

Medicine summary -fluvoxamine (to date)

			Case Group	Death Outcomes	Sole
Case Count			338	8	208
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0	1
		Coagulopathy	1	0	0
		Platelet disorder	1	0	1
		Thrombocytopenia	3	0	1
		Leukocytosis	1	0	0
		Neutropenia	4	0	4
		Blood and lymphatic system disorders	12	0	7
	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	6	0	5
		Cardiac failure	1	0	0
		Cardiac failure congestive	1	0	0
		Cardiomyopathy	1	0	0
		Atrial hypertrophy	1	0	0
		Myocarditis	1	0	0
		Cardiac disorders	23	1	7
		Congenital, familial and genetic disorders	Coloboma	1	0
	Congenital, familial and genetic disorders		1	0	1
	Ear and labyrinth disorders	Tinnitus	2	0	2
		Vertigo	1	0	1
		Ear and labyrinth disorders	3	0	3
	Endocrine disorders	Cushing's syndrome	1	0	0
		Diabetes insipidus	1	0	1
		Inappropriate antidiuretic hormone secretion	2	0	2
Hyperthyroidism		1	0	0	
Endocrine disorders		5	0	3	
Eye disorders	Lacrimal disorder	1	0	0	
	Periorbital oedema	2	0	1	
	Oculogyric crisis	1	0	1	
	Mydriasis	3	0	0	
	Vision blurred	2	0	0	
	Visual impairment	8	0	6	
	Eye disorders	17	0	8	
Gastrointestinal disorders	Gingivitis	1	0	1	
	Gastric haemorrhage	1	0	0	
	Gastrointestinal haemorrhage	2	0	0	
	Haematemesis	1	0	0	
	Reflux oesophagitis	1	0	1	

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Reaction Count	Gastrointestinal disorders	Diarrhoea	15	0	10
		Constipation	3	0	2
		Gastrooesophageal reflux disease	3	0	3
		Ileus paralytic	1	0	0
		Dyspepsia	1	0	1
		Eructation	1	0	1
		Abdominal distension	1	0	1
		Abdominal pain	6	1	5
		Dysphagia	2	0	1
		Nausea	37	0	25
		Vomiting	12	0	9
		Intestinal obstruction	1	0	0
		Dry mouth	6	0	5
		Salivary hypersecretion	1	0	0
		Glossitis	1	0	0
		Tongue oedema	2	0	0
		Gastrointestinal disorders	99	1	65
	General disorders and administration site conditions	Hypothermia	1	0	0
		Pyrexia	3	0	0
		Death	1	1	1
		Sudden death	2	2	1
		Asthenia	7	0	3
		Fatigue	3	0	1
		Malaise	6	0	5
		Gait disturbance	2	0	1
		Condition aggravated	2	0	1
		Energy increased	1	0	0
		Irritability	1	0	1
		Generalised oedema	1	0	1
Oedema		1	0	0	
Oedema peripheral		2	0	2	
Chest pain		2	0	2	
Pain		4	0	2	
Chest discomfort		2	0	2	
Chills		3	0	1	
Feeling abnormal		1	0	1	
Drug interaction		8	1	0	
Drug ineffective		5	0	5	
Paradoxical drug reaction		1	0	0	
Therapeutic response unexpected	1	0	1		
Therapeutic response unexpected with drug substitution	1	0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	General disorders and administration site conditions	61	4	32
	Hepatobiliary disorders	Liver injury	1	0	1
		Hepatic function abnormal	3	0	1
		Hepatic failure	1	1	1
		Hepatitis	6	0	5
		Hepatobiliary disorders	11	1	8
	Immune system disorders	Hypersensitivity	4	0	3
		Immune system disorders	4	0	3
	Infections and infestations	Cellulitis	1	0	0
		Nasopharyngitis	1	0	0
		Infections and infestations	2	0	0
	Injury, poisoning and procedural complications	Drug toxicity	3	0	0
		Drug exposure during pregnancy	6	1	5
		Fall	1	0	0
		Contusion	5	0	5
		Drug prescribing error	1	0	0
		Drug exposure via breast milk	1	0	1
		Multiple drug overdose intentional	1	0	0
		Overdose	1	0	1
		Injury, poisoning and procedural complications	19	1	12
	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	4	0	0
		Prothrombin level decreased	4	0	1
		Red blood cell sedimentation rate increased	1	0	0
		Platelet count decreased	1	0	1
		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		2	1	2	
Weight increased		4	0	3	
C-reactive protein increased		1	0	0	
Sperm count decreased		1	0	0	
Drug level increased		12	0	0	
Investigations		42	1	9	
Metabolism and nutrition disorders		Decreased appetite	3	0	3
	Increased appetite	1	0	0	

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		Case Group	Death Outcomes	Sole	
Reaction Count	Metabolism and nutrition disorders	Abnormal weight gain	1	0	0
		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	8	0	7
		Dehydration	2	0	2
		Diabetes mellitus inadequate control	1	0	0
		Type 2 diabetes mellitus	1	0	0
		Hyperglycaemia	1	0	0
		Hyperlipidaemia	1	0	0
		Metabolism and nutrition disorders	27	0	15
		Musculoskeletal and connective tissue disorders	Bone pain	1	0
	Arthralgia		4	0	4
	Myalgia		5	0	3
	Muscle spasms		1	0	1
	Muscle twitching		2	0	0
	Trismus		1	0	1
	Muscular weakness		1	0	1
	Mobility decreased		1	0	1
	Musculoskeletal stiffness		1	0	0
	Back pain		1	0	1
	Musculoskeletal and connective tissue disorders		18	0	13
	Nervous system disorders	Encephalopathy	1	1	1
		Headache	15	1	10
		Migraine	1	0	1
		Autism	1	0	1
		Amnesia	8	0	4
		Memory impairment	1	0	0
		Cognitive disorder	1	0	1
		Disturbance in attention	6	0	5
		Mental impairment	1	0	1
		Choreoathetosis	3	0	2
		Akathisia	10	2	5
		Dyskinesia	4	0	2
		Extrapyramidal disorder	2	0	1
		Hyperkinesia	3	0	2
		Dystonia	7	0	4
		Cogwheel rigidity	1	0	1

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Reaction Count	Nervous system disorders	Tremor	12	0	8
		Hyperreflexia	1	0	0
		Hyporeflexia	2	0	2
		Ataxia	4	0	2
		Coordination abnormal	1	0	0
		Nystagmus	2	0	1
		Coma	2	0	1
		Lethargy	4	0	3
		Loss of consciousness	1	0	1
		Sedation	5	0	2
		Somnolence	16	0	8
		Syncope	3	0	1
		Clonus	2	0	1
		Dizziness	13	0	9
		Crying	3	0	3
		Paraesthesia	7	0	4
		Aura	1	0	0
		Hypoaesthesia	5	0	4
		Sensory disturbance	3	0	2
		Dysarthria	5	0	1
		Speech disorder	1	0	1
		Anticholinergic syndrome	1	0	0
		Hypertonia	7	0	5
		Neuroleptic malignant syndrome	2	0	0
		Serotonin syndrome	9	0	3
		Grand mal convulsion	1	0	1
		Convulsion	12	0	7
		Drug withdrawal convulsions	1	0	0
	Poor quality sleep	1	1	1	
	Nervous system disorders		192	5	112
	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	2	0	1
		Polyhydramnios	1	0	1
		Pregnancy, puerperium and perinatal conditions	3	0	2
	Psychiatric disorders	Agitation	18	0	9
		Anxiety	8	0	6
		Nervousness	1	0	1
		Panic attack	1	0	1
		Neurosis	3	0	3
Obsessive-compulsive disorder		3	0	1	
Restlessness		3	0	0	
Bruxism		4	0	4	

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Reaction Count	Psychiatric disorders	Communication disorder	1	0	1
		Expressive language disorder	1	0	0
		Confusional state	16	0	8
		Disorientation	3	0	1
		Delirium	2	0	0
		Depression	6	0	3
		Depressed mood	1	0	1
		Depersonalisation	2	0	2
		Dissociation	1	0	1
		Delusion	1	0	0
		Deja vu	1	0	0
		Hallucination	5	0	3
		Hallucination, auditory	1	0	1
		Hallucination, visual	2	0	1
		Thinking abnormal	2	0	0
		Bipolar disorder	1	0	0
		Mania	8	1	4
		Affect lability	3	0	3
		Inappropriate affect	1	0	1
		Anger	1	0	1
		Euphoric mood	2	0	0
		Aggression	9	0	6
		Homicidal ideation	2	0	2
		Paranoia	1	1	1
		Personality change	1	0	0
		Violence-related symptom	1	0	1
		Abnormal behaviour	1	0	0
		Mental status changes	1	0	0
		Withdrawal syndrome	12	0	11
		Psychotic disorder	5	1	2
		Anorgasmia	3	0	3
		Libido decreased	2	0	2
		Insomnia	14	0	11
		Abnormal sleep-related event	2	0	0
		Nightmare	7	1	6
		Somnambulism	5	0	3
		Sleep disorder	1	0	1
		Completed suicide	5	5	3
		Suicidal ideation	12	0	7
		Suicide attempt	9	0	3
		Psychiatric disorders	195	9	118
	Renal and urinary disorders	Renal failure	1	0	1

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Reaction Count	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
		Renal and urinary disorders	14	0	8
	Reproductive system and breast disorders	Breast enlargement	1	0	1
		Gynaecomastia	1	0	0
		Galactorrhoea	4	0	3
		Amenorrhoea	1	0	1
		Ejaculation failure	1	0	1
		Erectile dysfunction	2	0	1
		Reproductive system and breast disorders	10	0	7
	Respiratory, thoracic and mediastinal disorders	Asthma	1	0	0
		Bronchospasm	1	0	1
		Pleural effusion	1	0	0
		Pulmonary embolism	1	0	0
		Dyspnoea	7	0	5
		Hypoventilation	1	0	0
		Respiratory depression	1	0	0
		Hypercapnia	1	0	0
		Hypoxia	2	0	1
		Cough	2	0	1
		Sputum increased	1	0	0
		Dry throat	1	0	0
		Throat irritation	1	0	1
		Throat tightness	1	0	1
		Epistaxis	1	0	0
		Respiratory, thoracic and mediastinal disorders	23	0	10
	Skin and subcutaneous tissue disorders	Angioedema	3	0	1
		Urticaria	6	0	5
		Dermatitis bullous	2	0	2
		Skin disorder	2	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

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Reaction Count	Skin and subcutaneous tissue disorders	Fixed eruption	1	0	1		
		Rash	9	1	5		
		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	13	0	9		
		Ecchymosis	1	0	1		
		Purpura	4	0	3		
		Leukocytoclastic vasculitis	1	0	1		
		Skin and subcutaneous tissue disorders			61	1	43
		Social circumstances	Physical assault	1	0	0	
	Social circumstances		1	0	0		
	Surgical and medical procedures	Drug therapy changed	1	0	1		
		Therapy regimen changed	9	0	4		
		Surgical and medical procedures	10	0	5		
	Vascular disorders	Circulatory collapse	3	0	3		
		Hypotension	3	0	1		
		Deep vein thrombosis	1	0	0		
		Flushing	5	0	3		
		Hot flush	1	0	1		
		Pallor	1	0	1		
		Haematoma	1	0	0		
		Hypertension	2	0	1		
		Vascular disorders	17	0	10		
	Reaction			870	24	501	