferase increased	3	0	2
	Hepatic enzyme abnormal	1	0	1
	Hepatic enzyme increased	1	0	1
	Liver function test abnormal	8	0	6
	Antinuclear antibody increased	1	0	1
	Laboratory test abnormal	1	0	1
	Blood cholesterol increased	1	0	0
	Blood folate decreased	1	0	1
	CSF pressure increased	1	0	1
	Electroencephalogram abnormal	2	0	1
	Nerve conduction studies abnormal	1	0	1
	Apgar score low	1	0	1
	Body temperature increased	1	0	0
	Weight decreased	42	0	34
	Weight increased	79	1	70
	Blood albumin decreased	1	0	1
	C-reactive protein increased	1	0	1
	Blood creatinine decreased	1	0	1
	Blood creatinine increased	1	0	1
	Semen abnormal	1	0	1
	Drug level above therapeutic	1	0	0
	Drug level decreased	2	0	0
	Drug level increased	15	1	0
	Blood sodium decreased	5	0	4
Blood osmolarity decreased	1	0	0	
Urine osmolarity decreased	1	0	0	
Metabolism and nutrition disorders	Ketosis	1	0	1
	Acidosis	3	0	2
	Anorexia	45	1	37
	Decreased appetite	4	1	3
	Increased appetite	11	0	9

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Metabolism and nutrition disorders	Failure to thrive	1	0	1
	Feeding disorder neonatal	2	0	2
	Hypocalcaemia	1	0	0
	Tetany	6	0	5
	Hypermagnesaemia	1	0	1
	Hypochloraemia	2	0	2
	Electrolyte imbalance	1	0	1
	Oligodipsia	1	0	1
	Polydipsia	2	0	2
	Hyperkalaemia	2	0	0
	Hypokalaemia	10	1	6
	Hypernatraemia	6	0	4
	Hyponatraemia	180	3	120
	Dehydration	6	0	4
	Hypovolaemia	1	0	0
	Alcohol intolerance	8	0	5
	Lactose intolerance	1	0	1
	Diabetes mellitus	4	0	4
	Hyperglycaemia	7	0	7
	Hypoglycaemia	15	0	10
	Hyperlipidaemia	1	0	1
	Hypoproteinaemia	1	0	0
Gout	1	0	1	
Musculoskeletal and connective tissue disorders	Bone pain	2	0	2
	Pain in jaw	3	0	3
	Osteoporosis	1	0	1
	Collagen disorder	2	0	2
	Scleroderma	1	0	1
	Systemic lupus erythematosus	2	0	1
	Arthritis	4	0	4
	Arthralgia	34	0	26
	Joint stiffness	1	0	0
	Osteoarthritis	5	0	4
	Myalgia	57	0	45
	Muscle spasms	19	0	14

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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Musculoskeletal and connective tissue disorders	Muscle tightness	1	0	1
	Muscle twitching	63	0	49
	Hypotonia neonatal	3	0	3
	Muscle rigidity	4	0	3
	Trismus	1	0	1
	Muscular weakness	5	0	4
	Myopathy	1	0	0
	Rhabdomyolysis	5	0	3
	Back pain	11	0	8
	Musculoskeletal stiffness	5	0	2
	Neck pain	2	0	1
	Sensation of heaviness	1	0	1
	Bursitis	2	0	2
	Tendonitis	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic neoplasm malignant	1	1	1
	Leukaemia	1	0	0
	Hairy cell leukaemia	1	0	0
	Metastasis	1	0	1
	Paraproteinaemia	1	0	1
	Sarcoma	2	0	2
Nervous system disorders	Cerebral haemorrhage	3	1	0
	Cerebrovascular accident	2	0	2
	Haemorrhage intracranial	1	0	0
	Cerebrovascular disorder	4	2	3
	Facial palsy	3	0	3
	Parosmia	3	0	2
	Encephalopathy	2	1	1
	Headache	295	0	262
	Tension headache	2	0	2
	Migraine	27	0	24
	Brain oedema	1	1	0
	Intracranial pressure increased	1	0	1
	Dementia	2	0	0
	Amnesia	49	0	40
	Cognitive disorder	5	0	2



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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Nervous system disorders	Disturbance in attention	28	1	24
	Mental impairment	2	0	1
	Choreoathetosis	5	0	3
	Akathisia	14	0	9
	Bradykinesia	1	0	1
	Dyskinesia	38	0	29
	Extrapyramidal disorder	18	1	12
	Hyperkinesia	38	0	28
	Hypokinesia	8	0	7
	Movement disorder	1	0	1
	Psychomotor hyperactivity	2	0	2
	Tardive dyskinesia	6	0	5
	Dystonia	54	0	40
	Hemiparesis	3	0	2
	Paralysis	3	0	3
	Paresis	3	0	3
	Parkinsonism	1	0	0
	Tremor	247	1	192
	Tremor neonatal	1	0	1
	Hyperreflexia	11	0	4
	Reflexes abnormal	1	0	1
	Balance disorder	1	0	1
	Coordination abnormal	46	0	38
	Nystagmus	6	0	3
	Coma	9	1	5
	Aphasia	5	0	5
	Consciousness fluctuating	7	0	1
	Depressed level of consciousness	1	0	1
	Lethargy	7	0	6
	Loss of consciousness	5	0	4
	Sedation	1	0	0
	Somnolence	131	1	114
	Somnolence neonatal	2	0	2
	Stupor	3	0	3
Syncope	62	2	46	



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Nervous system disorders	Clonus	1	0	0
	Dizziness	295	0	299
	Myoclonus	4	0	1
	Burning sensation	5	0	5
	Formication	3	0	3
	Hyperaesthesia	7	0	5
	Hypoaesthesia	37	0	32
	Paraesthesia	108	0	97
	Ageusia	2	0	1
	Dysgeusia	11	0	10
	Neuralgia	1	0	1
	Restless legs syndrome	2	0	2
	Sensory disturbance	9	0	9
	Dysarthria	12	0	8
	Incoherent	1	0	0
	Speech disorder	19	0	15
	Visual field defect	4	0	3
	Hypertonia	63	0	43
	Hypotonia	1	0	1
	Neuroleptic malignant syndrome	8	0	0
	Serotonin syndrome	76	0	29
	Muscle contractions involuntary	3	0	2
	Muscle spasticity	1	0	0
	Guillain-Barre syndrome	1	0	0
	Peroneal nerve palsy	1	0	1
	Neuropathy peripheral	3	0	3
	Convulsion neonatal	2	0	1
	Grand mal convulsion	31	1	17
	Convulsion	131	3	93
	Convulsive threshold lowered	1	0	0
	Epilepsy	2	0	2
	Tonic convulsion	1	0	0
	Hypersomnia	2	0	1
Poor quality sleep	2	0	2	
Nerve root lesion	1	0	1	

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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Pregnancy, puerperium and perinatal conditions	Abortion	2	0	2
	Abortion spontaneous	6	0	4
	Intra-uterine death	9	1	8
	Stillbirth	1	0	1
	Foetal distress syndrome	1	0	0
	Premature labour	1	0	1
	Premature rupture of membranes	2	0	2
	Premature separation of placenta	1	0	1
	Ectopic pregnancy	1	0	1
	Neonatal disorder	12	0	7
	Unintended pregnancy	2	0	0
	Psychiatric disorders	Neurosis	27	0
Obsessive-compulsive disorder		3	0	2
Agitation		434	2	372
Agitation neonatal		5	0	5
Anxiety		202	0	179
Nervousness		28	0	17
Obsessive thoughts		2	0	2
Stress		1	0	1
Fear		1	0	1
Panic attack		7	0	6
Panic reaction		1	0	1
Post-traumatic stress disorder		1	0	0
Catatonia		2	0	2
Restlessness		8	0	3
Automatism		2	0	1
Bruxism		46	0	43
Tic		2	0	2
Change in sustained attention		1	0	1
Reading disorder		1	0	1
Screaming		2	0	2
Confusional state		146	1	85
Disorientation		7	0	6
Delirium		25	0	16
Agitated depression		1	0	1



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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Psychiatric disorders	Depression	57	1	39
	Depressed mood	2	0	2
	Tearfulness	4	0	3
	Depersonalisation	72	0	66
	Delusion	14	0	11
	Thought insertion	1	0	1
	Hallucination	81	0	58
	Hallucination, auditory	4	0	3
	Hallucination, visual	4	0	1
	Hallucinations, mixed	1	0	0
	Thinking abnormal	41	0	31
	Eating disorder	2	0	1
	Pathological gambling	1	0	1
	Bipolar disorder	1	0	1
	Hypomania	1	0	1
	Mania	55	0	47
	Affect lability	22	0	19
	Anger	4	0	3
	Crying	8	0	7
	Emotional disorder	1	0	1
	Emotional distress	2	0	2
	Euphoric mood	13	0	11
	Mood swings	7	0	6
	Apathy	8	0	7
	Aggression	67	0	44
	Homicidal ideation	9	0	6
	Paranoia	19	0	10
	Personality change	1	0	0
	Violent ideation	3	0	2
	Personality disorder	3	0	1
	Abnormal behaviour	2	0	1
	Staring	1	0	1
	Hypervigilance	1	0	1
	Mental disorder	4	0	1
Mental status changes	1	0	1	

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SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Psychiatric disorders	Alcoholism	3	0	2
	Drug dependence	1	0	1
	Delusional disorder, persecutory type	1	0	0
	Delusional disorder, unspecified type	1	0	0
	Psychotic disorder	37	0	29
	Schizophreniform disorder	3	0	2
	Schizophrenia	1	0	1
	Anorgasmia	60	0	57
	Libido decreased	139	0	129
	Libido increased	6	0	6
	Loss of libido	1	0	0
	Insomnia	248	1	224
	Abnormal dreams	11	0	9
	Nightmare	55	0	47
	Sleep walking	2	0	2
	Sleep disorder	15	0	14
	Conversion disorder	1	0	1
	Completed suicide	4	4	4
	Intentional self-injury	4	0	3
	Self injurious behaviour	1	0	1
	Self-injurious ideation	1	0	1
	Suicidal ideation	43	0	35
	Suicide attempt	53	6	40
Renal and urinary disorders	Glomerulonephritis	1	0	0
	Nephrotic syndrome	1	0	1
	Oliguria	1	0	1
	Renal failure	2	0	1
	Renal failure acute	4	0	0
	Renal failure chronic	1	0	0
	Renal impairment	7	0	4
	Bladder spasm	1	0	1
	Dysuria	9	0	7
	Enuresis	1	0	1
	Micturition disorder	13	0	11
	Micturition urgency	1	0	1

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Renal and urinary disorders	Pollakiuria	17	0	16
	Urinary hesitation	1	0	1
	Urinary incontinence	25	1	21
	Urinary retention	22	0	21
	Albuminuria	2	0	1
	Haematuria	7	0	5
	Nocturia	8	0	8
	Polyuria	2	0	2
	Renal pain	2	0	2
	Nephrolithiasis	1	0	1
	Calculus bladder	1	0	0
Reproductive system and breast disorders	Breast enlargement	5	0	3
	Breast mass	4	0	3
	Breast microcalcification	1	0	0
	Gynaecomastia	7	0	6
	Breast engorgement	1	0	1
	Breast pain	9	0	9
	Galactorrhoea	31	0	26
	Suppressed lactation	8	0	7
	Atrophic vulvovaginitis	2	0	2
	Menstrual disorder	12	0	10
	Amenorrhoea	7	0	5
	Menorrhagia	12	0	11
	Metrorrhagia	18	0	16
	Ovarian cyst	1	0	1
	Penis disorder	1	0	1
	Prostatic disorder	1	0	1
	Genital discharge	1	0	0
	Perineal pain	3	0	3
	Ejaculation delayed	1	0	1
	Ejaculation disorder	3	0	3
	Ejaculation failure	91	0	88
	Erectile dysfunction	62	0	61
	Priapism	6	0	4
Dyspareunia	2	0	2	

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Reproductive system and breast disorders	Infertility female	2	0	2
	Sexual dysfunction	35	0	34
	Azoospermia	1	0	1
	Testicular disorder	2	0	2
	Uterine haemorrhage	7	0	7
	Uterine pain	1	0	1
	Vaginal haemorrhage	18	0	16
	Vulval disorder	2	0	2
	Vulvovaginal discomfort	1	0	1
	Respiratory, thoracic and mediastinal disorders	Asthma	2	0
Bronchospasm		12	0	10
Wheezing		1	0	1
Pneumonitis		2	0	2
Pulmonary oedema		1	0	1
Infantile apnoeic attack		1	0	1
Neonatal respiratory depression		2	0	2
Pulmonary hypertension		1	0	0
Pulmonary embolism		3	0	1
Apnoea		2	0	2
Dyspnoea		48	0	34
Hyperventilation		9	0	7
Respiratory arrest		1	0	1
Tachypnoea		1	0	0
Asphyxia		1	1	1
Hypoxia		1	0	1
Cough		15	0	15
Haemoptysis		1	0	1
Productive cough		1	0	1
Hiccups		2	0	2
Pleuritic pain		1	0	0
Respiratory failure		1	1	0
Respiratory disorder		4	0	3
Choking		1	0	1
Dysphonia		2	0	2
Pharyngolaryngeal pain		2	0	2

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Respiratory, thoracic and mediastinal disorders	Throat irritation	1	0	0
	Throat tightness	5	0	4
	Yawning	43	0	40
	Stridor	1	0	1
	Nasal congestion	1	0	1
	Epistaxis	21	0	17
	Pharyngeal oedema	2	0	2
Skin and subcutaneous tissue disorders	Angioedema	10	0	6
	Periorbital oedema	5	0	5
	Urticaria	49	0	43
	Lichenoid keratosis	2	0	2
	Skin atrophy	1	0	0
	Dermatitis bullous	8	0	8
	Erythema multiforme	7	0	4
	Stevens-Johnson syndrome	2	0	0
	Dry skin	8	0	7
	Hypoaesthesia facial	1	0	1
	Skin burning sensation	1	0	0
	Skin discolouration	4	0	4
	Skin disorder	2	0	1
	Skin odour abnormal	2	0	2
	Swelling face	3	0	2
	Yellow skin	1	0	1
	Dermatitis	1	0	1
	Dermatitis allergic	1	0	1
	Eczema	3	0	2
	Neurodermatitis	1	0	1
	Drug eruption	1	0	1
	Rash erythematous	34	0	30
	Dermatitis exfoliative	1	0	0
	Exfoliative rash	1	0	1
	Skin exfoliation	9	0	9
	Rash papular	1	0	1
	Photosensitivity reaction	18	0	15
Pruritus	103	1	89	

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Skin and subcutaneous tissue disorders	Rash pruritic	2	0	1
	Dermatitis psoriasiform	1	0	1
	Psoriasis	3	0	3
	Pustular psoriasis	1	0	1
	Rash follicular	1	0	0
	Rash	155	0	139
	Rash maculo-papular	47	0	37
	Rash morbilliform	2	0	2
	Rash vesicular	3	0	3
	Chloasma	1	0	1
	Erythema nodosum	6	0	6
	Acne	23	0	18
	Alopecia	41	0	35
	Cold sweat	6	0	5
	Hyperhidrosis	210	0	170
	Night sweats	2	0	2
	Hirsutism	1	0	1
	Nail disorder	1	0	1
	Hair texture abnormal	2	0	2
	Ecchymosis	1	0	1
Increased tendency to bruise	1	0	1	
Purpura	49	0	38	
Surgical and medical procedures	Drug therapy changed	20	0	20
	Therapy regimen changed	11	0	10
Vascular disorders	Aortic stenosis	1	0	1
	Ischaemia	1	0	1
	Peripheral ischaemia	2	0	1
	Blood pressure fluctuation	1	0	0
	Circulatory collapse	6	0	4
	Shock	1	0	0
	Hypotension	28	1	13
	Orthostatic hypotension	25	0	19
	Thrombosis	2	0	2
	Deep vein thrombosis	2	0	1
	Vasodilatation	2	0	2



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

SERTRALINE HYDROCHLORIDE		Layer 1 of 1		
Vascular disorders	Vein disorder	1	0	1
	Flushing	55	0	48
	Hot flush	25	0	21
	Pallor	3	0	3
	Haematoma	2	0	1
	Haemorrhage	5	0	5
	Wound haemorrhage	1	0	0
	Hypertension	39	0	31
	Vasculitis	1	0	0