



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

FLUVOXAMINE MALEATE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		279	7	172
- Occurrences of Medicine		281	7	172
- Reactions Related to Medicine		726	17	413
Blood and lymphatic system disorders	Anaemia	2	0	1
	Coagulopathy	1	0	0
	Platelet disorder	1	0	1
	Thrombocythaemia	1	0	0
	Leukocytosis	1	0	0
	Neutropenia	3	0	3
Cardiac disorders	Bradycardia	2	0	0
	Tachycardia	7	0	2
	Atrial fibrillation	1	0	0
	Sinus tachycardia	1	0	0
	Cardiac arrest	1	1	0
	Palpitations	5	0	4
	Cardiac failure	1	0	0
	Cardiac failure congestive	1	0	0
	Cardiomyopathy	1	0	0
	Atrial hypertrophy	1	0	0
	Myocarditis	1	0	0
Ear and labyrinth disorders	Tinnitus	2	0	2
	Vertigo	1	0	1
Endocrine disorders	Cushing's syndrome	1	0	0
	Diabetes insipidus	1	0	1
	Hyperthyroidism	1	0	0
Eye disorders	Lacrimal disorder	1	0	0
	Oculogyration	1	0	1
	Mydriasis	3	0	0
	Vision blurred	2	0	0
	Visual disturbance	7	0	5
Gastrointestinal disorders	Gingivitis	1	0	1

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Gastrointestinal disorders	Gastric haemorrhage	1	0	0
	Gastrointestinal haemorrhage	2	0	0
	Haematemesis	1	0	0
	Reflux oesophagitis	1	0	1
	Diarrhoea	13	0	9
	Constipation	3	0	2
	Gastrooesophageal reflux disease	2	0	2
	Dyspepsia	1	0	1
	Eructation	1	0	1
	Abdominal distension	1	0	1
	Abdominal pain	4	0	3
	Dysphagia	2	0	1
	Nausea	31	0	22
	Vomiting	10	0	9
	Dry mouth	6	0	5
	Salivary hypersecretion	1	0	0
	Glossitis	1	0	0
	Tongue oedema	2	0	0
General disorders and administration site conditions	Hypothermia	1	0	0
	Chills	4	0	1
	Pyrexia	3	0	0
	Death	1	1	1
	Sudden death	2	2	1
	Asthenia	7	0	3
	Fatigue	3	0	1
	Malaise	5	0	4
	Gait disturbance	2	0	1
	Chest discomfort	1	0	1
	Energy increased	1	0	0
	Feeling abnormal	1	0	1
	Generalised oedema	1	0	1
	Oedema	1	0	0
	Oedema peripheral	2	0	2
	Chest pain	1	0	1
	Pain	5	0	2

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General disorders and administration site conditions	Drug interaction	7	1	0
	Drug ineffective	4	0	4
	Drug withdrawal syndrome	12	0	11
	Paradoxical drug reaction	1	0	0
	Therapeutic response unexpected	1	0	1
Hepatobiliary disorders	Hepatic function abnormal	3	0	1
	Hepatic failure	1	1	1
	Hepatitis	4	0	4
Immune system disorders	Hypersensitivity	3	0	2
Infections and infestations	Cellulitis	1	0	0
	Nasopharyngitis	1	0	0
Injury, poisoning and procedural complications	Drug toxicity	2	0	0
	Drug exposure during pregnancy	4	1	3
	Contusion	4	0	4
	Drug prescribing error	1	0	0
	Drug exposure via breast milk	1	0	1
	Overdose	1	0	1
Investigations	Ejection fraction decreased	1	0	0
	Electrocardiogram abnormal	1	0	0
	Blood creatine phosphokinase increased	4	0	0
	Troponin increased	1	0	0
	International normalised ratio increased	2	0	0
	Prothrombin level decreased	4	0	1
	Red blood cell sedimentation rate increased	1	0	0
	Eosinophil count increased	1	0	0
	White blood cell count increased	1	0	0
	Liver function test abnormal	2	0	2
	Blood glucose increased	1	0	0
	Weight decreased	1	0	1
	Weight increased	4	0	3
	C-reactive protein increased	1	0	0
	Sperm count decreased	1	0	0
	Drug level increased	11	1	0
Metabolism and nutrition disorders	Anorexia	2	0	2
	Increased appetite	1	0	0

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Metabolism and nutrition disorders	Obesity	1	0	0
	Hypocalcaemia	1	0	0
	Tetany	1	0	1
	Hypochloraemia	1	0	1
	Polydipsia	1	0	1
	Hypokalaemia	3	0	0
	Hyponatraemia	7	0	6
	Dehydration	1	0	1
	Diabetes mellitus inadequate control	1	0	0
	Diabetes mellitus non-insulin-dependent	1	0	0
	Hyperglycaemia	1	0	0
	Hyperlipidaemia	1	0	0
	Musculoskeletal and connective tissue disorders	Bone pain	1	0
Arthralgia		4	0	4
Myalgia		4	0	2
Muscle twitching		2	0	0
Trismus		1	0	1
Muscular weakness		1	0	1
Back pain		1	0	1
Musculoskeletal stiffness		1	0	0
Nervous system disorders	Encephalopathy	1	1	1
	Headache	10	0	6
	Amnesia	3	0	3
	Cognitive disorder	1	0	1
	Disturbance in attention	6	0	5
	Mental impairment	1	0	1
	Choreoathetosis	3	0	2
	Akathisia	8	2	4
	Dyskinesia	3	0	2
	Extrapyramidal disorder	2	0	1
	Hyperkinesia	3	0	2
	Dystonia	7	0	4
	Tremor	11	0	7
	Hyperreflexia	1	0	0
	Hyporeflexia	2	0	2

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Nervous system disorders	Coordination abnormal	5	0	2
	Nystagmus	2	0	1
	Coma	2	0	1
	Lethargy	4	0	3
	Loss of consciousness	1	0	1
	Sedation	5	0	1
	Somnolence	16	0	8
	Syncope	3	0	1
	Clonus	1	0	0
	Dizziness	12	0	8
	Hypoaesthesia	5	0	4
	Paraesthesia	7	0	4
	Aura	1	0	0
	Sensory disturbance	3	0	2
	Dysarthria	4	0	1
	Hypertonia	6	0	4
	Neuroleptic malignant syndrome	2	0	0
	Serotonin syndrome	8	0	3
	Convulsion	11	0	7
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	0
	Polyhydramnios	1	0	1
Psychiatric disorders	Neurosis	3	0	3
	Obsessive-compulsive disorder	3	0	1
	Agitation	18	0	9
	Anxiety	6	0	5
	Nervousness	1	0	1
	Panic attack	1	0	1
	Restlessness	3	0	0
	Bruxism	2	0	2
	Communication disorder	1	0	1
	Expressive language disorder	1	0	0
	Confusional state	12	0	7
	Disorientation	2	0	1
	Delirium	1	0	0
	Depression	3	0	0

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Psychiatric disorders	Depersonalisation	2	0	2
	Delusion	1	0	0
	Hallucination	4	0	3
	Hallucination, auditory	1	0	1
	Hallucination, visual	2	0	1
	Thinking abnormal	2	0	0
	Bipolar disorder	1	0	0
	Mania	7	1	4
	Affect lability	3	0	3
	Crying	1	0	1
	Euphoric mood	2	0	0
	Aggression	6	0	5
	Homicidal ideation	2	0	2
	Paranoia	1	1	1
	Mental status changes	1	0	0
	Psychotic disorder	4	1	2
	Anorgasmia	3	0	3
	Libido decreased	2	0	2
	Insomnia	13	0	10
	Nightmare	5	0	5
	Sleep walking	3	0	3
	Sleep disorder	1	0	1
	Completed suicide	3	3	2
Suicidal ideation	9	0	4	
Suicide attempt	5	0	0	
Renal and urinary disorders	Renal failure chronic	1	0	0
	Renal impairment	1	0	0
	Pollakiuria	1	0	1
	Urinary incontinence	6	0	3
	Urinary retention	2	0	1
	Polyuria	2	0	2
Reproductive system and breast disorders	Breast enlargement	1	0	1
	Gynaecomastia	1	0	0
	Galactorrhoea	4	0	3
	Amenorrhoea	1	0	1

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Reproductive system and breast disorders	Ejaculation failure	1	0	1
	Erectile dysfunction	2	0	1
Respiratory, thoracic and mediastinal disorders	Asthma	1	0	0
	Bronchospasm	1	0	1
	Pleural effusion	1	0	0
	Dyspnoea	4	0	2
	Hypoventilation	1	0	0
	Respiratory depression	1	0	0
	Hypercapnia	1	0	0
	Hypoxia	2	0	1
	Cough	2	0	1
	Productive cough	1	0	0
	Dry throat	1	0	0
	Throat tightness	1	0	1
	Skin and subcutaneous tissue disorders	Angioedema	3	0
Periorbital oedema		2	0	1
Urticaria		4	0	3
Dermatitis bullous		2	0	2
Skin disorder		1	0	0
Skin reaction		1	0	1
Swelling face		1	0	0
Eczema		1	0	1
Erythema		1	0	0
Photosensitivity reaction		1	0	1
Pruritus		7	0	6
Rash pruritic		1	0	1
Fixed eruption		1	0	1
Rash		7	0	3
Rash maculo-papular		2	0	2
Rash neonatal		1	0	1
Skin hyperpigmentation		1	0	0
Erythema nodosum		1	0	1
Alopecia		1	0	1
Hyperhidrosis		12	0	8
Ecchymosis	1	0	1	



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Skin and subcutaneous tissue disorders	Purpura	4	0	3
	Leukocytoclastic vasculitis	1	0	1
Surgical and medical procedures	Drug therapy changed	1	0	1
	Therapy regimen changed	8	0	4
Vascular disorders	Circulatory collapse	2	0	2
	Shock	1	0	1
	Hypotension	2	0	0
	Deep vein thrombosis	1	0	0
	Flushing	5	0	3
	Hot flush	1	0	1
	Pallor	1	0	1
	Hypertension	2	0	1