

Medicine summary - fluvoxamine (to end January 2009)

			Case Group	Death Outcomes	Sole	
Case Count			306	7	193	
Reaction Count	Blood and lymphatic system disorders	Anaemia	2	0	1	
		Coagulopathy	1	0	0	
		Platelet disorder	1	0	1	
		Leukocytosis	1	0	0	
		Neutropenia	3	0	3	
		Blood and lymphatic system disorders	8	0	5	
	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	
		Cardiac disorders	22	1	6	
		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	1	0	1	
		Hyperthyroidism	1	0	0	
		Endocrine disorders	4	0	2	
	Eye disorders	Lacrimal disorder	1	0	0	
		Oculogyric crisis	1	0	1	
		Mydriasis	3	0	0	
		Vision blurred	2	0	0	
		Visual impairment	8	0	6	
		Eye disorders	15	0	7	
	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	
		Diarrhoea	14	0	10	
		Constipation	3	0	2	
		Gastrooesophageal reflux disease	3	0	3	
		Dyspepsia	1	0	1	

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Reaction Count	Gastrointestinal disorders	Eructation	1	0	1		
		Abdominal distension	1	0	1		
		Abdominal pain	6	1	5		
		Dysphagia	2	0	1		
		Nausea	34	0	25		
		Vomiting	10	0	9		
		Dry mouth	6	0	5		
		Salivary hypersecretion	1	0	0		
		Glossitis	1	0	0		
		Tongue oedema	2	0	0		
	Gastrointestinal disorders		91	1	65		
Reaction Count	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	5	0	4		
		Gait disturbance	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	6	0	0		
		Drug ineffective	4	0	4		
		Paradoxical drug reaction	1	0	0		
		Therapeutic response unexpected	1	0	1		
		Therapeutic response unexpected with drug substitution	1	0	1		
			General disorders and administration site conditions		55	3	29
		Reaction Count	Hepatobiliary disorders	Hepatic function abnormal	3	0	1
				Hepatic failure	1	1	1
Hepatitis	4			0	4		
Hepatobiliary disorders	8			1	6		
Reaction Count	Immune system disorders	Hypersensitivity	4	0	3		

Medicine summary - fluvoxamine (to end January 2009)

			Case Group	Death Outcomes	Sole	
Reaction Count	Immune system disorders	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		2	0	0
		Drug exposure during pregnancy		5	1	4
		Fall		1	0	0
		Contusion		4	0	4
		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		16	1	10
		Investigations	Ejection fraction decreased		1	0
	Electrocardiogram abnormal			1	0	0
	Blood creatine phosphokinase increased			4	0	0
	Troponin increased			1	0	0
	International normalised ratio increased			3	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			2	1	2
	Weight increased			4	0	3
	C-reactive protein increased			1	0	0
	Sperm count decreased			1	0	0
	Drug level increased			11	0	0
	Investigations			39	1	8
	Metabolism and nutrition disorders		Decreased appetite		2	0
		Increased appetite		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		7	0	6
		Dehydration		2	0	2
		Diabetes mellitus inadequate control		1	0	0

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Reaction Count	Metabolism and nutrition disorders	Type 2 diabetes mellitus	1	0	0
		Hyperglycaemia	1	0	0
		Hyperlipidaemia	1	0	0
		Metabolism and nutrition disorders	24	0	13
	Musculoskeletal and connective tissue disorders	Bone pain	1	0	1
		Arthralgia	4	0	4
		Myalgia	4	0	2
		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	17	0	12
	Nervous system disorders	Encephalopathy	1	1	1
		Headache	14	1	10
		Migraine	1	0	1
		Autism	1	0	1
		Amnesia	6	0	3
		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	9	2	5
		Dyskinesia	3	0	2
		Extrapyramidal disorder	2	0	1
		Hyperkinesia	3	0	2
		Dystonia	7	0	4
		Cogwheel rigidity	1	0	1
		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	4	0	1		

Medicine summary - fluvoxamine (to end January 2009)

			Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Somnolence	16	0	8	
		Syncope	3	0	1	
		Clonus	2	0	1	
		Dizziness	13	0	9	
		Crying	2	0	2	
		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	8	0	3	
		Grand mal convulsion	1	0	1	
		Convulsion	11	0	7	
		Poor quality sleep	1	1	1	
			Nervous system disorders	182	5	109
		Pregnancy, puerperium and perinatal conditions	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	2	0
Polyhydramnios	1			0	1	
Pregnancy, puerperium and perinatal conditions	3			0	2	
Psychiatric disorders	Psychiatric disorders	Agitation	18	0	9	
		Anxiety	6	0	5	
		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	
		Communication disorder	1	0	1	
		Expressive language disorder	1	0	0	
		Confusional state	15	0	8	
		Disorientation	3	0	1	
		Delirium	2	0	0	
		Depression	3	0	0	
		Depersonalisation	2	0	2	
		Dissociation	1	0	1	
		Delusion	1	0	0	
		Hallucination	5	0	3	
		Hallucination, auditory	1	0	1	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Psychiatric disorders	Hallucination, visual	2	0	1	
		Thinking abnormal	2	0	0	
		Bipolar disorder	1	0	0	
		Mania	7	1	4	
		Affect lability	3	0	3	
		Inappropriate affect	1	0	1	
		Anger	1	0	1	
		Euphoric mood	2	0	0	
		Aggression	8	0	5	
		Homicidal ideation	2	0	2	
		Paranoia	1	1	1	
		Personality change	1	0	0	
		Abnormal behaviour	1	0	0	
		Mental status changes	1	0	0	
		Withdrawal syndrome	12	0	11	
		Psychotic disorder	4	1	2	
		Anorgasmia	3	0	3	
		Libido decreased	2	0	2	
		Insomnia	13	0	10	
		Abnormal sleep-related event	2	0	0	
		Nightmare	6	1	6	
		Somnambulism	4	0	3	
		Sleep disorder	1	0	1	
		Completed suicide	4	4	3	
		Suicidal ideation	10	0	5	
		Suicide attempt	5	0	0	
			Psychiatric disorders	173	8	105
			Renal and urinary disorders	Renal failure	1	0
		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

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Reaction Count	Respiratory, thoracic and mediastinal disorders	Asthma	1	0	0
		Bronchospasm	1	0	1
		Pleural effusion	1	0	0
		Dyspnoea	6	0	4
		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	21	0	9
	Skin and subcutaneous tissue disorders	Angioedema	3	0	1
		Periorbital oedema	2	0	1
		Urticaria	5	0	4
		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		8	1	4	
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	60	1	42		
Social circumstances	Physical assault	1	0	0	
	Social circumstances	1	0	0	

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			Case Group	Death Outcomes	Sole
Reaction Count	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	799	22	466