

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole
Case Count			5336	48	4493
Reaction Count	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	
Thrombocytopenia		9	0	7	
Thrombocytosis		2	0	0	
Lymphadenopathy		3	0	3	
Eosinophilia		4	0	0	
Leukocytosis		7	1	3	
Neutrophilia		1	0	0	
Leukopenia		7	1	4	
Lymphopenia		1	0	0	
Agranulocytosis		3	0	1	
Neutropenia		10	0	4	
		Blood and lymphatic system disorders	65	2	33
	Cardiac disorders	Atrioventricular block	3	0	2
		Conduction disorder	1	0	1
		Arrhythmia	10	2	6
		Bradycardia	8	0	3
		Extrasystoles	4	0	3
		Tachycardia	51	0	31
		Atrial fibrillation	7	0	4
		Sinus tachycardia	2	0	1
		Supraventricular tachycardia	1	0	0
		Cardiac arrest	5	3	1
		Cardio-respiratory arrest	1	1	0
		Ventricular tachycardia	3	1	2
		Cardiac disorder	1	0	0
		Cyanosis	2	0	2
		Palpitations	108	0	89
		Mitral valve incompetence	2	0	1
		Coronary artery occlusion	1	0	1
		Angina pectoris	1	0	1
		Myocardial infarction	2	0	0
		Myocardial ischaemia	1	1	0
	Cardiac failure	1	0	0	

Medicine summary -sertraline (to date)

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Reaction Count	Cardiac disorders	Cardiac failure congestive	2	1	1
		Left ventricular failure	1	0	0
		Cardiomyopathy	3	0	1
		Cardiomegaly	1	1	0
		Dilatation ventricular	2	0	0
		Myocarditis	2	0	0
		Cardiac disorders	226	10	150
	Congenital, familial and genetic disorders	Heart disease congenital	3	0	2
		Falot's tetralogy	1	1	1
		Cytogenetic 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
		Congenital, familial and genetic disorders	20	2	14
	Ear and labyrinth disorders	Ear discomfort	1	0	1
		Ear pain	3	0	3
		Deafness	14	0	11
		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	26	0	23
		Vertigo	21	0	20
		Vertigo positional	1	0	1
		Otosclerosis	1	0	1
		Tympanic membrane hyperaemia	1	0	0
		Ear and labyrinth disorders	78	0	68
	Endocrine disorders	Cushing's syndrome	1	0	0
		Hyperprolactinaemia	14	0	11
Inappropriate antidiuretic hormone secretion		29	0	23	
Hyperparathyroidism		1	0	1	
Thyroiditis		1	0	1	
Goitre		1	0	1	
Thyroid disorder		1	0	1	

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole		
Reaction Count	Endocrine disorders	Hypothyroidism	5	0	2		
		Endocrine disorders	53	0	40		
	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	9	0	7		
		Ocular discomfort	1	0	1		
		Retinal disorder	2	0	2		
		Periorbital oedema	6	0	6		
		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	6	0	5		
		Eyelid oedema	1	0	1		
		Blepharospasm	1	0	0		
		Eye movement disorder	1	0	1		
		Oculogyric crisis	3	0	3		
		Miosis	1	0	0		
		Mydriasis	11	0	8		
		Eye rolling	2	0	0		
		Photophobia	8	0	6		
		Vitreous floaters	1	0	1		
		Macular degeneration	1	0	0		
		Retinal degeneration	1	0	0		
		Exophthalmos	1	0	1		
		Retinal haemorrhage	1	0	1		
		Blindness	1	0	1		
		Night blindness	1	0	1		
		Sudden visual loss	1	0	1		
		Visual acuity reduced	4	0	3		
		Accommodation disorder	8	0	8		
		Diplopia	8	0	6		
		Photopsia	1	0	1		
		Scintillating scotoma	1	0	1		
		Vision blurred	13	1	12		
		Visual impairment	70	1	62		
			Eye disorders	191	2	162	
			Gastrointestinal disorders	Hiatus hernia	1	0	1

Medicine summary -sertraline (to date)

Reaction Count		Case Group	Death Outcomes	Sole	
	Gastrointestinal disorders	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	6	0	4
		Pancreatitis acute	1	0	0
		Gastrointestinal disorder	4	0	4
		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	333	1	294
		Diarrhoea neonatal	1	0	1
		Constipation	18	0	15
		Gastrooesophageal reflux disease	4	0	4
		Impaired gastric emptying	1	0	0
		Oesophageal spasm	4	0	4
		Dyspepsia	47	1	43
		Eructation	3	0	3
		Abdominal distension	1	0	0
		Flatulence	11	0	10
		Abdominal pain	93	0	72
		Abdominal pain upper	6	0	5
		Oesophageal pain	1	0	1
		Abdominal discomfort	1	0	1
		Dysphagia	18	0	16
		Faecal incontinence	4	0	4
		Nausea	568	1	512
		Retching	2	0	2
		Vomiting	175	1	146

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole		
Reaction Count	Gastrointestinal disorders	Vomiting neonatal	2	0	2		
		Intestinal obstruction	1	0	1		
		Oesophageal stenosis	1	0	0		
		Duodenal ulcer	3	0	0		
		Duodenal ulcer haemorrhage	4	0	1		
		Duodenal ulcer perforation	1	0	0		
		Gastric ulcer	1	0	0		
		Gastric ulcer haemorrhage	1	0	0		
		Oesophagitis ulcerative	1	0	0		
		Peptic ulcer haemorrhage	1	0	1		
		Coeliac disease	1	0	1		
		Chapped lips	1	0	1		
		Cheilitis	2	0	2		
		Lip oedema	1	0	1		
		Lip swelling	3	0	1		
		Palatal disorder	1	0	1		
		Lip haemorrhage	1	0	1		
		Aphthous stomatitis	1	0	1		
		Mouth ulceration	14	0	14		
		Stomatitis	1	0	1		
		Ascites	1	1	0		
		Dry mouth	50	1	44		
		Salivary hypersecretion	15	1	12		
		Glossitis	7	0	7		
		Tongue disorder	3	0	2		
		Tongue ulceration	2	0	2		
		Swollen tongue	2	0	1		
		Tongue discolouration	1	0	1		
		Tongue oedema	4	0	4		
			Gastrointestinal disorders		1472	8	1280
		General disorders and administration site conditions		Fever neonatal	1	0	1
				Hyperpyrexia	1	0	0
				Pyrexia	41	0	23
				Death	5	5	1
				Death neonatal	1	0	1
				Sudden death	9	9	2
Asthenia	44			0	32		
Chronic fatigue syndrome	1			0	1		
Fatigue	118			1	104		
Malaise	80			1	60		
Gait disturbance	22			0	18		
Condition aggravated	3			0	0		

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole	
Reaction Count	General disorders and administration site conditions	General physical health deterioration	1	0	1	
		Influenza like illness	9	0	8	
		Irritability	7	0	7	
		Face oedema	22	0	17	
		Gravitational oedema	4	0	2	
		Oedema	9	1	5	
		Oedema peripheral	8	0	8	
		Breakthrough pain	1	0	0	
		Chest pain	54	0	38	
		Discomfort	1	0	1	
		Pain	32	0	28	
		Chest discomfort	5	0	4	
		Chills	27	0	16	
		Feeling abnormal	9	1	9	
		Feeling cold	1	0	1	
		Feeling hot	1	0	1	
		Thirst	6	0	5	
		Drug interaction	10	2	0	
		Drug ineffective	88	5	73	
		Drug tolerance increased	1	0	1	
		Therapeutic response decreased	3	0	1	
		Therapeutic response unexpected	11	0	11	
		Therapeutic response unexpected with drug substitution	11	0	11	
	Drug withdrawal syndrome	12	0	11		
	Drug withdrawal syndrome neonatal	11	0	7		
	Product substitution issue	7	0	7		
		General disorders and administration site conditions	677	25	516	
		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		19	2	12	
	Liver injury		1	0	0	
	Hepatic function abnormal		59	1	34	
	Hepatic failure		3	2	2	
	Hepatic cirrhosis		2	1	0	
	Hepatomegaly		2	0	0	
	Hepatosplenomegaly	2	0	0		

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole	
Reaction Count	Hepatobiliary disorders	Hepatic necrosis	1	1	0	
		Hepatitis	16	0	8	
		Hepatocellular injury	2	0	1	
		Hepatobiliary disorders	119	7	67	
	Immune system disorders	Hypersensitivity	4	0	4	
		Serum sickness	1	0	1	
		Drug hypersensitivity	2	0	2	
		Food allergy	1	0	1	
		Anaphylactic reaction	2	0	1	
		Anaphylactoid reaction	2	0	2	
		Immune system disorders	12	0	11	
		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	
	Bronchiectasis		1	0	1	
	Lower respiratory tract infection		2	0	2	
	Lung infection		1	0	1	
	Pneumonia		4	2	1	
	Sepsis		1	1	0	
	Rash pustular		4	0	3	
	Laryngitis		1	0	1	
	Pharyngitis		6	0	5	
	Rhinitis		6	0	5	
	Sinusitis		2	0	2	
	Cystitis		1	0	1	
	Urinary tract infection		8	0	5	
	Herpes simplex		2	0	2	
	Viral infection		1	0	0	
	Infections and infestations		52	3	37	
	Injury, poisoning and procedural complications	Drug toxicity	3	3	0	
		Therapeutic agent toxicity	1	0	0	
Drug exposure during pregnancy		20	1	14		
Fall		12	0	6		
Wound haemorrhage		1	0	0		
Anal injury		1	0	1		
Contusion		7	0	7		

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Injury, poisoning and procedural complications	Drug administration error	2	1	1
		Drug dose omission	1	0	0
		Inappropriate schedule of drug administration	1	0	1
		Underdose	1	0	1
		Medication error	3	0	2
		Drug exposure via breast milk	2	0	2
		Accidental overdose	1	0	1
		Intentional overdose	7	2	4
		Overdose	8	1	3
		Post procedural haemorrhage	1	0	1
		Injury, poisoning and procedural complications	72	8	44
	Investigations	Electrocardiogram QT prolonged	2	0	1
		Electrocardiogram abnormal	6	0	1
		Heart rate increased	2	0	2
		Blood pressure decreased	5	0	2
		Blood pressure increased	6	0	6
		Blood pressure systolic increased	1	0	0
		Glucocorticoids increased	1	0	0
		Hormone level abnormal	1	0	1
		Blood prolactin increased	1	0	0
		Blood thyroid stimulating hormone decreased	1	0	1
		Thyroid function test abnormal	1	0	1
Blood creatine phosphokinase increased		15	1	5	
Blood alkaline phosphatase increased		1	0	1	
Blood amylase increased		1	0	0	
Bleeding time prolonged		3	0	3	
International normalised ratio increased		1	0	0	
Prothrombin level decreased		8	0	1	
Red blood cell sedimentation rate increased		1	0	1	
White blood cell count increased		1	0	1	
Alanine aminotransferase increased		1	0	0	
Aspartate aminotransferase increased		2	0	1	
Gamma-glutamyltransferase increased		3	0	2	
Hepatic enzyme abnormal		1	0	1	
Hepatic enzyme increased		1	0	1	
Liver function test abnormal		9	1	7	
Antinuclear antibody increased		1	0	1	
Laboratory test abnormal		1	0	1	
Blood cholesterol increased		2	0	1	
Blood glucose increased		1	0	1	
Blood folate decreased	1	0	1		

Medicine summary -sertraline (to date)

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Reaction Count	Investigations	CSF pressure increased	1	0	1	
		Electroencephalogram abnormal	2	0	1	
		Nerve conduction studies abnormal	1	0	1	
		Apgar score low	2	0	2	
		Body temperature increased	1	0	0	
		Weight decreased	45	0	36	
		Weight increased	85	1	75	
		Blood albumin decreased	1	0	1	
		C-reactive protein increased	2	0	2	
		Globulins increased	1	0	1	
		Blood creatinine decreased	1	0	1	
		Blood creatinine increased	1	0	1	
		Blood urine present	2	0	1	
		Semen analysis abnormal	1	0	1	
		Antipsychotic drug level increased	1	0	0	
		Drug level above therapeutic	1	0	0	
		Drug level decreased	2	0	0	
		Drug level increased	16	2	0	
		Blood sodium decreased	6	0	5	
		Blood osmolarity decreased	1	0	0	
		Urine osmolarity decreased	1	0	0	
		Investigations		255	5	173
		Metabolism and nutrition disorders	Ketosis	1	0	1
			Metabolic acidosis	1	0	0
			Acidosis	3	0	2
Decreased appetite	55		2	46		
Increased appetite	12		0	10		
Failure to thrive	1		0	1		
Feeding disorder neonatal	2		0	2		
Hypocalcaemia	1		0	0		
Tetany	6		0	5		
Hypermagnesaemia	1		0	1		
Diabetic ketoacidosis	1		0	0		
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	196		3	128		
Dehydration	6		0	4		

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Metabolism and nutrition disorders	Hypovolaemia	1	0	0
		Alcohol intolerance	8	0	5
		Lactose intolerance	1	0	1
		Diabetes mellitus	5	0	5
		Glucose tolerance impaired	1	0	1
		Hyperglycaemia	7	0	7
		Hypoglycaemia	15	0	10
		Mineral deficiency	1	0	1
		Hyperlipidaemia	1	0	1
		Hypoproteinaemia	1	0	0
		Gout	1	0	1
		Metabolism and nutrition disorders	352	6	248
		Musculoskeletal and connective tissue disorders	Bone pain	2	0
	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		5	0	4
	Arthralgia		38	0	29
	Joint stiffness		1	0	0
	Joint swelling		2	0	2
	Osteoarthritis		5	0	4
	Rheumatoid arthritis		1	0	1
	Myalgia		58	0	48
	Muscle atrophy		1	0	1
	Muscle spasms		20	0	14
Muscle tightness	1		0	1	
Muscle twitching	64		0	49	
Hypotonia neonatal	3		0	3	
Muscle rigidity	7		0	4	
Trismus	1		0	1	
Muscular weakness	6		0	5	
Myopathy	1		0	0	
Rhabdomyolysis	5		0	3	
Mobility decreased	1		0	1	
Musculoskeletal stiffness	5	0	2		
Sensation of heaviness	1	0	1		
Back pain	11	0	8		
Neck pain	2	0	1		
Pain in extremity	3	0	3		
Bursitis	2	0	2		

Medicine summary -sertraline (to date)

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Reaction Count	Musculoskeletal and connective tissue disorders	Tendonitis	1	0	1
		Musculoskeletal and connective tissue disorders	256	0	198
	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
		Lymphoma	1	0	1
		Non-Hodgkin's Lymphoma	1	0	0
		Metastasis	1	0	1
		Prolactinoma	1	0	1
		Paraproteinaemia	1	0	1
		Sarcoma	2	0	2
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10	1	7
			Nervous system disorders	Cerebral haemorrhage	3
Cerebrovascular accident	3			0	3
Haemorrhage intracranial	1			0	0
Cerebrovascular disorder	4			2	3
Cerebrovascular spasm	1			0	1
Facial spasm	1			0	0
VIIth nerve paralysis	3			0	3
Tongue paralysis	1			0	0
Parosmia	3			0	2
Multiple sclerosis	1			0	1
Encephalopathy	2			1	1
Headache	303			0	266
Tension headache	3			0	2
Migraine	29			0	25
Brain oedema	1			1	0
Intracranial pressure increased	1			0	1
Dementia	2			0	0
Amnesia	53			0	43
Memory impairment	3			0	2
Cognitive disorder	6			0	3
Disturbance in attention	30			1	26
Judgement impaired	1			0	1
Mental impairment	2			0	1
Choreoathetosis	5			0	3
Akathisia	17			0	12
Bradykinesia	1			0	1
Dyskinesia	40			0	30
Extrapyramidal disorder	18	1	12		

Medicine summary -sertraline (to date)

Reaction Count			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Hyperkinesia	37	0	27
		Hypokinesia	8	0	7
		Movement disorder	1	0	1
		Psychomotor hyperactivity	3	0	3
		Tardive dyskinesia	6	0	5
		Dystonia	55	0	40
		Hemiparesis	4	0	2
		Paralysis	3	0	3
		Paresis	3	0	3
		Parkinsonism	2	0	1
		Tremor	257	1	198
		Tremor neonatal	1	0	1
		Hyperreflexia	12	0	4
		Hyporeflexia	1	0	0
		Reflexes abnormal	1	0	1
		Ataxia	30	0	25
		Balance disorder	3	0	3
		Coordination abnormal	17	0	13
		Nystagmus	6	0	3
		Coma	10	2	5
		Aphasia	6	0	6
		Dysgraphia	2	0	2
		Consciousness fluctuating	7	0	1
		Depressed level of consciousness	1	0	1
		Lethargy	11	0	8
		Loss of consciousness	7	0	5
		Sedation	1	0	0
		Somnolence	131	1	114
		Somnolence neonatal	2	0	2
		Stupor	3	0	3
		Syncope	65	2	49
		Central nervous system lesion	1	0	0
		Clonus	1	0	0
		Dizziness	300	0	263
		Myoclonus	6	0	2
		Neurological symptom	1	0	0
		Presyncope	1	0	1
		Unresponsive to stimuli	1	0	0
		Crying	10	0	9
		Burning sensation	5	0	5
Formication	3	0	3		
Hyperaesthesia	7	0	5		

Medicine summary -sertraline (to date)

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Reaction Count	Nervous system disorders	Paraesthesia	116	0	104		
		Ageusia	3	0	1		
		Dysgeusia	12	0	11		
		Hypoaesthesia	38	0	32		
		Neuralgia	2	0	2		
		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	6	0	4		
		Hypertonia	62	0	42		
		Hypotonia	1	0	1		
		Neuroleptic malignant syndrome	8	0	0		
		Serotonin syndrome	89	0	31		
		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	33	1	18		
		Convulsion	142	3	97		
		Convulsive threshold lowered	1	0	0		
		Epilepsy	4	0	4		
		Tonic convulsion	2	0	0		
		Hypersomnia	2	0	1		
		Poor quality sleep	3	0	3		
		Nerve root lesion	1	0	1		
			Nervous system disorders		2149	17	1659
		Pregnancy, puerperium and perinatal conditions	Abortion	2	0	2	
			Abortion spontaneous	9	0	6	
			Intra-uterine death	9	1	8	
			Stillbirth	1	0	1	
Foetal distress syndrome	1		0	0			
Labour onset delayed	1		0	1			
Premature labour	1		0	1			
Premature rupture of membranes	2		0	2			
Premature separation of placenta	1		0	1			
Ectopic pregnancy	1		0	1			
Hyperemesis gravidarum	1		0	0			
Premature baby	3		0	0			

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	1	0	0
		Neonatal disorder	12	0	7
		Postpartum haemorrhage	1	0	1
		Unintended pregnancy	2	0	0
		Pregnancy, puerperium and perinatal conditions	48	1	31
	Psychiatric disorders	Agitation	429	2	367
		Agitation neonatal	7	0	7
		Anxiety	216	0	191
		Nervousness	29	0	18
		Stress	3	1	2
		Tension	1	0	1
		Fear	2	0	2
		Panic attack	12	0	11
		Panic reaction	2	0	2
		Post-traumatic stress disorder	1	0	0
		Neurosis	27	0	21
		Obsessive thoughts	2	0	2
		Obsessive-compulsive disorder	3	0	2
		Catatonia	2	0	2
		Restlessness	10	0	5
		Automatism	2	0	1
		Bruxism	47	0	44
		Tic	2	0	2
		Change in sustained attention	1	0	1
		Reading disorder	1	0	1
		Screaming	2	0	2
		Confusional state	155	1	93
Disorientation		8	0	7	
Delirium		26	0	17	
Agitated depression	1	0	1		
Depression	66	2	45		
Depressed mood	5	0	3		
Tearfulness	5	0	3		
Depersonalisation	72	0	66		
Dissociation	1	0	1		
Delusion	14	0	11		
Thought insertion	1	0	1		
Hallucination	81	0	58		
Hallucination, auditory	4	0	3		
Hallucination, visual	5	0	1		
Hallucinations, mixed	1	0	0		

Medicine summary -sertraline (to date)

Reaction Count	Psychiatric disorders		Case Group	Death Outcomes	Sole
		Bradyphrenia	1	0	1
		Tachyphrenia	1	0	1
		Thinking abnormal	44	0	33
		Eating disorder	2	0	1
		Compulsive shopping	1	0	1
		Pathological gambling	2	0	2
		Bipolar disorder	1	0	1
		Hypomania	2	0	2
		Mania	56	0	48
		Affect lability	24	0	21
		Anger	5	0	4
		Dysphoria	1	0	0
		Emotional disorder	1	0	1
		Emotional distress	2	0	2
		Euphoric mood	13	0	11
		Mood altered	2	0	0
		Mood swings	9	1	7
		Apathy	9	1	7
		Aggression	70	0	47
		Homicidal ideation	9	0	6
		Paranoia	25	1	14
		Personality change	4	1	2
		Social avoidant behaviour	1	1	0
		Violence-related symptom	3	0	2
		Personality disorder	3	0	1
		Abnormal behaviour	4	0	3
		Staring	1	0	1
		Hypervigilance	1	0	1
		Mental disorder	5	0	2
		Mental status changes	1	0	1
		Alcoholism	3	0	2
		Drug dependence	3	0	3
		Withdrawal syndrome	214	0	195
		Delusional disorder, unspecified type	1	0	0
		Acute psychosis	1	0	1
		Psychotic disorder	40	0	29
		Schizophreniform disorder	3	0	2
		Schizophrenia	1	0	1
		Anorgasmia	60	0	57
		Libido decreased	139	0	129
		Libido increased	7	0	7
		Loss of libido	3	1	1

Medicine summary -sertraline (to date)

		Case Group	Death Outcomes	Sole		
Reaction Count	Psychiatric disorders	Insomnia	259	1	234	
		Abnormal dreams	12	0	10	
		Abnormal sleep-related event	1	0	1	
		Nightmare	55	0	47	
		Somnambulism	3	0	3	
		Sleep disorder	16	0	15	
		Conversion disorder	1	0	1	
		Completed suicide	8	8	5	
		Intentional self-injury	4	0	3	
		Self injurious behaviour	3	0	3	
		Self-injurious ideation	1	0	1	
		Suicidal behaviour	4	1	3	
		Suicidal ideation	55	0	44	
		Suicide attempt	56	6	42	
			Psychiatric disorders	2502	28	2056
Reaction Count	Renal and urinary disorders	Glomerulonephritis	1	0	0	
		Nephrotic syndrome	1	0	1	
		Goodpasture's syndrome	1	0	1	
		Tubulointerstitial nephritis	1	0	0	
		Oliguria	1	0	1	
		Renal failure	2	0	1	
		Renal failure acute	5	0	0	
		Renal failure chronic	1	0	0	
		Renal impairment	7	0	4	
		Bladder spasm	1	0	1	
		Dysuria	10	0	8	
		Enuresis	2	0	2	
		Micturition disorder	13	0	11	
		Micturition urgency	1	0	1	
		Pollakiuria	17	0	16	
		Urinary hesitation	1	0	1	
		Urinary incontinence	25	1	21	
		Urinary retention	26	0	23	
		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	
			Renal and urinary disorders	139	1	111
		Reaction Count	Reproductive system and breast disorders	Breast calcifications	1	0

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole		
Reaction Count	Reproductive system and breast disorders	Breast enlargement	5	0	3		
		Breast mass	4	0	3		
		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		
		Metrorrhagia	19	0	17		
		Amenorrhoea	7	0	5		
		Menorrhagia	14	0	12		
		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		
		Infertility female	2	0	2		
		Sexual dysfunction	37	0	36		
		Azoospermia	1	0	1		
		Testicular disorder	2	0	2		
		Uterine disorder	1	0	1		
		Uterine haemorrhage	7	0	7		
		Uterine pain	1	0	1		
		Vaginal haemorrhage	19	0	17		
		Vaginal mucosal blistering	1	0	1		
		Vulval disorder	2	0	2		
		Vulvovaginal pain	1	0	1		
			Reproductive system and breast disorders		366	0	337
			Respiratory, thoracic and mediastinal disorders	Asthma	2	0	2
				Bronchospasm	12	0	10
				Wheezing	1	0	1
				Eosinophilic pneumonia	1	0	1
				Pneumonitis	2	0	2
				Pulmonary oedema	1	0	1
				Infantile apnoeic attack	1	0	1

Medicine summary -sertraline (to date)

		Case Group	Death Outcomes	Sole			
Reaction Count	Respiratory, thoracic and mediastinal disorders	Neonatal respiratory depression	2	0	2		
		Neonatal respiratory distress syndrome	2	0	0		
		Neonatal respiratory failure	1	0	0		
		Pulmonary hypertension	2	0	0		
		Pulmonary embolism	3	0	1		
		Apnoea	2	0	2		
		Dyspnoea	56	1	37		
		Hyperventilation	9	0	7		
		Respiratory arrest	1	0	1		
		Tachypnoea	1	0	0		
		Asphyxia	1	1	1		
		Hypoxia	1	0	1		
		Cough	16	0	16		
		Haemoptysis	1	0	1		
		Sputum increased	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		
		Oropharyngeal pain	2	0	2		
		Rhinorrhoea	2	0	2		
		Throat irritation	1	0	0		
		Throat tightness	8	0	6		
		Yawning	44	0	41		
		Stridor	1	0	1		
		Nasal congestion	1	0	1		
		Epistaxis	21	0	17		
		Pharyngeal oedema	2	0	2		
			Respiratory, thoracic and mediastinal disorders	212	3	168	
		Reaction Count	Skin and subcutaneous tissue disorders	Angioedema	10	0	6
				Urticaria	50	0	44
				Lichenoid keratosis	3	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		

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	Skin discolouration	4	0	4
		Skin disorder	2	0	1
		Skin odour abnormal	2	0	2
		Swelling face	6	0	5
		Yellow skin	1	0	1
		Dermatitis	2	0	1
		Dermatitis allergic	1	0	1
		Eczema	3	0	2
		Neurodermatitis	1	0	1
		Drug eruption	1	0	1
		Erythema	1	0	1
		Rash erythematous	35	0	31
		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	105	1	91
		Rash pruritic	5	0	4
		Dermatitis psoriasiform	1	0	1
		Psoriasis	3	0	3
		Pustular psoriasis	1	0	1
		Rash follicular	1	0	0
		Rash	160	0	143
		Rash macular	1	0	0
		Rash maculo-papular	50	0	40
		Rash morbilliform	2	0	2
		Rash vesicular	3	0	3
		Chloasma	1	0	1
		Erythema nodosum	6	0	6
		Acne	23	0	18
		Alopecia	40	0	34
		Cold sweat	7	0	5
		Hyperhidrosis	217	1	176
		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	2	0	1
Purpura	50	0	39		
	Skin and subcutaneous tissue disorders	865	2	724	

Medicine summary -sertraline (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Social circumstances	Physical assault	1	0	1
		Activities of daily living impaired	1	0	1
		Learning disability	1	0	1
		Social circumstances	3	0	3
	Surgical and medical procedures	Drug therapy changed	20	0	20
		Therapy regimen changed	14	0	12
		Surgical and medical procedures	34	0	32
	Vascular disorders	Aortic stenosis	1	0	1
		Ischaemia	1	0	1
		Peripheral ischaemia	2	0	1
		Peripheral coldness	1	0	1
		Blood pressure fluctuation	1	0	0
		Circulatory collapse	7	0	4
		Hypotension	29	1	14
		Orthostatic hypotension	28	0	21
		Thrombosis	2	0	2
		Deep vein thrombosis	2	0	1
		Vasodilatation	2	0	2
		Vein disorder	1	0	1
		Flushing	58	0	50
		Hot flush	28	0	23
		Pallor	3	0	3
		Haematoma	3	0	1
		Haemorrhage	10	0	5
		Hypertension	45	0	34
		Vasculitis	1	0	0
		Vascular disorders	225	1	165
Reaction			10456	132	8337