



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

FLUOXETINE HYDROCHLORIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		1306	14	943
- Occurrences of Medicine		1320	14	943
- Reactions Related to Medicine		3018	37	2081
Blood and lymphatic system disorders	Normochromic normocytic anaemia	1	0	1
	Aplastic anaemia	1	0	0
	Thrombocythaemia	1	0	0
	Thrombocytopenia	8	0	4
	Thrombocytopenic purpura	2	0	1
	Lymphadenopathy	3	0	3
	Splenomegaly	1	0	1
	Eosinophilia	2	0	0
	Leukocytosis	4	0	2
	Lymphocytosis	1	0	0
	Leukopenia	5	0	3
	Lymphopenia	3	0	1
	Agranulocytosis	2	0	0
	Neutropenia	9	0	6
Cardiac disorders	Atrioventricular block	3	0	1
	Bundle branch block	1	0	1
	Arrhythmia	5	0	4
	Bradycardia	6	0	2
	Extrasystoles	2	0	1
	Tachycardia	17	0	13
	Sinus tachycardia	1	0	0
	Cardiac arrest	1	0	0
	Ventricular arrhythmia	1	0	1
	Ventricular fibrillation	1	0	0
	Ventricular tachycardia	1	0	0
	Cyanosis	2	0	2
	Palpitations	16	0	12
	Mitral valve incompetence	1	0	0

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Cardiac disorders	Myocardial infarction	2	2	1
	Cardiac failure	3	0	1
	Cardiomyopathy	1	0	0
	Cardiomegaly	1	0	0
	Pericardial effusion	1	0	0
Congenital, familial and genetic disorders	Heart disease congenital	1	0	1
	Ventricular septal defect	1	0	1
	Coarctation of the aorta	2	0	2
	Vascular malformation peripheral	2	0	1
	Trisomy 21	1	0	1
	Congenital foot malformation	1	0	0
	Talipes	1	0	1
	Hypospadias	1	0	0
Ear and labyrinth disorders	Tinnitus	6	0	6
	Vertigo	6	0	3
Endocrine disorders	Hyperprolactinaemia	9	0	8
	Inappropriate antidiuretic hormone secretior	12	2	7
	Thyroiditis	1	0	1
	Goitre	1	0	1
	Hyperthyroidism	2	0	2
Eye disorders	Cataract	2	0	0
	Eye pain	2	0	1
	Glaucoma	4	0	4
	Conjunctivitis	3	0	1
	Oculogyration	1	0	0
	Miosis	1	0	0
	Mydriasis	5	0	3
	Retinal haemorrhage	1	0	0
	Accommodation disorder	2	0	2
	Diplopia	1	0	0
	Vision blurred	3	0	2
	Visual disturbance	20	0	15
	Scotoma	1	0	0
Gastrointestinal disorders	Tooth disorder	2	0	1
	Toothache	1	0	1

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Gastrointestinal disorders	Gingivitis	1	0	1
	Pancreatitis	1	0	1
	Rectal haemorrhage	5	0	4
	Gastrointestinal haemorrhage	3	0	0
	Melaena	1	0	1
	Gastritis	1	0	1
	Oesophagitis	1	0	1
	Proctitis	1	0	1
	Diarrhoea	42	0	35
	Constipation	2	0	1
	Dyspepsia	17	0	15
	Eructation	3	0	1
	Flatulence	9	0	5
	Abdominal pain	27	0	23
	Abdominal pain upper	1	0	1
	Infantile colic	1	0	1
	Dysphagia	6	0	3
	Faecal incontinence	1	0	1
	Nausea	110	0	89
	Vomiting	42	0	26
	Ileus	1	0	0
	Gastritis erosive	1	0	0
	Cheilitis	1	0	1
	Lip swelling	2	0	2
	Mouth ulceration	12	0	11
	Stomatitis	1	0	0
	Retroperitoneal fibrosis	1	0	0
	Dry mouth	11	0	8
	Salivary hypersecretion	3	0	3
	Glossitis	2	0	2
	Tongue ulceration	1	0	0
	Tongue discolouration	1	0	1
	Tongue oedema	3	0	2
General disorders and administration site conditions	Application site reaction	1	0	0
	Hypothermia	3	0	1



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General disorders and administration site conditions	Chills	15	0	9
	Feeling cold	1	0	0
	Feeling hot	1	0	1
	Feeling hot and cold	1	0	1
	Pyrexia	18	0	10
	Death	1	1	0
	Sudden death	2	2	0
	Asthenia	10	1	7
	Fatigue	38	0	30
	Malaise	21	0	17
	Gait disturbance	5	0	1
	Condition aggravated	1	0	0
	Feeling abnormal	1	0	0
	Feeling jittery	1	0	1
	Influenza like illness	6	0	5
	Irritability	3	0	2
	Thirst	3	0	1
	Face oedema	12	0	7
	Generalised oedema	1	0	1
	Gravitational oedema	5	0	4
	Oedema	6	0	4
	Oedema peripheral	14	0	10
	Chest pain	16	0	12
	Pain	10	0	10
	Drug interaction	1	0	0
	Drug ineffective	50	1	42
	Drug withdrawal syndrome	21	0	18
	Drug withdrawal syndrome neonatal	4	0	4
	Therapeutic response decreased	2	0	2
	Therapeutic response unexpected	2	0	2
Hepatobiliary disorders	Cholecystitis	2	0	1
	Cholelithiasis	2	0	1
	Cholestasis	1	0	1
	Hepatitis cholestatic	6	0	5
	Jaundice	3	0	2

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Hepatobiliary disorders	Jaundice cholestatic	1	0	1
	Hepatic function abnormal	30	0	12
	Hepatic cirrhosis	1	0	0
	Hepatomegaly	1	0	0
	Hepatosplenomegaly	1	0	1
	Hepatic steatosis	1	0	0
	Hepatitis	7	0	2
	Hepatocellular damage	1	0	1
Immune system disorders	Hypersensitivity	4	0	3
	Serum sickness	3	0	3
	Anaphylactic reaction	1	0	1
	Anaphylactoid reaction	2	0	1
Infections and infestations	Oral candidiasis	1	0	0
	Diverticulitis	1	0	1
	Vaginal infection	2	0	2
	Pneumonia	1	0	0
	Sepsis	2	0	1
	Furuncle	1	0	1
	Rash pustular	1	0	0
	Pharyngitis	4	0	2
	Rhinitis	4	0	3
	Cystitis	2	0	2
	Herpes simplex	3	0	3
	Influenza	2	0	1
Injury, poisoning and procedural complications	Drug exposure during pregnancy	4	0	3
	Fall	1	0	1
	Medication error	1	0	1
	Intentional overdose	1	0	0
Investigations	Electrocardiogram QT prolonged	4	0	1
	Blood pressure decreased	1	0	1
	Blood creatine phosphokinase increased	7	0	2
	Troponin increased	1	0	0
	Bleeding time prolonged	3	0	3
	Prothrombin level decreased	2	0	1
	Red blood cell sedimentation rate increased	4	0	4

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Investigations	Platelet aggregation abnormal	1	0	0
	White blood cell count increased	1	0	0
	Blood bilirubin increased	1	0	1
	Liver function test abnormal	3	0	1
	Antinuclear antibody positive	1	0	1
	Electroencephalogram abnormal	1	0	0
	Weight decreased	21	1	11
	Weight increased	14	0	8
	C-reactive protein increased	1	0	1
	Urine analysis abnormal	1	0	0
	Semen abnormal	1	0	1
	Drug level above therapeutic	1	0	0
	Drug level decreased	2	0	0
	Drug level increased	12	0	0
	Metabolism and nutrition disorders	Metabolic acidosis	1	0
Acidosis		1	0	0
Anorexia		28	1	23
Increased appetite		5	0	4
Feeding disorder neonatal		1	0	1
Hyperchloraemia		1	0	0
Hypokalaemia		2	0	1
Hypernatraemia		1	0	1
Hyponatraemia		55	1	40
Dehydration		6	0	3
Alcohol intolerance		2	0	1
Diabetes mellitus		2	0	2
Hyperglycaemia		5	0	3
Hypoglycaemia		5	0	4
Iron deficiency		1	0	1
Hypercholesterolaemia		2	0	2
Hypertriglyceridaemia		1	0	1
Hyperlipidaemia	2	0	2	
Musculoskeletal and connective tissue disorders	Osteoporosis	1	0	1
	Systemic lupus erythematosus	1	0	1
	Arthritis	5	0	4

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Musculoskeletal and connective tissue disorders	Arthralgia	30	0	26
	Osteoarthritis	2	0	2
	Myositis	1	0	1
	Myalgia	23	0	16
	Muscle spasms	2	0	2
	Muscle twitching	16	0	14
	Nuchal rigidity	1	0	0
	Torticollis	1	0	0
	Trismus	1	0	1
	Muscular weakness	1	0	0
	Rhabdomyolysis	1	0	0
	Upper limb deformity	1	0	1
	Back pain	8	0	3
	Mobility decreased	1	0	0
	Musculoskeletal stiffness	1	0	0
	Bursitis	1	0	1
	Synovitis	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer male	2	0	2
	Colon cancer	1	0	0
	Gastric cancer	1	1	1
	Angiocentric lymphoma	1	1	0
Nervous system disorders	Cerebral haemorrhage	1	1	0
	Cerebrovascular disorder	2	0	0
	Headache	66	1	54
	Migraine	7	0	3
	Dementia	1	0	0
	Amnesia	13	0	9
	Memory impairment	1	0	0
	Cognitive disorder	1	0	0
	Disturbance in attention	9	0	6
	Mental impairment	1	0	1
	Choreoathetosis	2	0	2
	Akathisia	9	1	5
	Dyskinesia	16	0	12
	Extrapyramidal disorder	8	1	4

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Nervous system disorders	Hyperkinesia	17	0	11
	Hypokinesia	1	0	1
	Psychomotor hyperactivity	2	0	1
	Tardive dyskinesia	1	0	0
	Dystonia	14	0	9
	Hemiparesis	3	0	1
	Paralysis	2	0	2
	Paresis	3	0	3
	Quadriplegia	1	0	0
	Tremor	70	0	48
	Hyperreflexia	4	0	0
	Reflexes abnormal	1	0	1
	Balance disorder	2	0	2
	Coordination abnormal	19	1	9
	Coma	5	0	1
	Consciousness fluctuating	2	1	0
	Loss of consciousness	3	0	2
	Sedation	1	0	0
	Somnolence	44	1	23
	Syncope	13	0	10
	Dizziness	51	0	38
	Meningism	1	0	1
	Myoclonus	3	0	1
	Hyperaesthesia	1	0	1
	Hypoaesthesia	8	0	7
	Paraesthesia	23	0	18
	Ageusia	1	0	1
	Dysgeusia	6	0	4
	Sensory disturbance	2	0	2
	Dysarthria	7	0	6
	Speech disorder	9	0	4
	Visual field defect	1	0	1
	Cholinergic syndrome	1	0	0
	Hypertonia	17	0	9
	Hypotonia	2	0	2

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Nervous system disorders	Neuroleptic malignant syndrome	2	1	0
	Serotonin syndrome	18	1	1
	Neuropathy	1	0	1
	Neuropathy peripheral	1	0	1
	Convulsion neonatal	2	0	2
	Grand mal convulsion	11	0	3
	Convulsion	31	0	18
	Poor quality sleep	2	0	1
Pregnancy, puerperium and perinatal conditions	Abortion	1	0	1
	Abortion missed	1	0	1
	Abortion spontaneous	1	0	1
	Foetal growth retardation	1	0	0
	Premature labour	1	0	0
	Premature baby	1	0	1
	Jaundice neonatal	1	0	1
	Neonatal disorder	6	0	5
Unintended pregnancy	2	0	1	
Psychiatric disorders	Neurosis	3	0	1
	Obsessive-compulsive disorder	1	0	1
	Agitation	70	0	51
	Agitation neonatal	3	0	3
	Anxiety	72	2	54
	Nervousness	13	0	10
	Stress	1	0	1
	Fear	1	0	1
	Panic disorder	1	0	1
	Panic attack	4	0	2
	Panic reaction	1	0	1
	Agoraphobia	1	1	0
	Restlessness	3	0	2
	Bruxism	5	0	3
	Change in sustained attention	1	0	0
	Mutism	1	0	0
	Confusional state	52	0	26
	Disorientation	3	0	0

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Psychiatric disorders	Delirium	13	0	5
	Depression	27	1	17
	Depression suicidal	1	0	0
	Feeling of despair	1	0	1
	Depersonalisation	7	0	3
	Dissociation	1	0	1
	Delusion	2	0	2
	Hallucination	20	0	13
	Hallucination, auditory	6	0	5
	Hallucination, visual	2	0	0
	Thinking abnormal	21	0	14
	Eating disorder	1	0	0
	Hypomania	2	0	2
	Mania	21	0	17
	Affect lability	6	0	4
	Anger	2	0	1
	Crying	4	0	2
	Dysphoria	1	0	0
	Euphoric mood	13	0	11
	Frustration	1	0	0
	Mood swings	3	0	1
	Apathy	5	0	4
	Aggression	28	0	17
	Homicidal ideation	5	0	3
	Paranoia	2	0	1
	Personality change	1	0	1
	Personality disorder	6	0	5
	Abnormal behaviour	2	0	0
	Hypervigilance	1	0	0
	Psychotic disorder	6	0	4
	Anorgasmia	7	0	7
	Libido decreased	14	0	13
	Libido increased	5	0	3
	Loss of libido	1	0	0
Insomnia	68	1	55	

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FLUOXETINE HYDROCHLORIDE		Layer 1 of 1		
Psychiatric disorders	Abnormal dreams	3	0	3
	Abnormal sleep-related event	2	0	0
	Nightmare	12	0	9
	Sleep walking	2	0	1
	Sleep disorder	2	0	2
	Conversion disorder	1	0	1
	Somatoform disorder pregnancy	1	0	1
	Completed suicide	1	1	0
	Intentional self-injury	2	0	1
	Self injurious behaviour	2	1	0
	Suicidal ideation	18	0	10
	Suicide attempt	51	4	28
	Renal and urinary disorders	Nephritis interstitial	1	0
Anuria		1	0	0
Oliguria		1	0	0
Renal failure acute		4	0	1
Renal impairment		1	0	0
Dysuria		4	0	3
Micturition disorder		3	0	3
Pollakiuria		6	0	4
Urinary incontinence		9	0	3
Urinary retention		11	0	8
Glycosuria		1	0	1
Haematuria		4	0	2
Pyuria		1	0	0
Nocturia		2	0	2
Renal pain		1	0	1
Reproductive system and breast disorders	Breast enlargement	8	0	6
	Gynaecomastia	7	0	6
	Breast pain	13	0	10
	Galactorrhoea	16	0	14
	Epididymitis	1	0	0
	Menopausal symptoms	1	0	1
	Dysmenorrhoea	1	0	1
	Amenorrhoea	4	0	4

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Reproductive system and breast disorders	Menorrhagia	5	0	4
	Ejaculation failure	7	0	7
	Erectile dysfunction	11	0	10
	Sexual dysfunction	3	0	3
	Testicular disorder	2	0	1
	Vaginal haemorrhage	2	0	2
	Vulval disorder	1	0	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	8	0	7
	Lung infiltration	1	0	1
	Infantile apnoeic attack	2	0	0
	Pulmonary hypertension	1	0	0
	Pulmonary embolism	1	1	0
	Dyspnoea	15	0	12
	Hypoventilation	1	0	1
	Hypoxia	2	0	0
	Cough	5	0	3
	Respiratory failure	1	0	0
	Respiratory disorder	1	0	1
	Choking	1	0	1
	Pharyngolaryngeal pain	1	0	0
	Throat irritation	1	0	1
	Throat tightness	1	0	1
	Yawning	2	0	2
	Laryngospasm	2	0	1
Epistaxis	5	0	4	
Skin and subcutaneous tissue disorders	Angioedema	10	0	8
	Periorbital oedema	4	0	3
	Urticaria	52	0	41
	Lichenoid keratosis	1	0	1
	Skin hypertrophy	1	0	1
	Dermatitis bullous	5	0	4
	Erythema multiforme	2	0	1
	Systemic lupus erythematosus rash	1	0	1
	Hypoaesthesia facial	1	0	1
	Skin discolouration	3	0	3

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Skin and subcutaneous tissue disorders	Skin odour abnormal	1	0	1
	Swelling face	2	0	2
	Rash erythematous	14	0	10
	Dermatitis exfoliative	1	0	1
	Skin exfoliation	3	0	3
	Rash papular	1	0	1
	Photosensitivity reaction	4	0	2
	Pruritus	63	0	54
	Rash pruritic	2	0	1
	Dermatitis psoriasiform	1	0	1
	Psoriasis	4	0	3
	Fixed eruption	1	0	1
	Rash	50	0	45
	Rash generalised	1	0	1
	Rash maculo-papular	30	0	27
	Rash morbilliform	3	0	2
	Rash vesicular	3	0	3
	Pityriasis	1	0	1
	Chloasma	1	0	0
	Acne	3	0	2
	Alopecia	14	0	8
	Hyperhidrosis	45	0	33
	Hirsutism	1	0	1
	Nail disorder	4	0	4
	Hair colour changes	1	0	1
	Hair texture abnormal	4	0	3
	Henoch-Schonlein purpura	1	0	1
Purpura	27	1	22	
Surgical and medical procedures	Drug therapy changed	2	0	2
	Therapy regimen changed	2	0	1
Vascular disorders	Circulatory collapse	2	0	0
	Hypotension	14	0	7
	Orthostatic hypotension	7	0	4
	Vasodilatation	3	1	2
	Flushing	7	0	6



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Vascular disorders	Hot flush	5	0	3
	Pallor	4	0	3
	Haematoma	4	0	3
	Hypertension	12	0	9
	Vasculitis	5	0	5