

fluoxetine hydrochloride to end January 2009

				Case Group	Death Outcomes	Sole
Case Count				1358	16	971
Medicine	Reaction Count	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	4	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	10	0	6
			Blood and lymphatic system disorders	45	0	22
		Cardiac disorders	Atrioventricular block	3	0	1
			Bundle branch block	1	0	1
			Bundle branch block bilateral	1	0	0
			Arrhythmia	5	0	4
			Bradycardia	7	0	2
			Extrasystoles	2	0	1
			Tachycardia	18	0	13
			Sinus tachycardia	1	0	0
			Cardiac arrest	3	0	2
			Ventricular arrhythmia	1	0	1
			Ventricular fibrillation	3	0	2
			Ventricular tachycardia	1	0	0
			Cyanosis	2	0	2
			Palpitations	16	0	12
			Mitral valve incompetence	1	0	0
			Acute myocardial infarction	1	0	1
			Myocardial infarction	2	2	1
			Cardiac failure	3	0	1
Cardiomyopathy	1		0	0		
Cardiomegaly	1		0	0		
Myocarditis	1	0	0			
Pericardial effusion	1	0	0			
Cardiac disorders	75	2	44			
Congenital, familial and genetic disorders	Heart disease congenital	1	0	1		
	Ventricular septal defect	1	0	1		
	Coarctation of the aorta	2	0	2		

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Congenital, familial and genetic disorders	Vascular malformation peripheral	2	0	1
			Trisomy 21	1	0	1
			Congenital anomaly	1	0	1
			Congenital foot malformation	1	0	0
			Talipes	1	0	1
			Dysmorphism	1	0	1
			Hypospadias	1	0	0
			Congenital, familial and genetic disorders	12	0	9
		Ear and labyrinth disorders	Tinnitus	6	0	6
			Vertigo	6	0	3
			Ear and labyrinth disorders	12	0	9
		Endocrine disorders	Hyperprolactinaemia	9	0	8
			Inappropriate antidiuretic hormone secretion	12	2	7
			Thyroiditis	1	0	1
			Goitre	1	0	1
			Hyperthyroidism	2	0	2
			Endocrine disorders	25	2	19
		Eye disorders	Cataract	2	0	0
			Pigment dispersion syndrome	1	0	1
			Eye pain	2	0	1
			Glaucoma	5	0	5
			Conjunctivitis	3	0	1
			Oculogyric crisis	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	4	0	3
			Visual impairment	20	0	15
			Scotoma	1	0	0
		Eye disorders	49	0	31	
		Gastrointestinal disorders	Tooth disorder	2	0	1
			Toothache	1	0	1
			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	

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Gastrointestinal disorders	Proctitis	1	0	1
			Diarrhoea	45	0	36
			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	115	0	90
			Vomiting	43	0	26
			Ileus	1	0	0
			Gastritis erosive	1	0	0
			Cheilitis	1	0	1
			Lip swelling	2	0	2
			Oral mucosal exfoliation	1	0	0
			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
			Gastrointestinal disorders	328	0	245
		General disorders and administration site conditions	Application site reaction	1	0	0
			Hypothermia	3	0	1
			Pyrexia	20	0	11
			Death	2	2	1
			Sudden death	2	2	0
			Asthenia	10	1	7
			Fatigue	39	0	31
			Malaise	21	0	17
			Gait disturbance	6	0	2
			Condition aggravated	1	0	0
			Influenza like illness	6	0	5
			Irritability	3	0	2
			Face oedema	13	0	8
			Generalised oedema	1	0	1

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	General disorders and administration site conditions	Gravitational oedema	5	0	4
			Oedema	6	0	4
			Oedema peripheral	14	0	10
			Chest pain	18	0	12
			Pain	10	0	10
			Chest discomfort	1	0	0
			Chills	15	0	9
			Feeling abnormal	1	0	0
			Feeling cold	1	0	0
			Feeling hot	1	0	1
			Feeling jittery	1	0	1
			Feeling of body temperature change	1	0	1
			Thirst	3	0	1
			Drug interaction	1	0	0
			Drug ineffective	53	1	45
			Therapeutic response decreased	2	0	2
			Therapeutic response unexpected	2	0	2
			Therapeutic response unexpected with drug substitution	1	0	1
			Drug withdrawal syndrome	1	0	0
			Drug withdrawal syndrome neonatal	4	0	4
		General disorders and administration site conditions	269	6	193	
		Hepatobiliary disorders	Cholecystitis	2	0	1
			Cholelithiasis	2	0	1
			Cholestasis	1	0	1
			Hepatitis cholestatic	6	0	5
			Jaundice	3	0	2
			Jaundice cholestatic	1	0	1
			Hepatic function abnormal	31	0	13
			Hepatic cirrhosis	1	0	0
			Hepatomegaly	1	0	0
			Hepatosplenomegaly	1	0	1
			Hepatic steatosis	1	0	0
			Hepatitis	7	0	2
			Hepatocellular injury	1	0	1
			Hepatobiliary disorders	58	0	28
		Immune system disorders	Hypersensitivity	4	0	3
			Serum sickness	3	0	3
			Anaphylactic reaction	1	0	1
			Anaphylactoid reaction	2	0	1
			Immune system disorders	10	0	8
		Infections and infestations	Oral candidiasis	1	0	0

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Infections and infestations	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
			Infections and infestations	24	0	16
			Injury, poisoning and procedural complications	Drug exposure during pregnancy	7	0
		Fall		1	0	1
		Medication error		1	0	1
		Drug exposure via breast milk		1	0	1
		Intentional overdose		2	0	0
		Injury, poisoning and procedural complications		12	0	7
		Investigations	Electrocardiogram QT prolonged	7	0	2
			Heart rate increased	1	0	0
			Blood pressure decreased	1	0	1
			Blood creatine phosphokinase increased	8	0	2
			Troponin I increased	1	0	0
			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
			Platelet aggregation abnormal	1	0	0
			Neutrophil count increased	1	0	0
			White blood cell count increased	2	0	0
			Blood bilirubin increased	1	0	1
			Liver function test abnormal	4	0	2
			Antinuclear antibody positive	1	0	1
			Lipids abnormal	1	0	0
			Electroencephalogram abnormal	1	0	0
			Body temperature increased	1	0	0
			Weight decreased	22	1	11
			Weight increased	16	0	8
		C-reactive protein increased	2	0	1	
		Urine analysis abnormal	1	0	0	
		Semen analysis abnormal	1	0	1	

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole
		Drug level above therapeutic	1	0	0
		Drug level decreased	2	0	0
		Drug level increased	12	0	0
		Investigations	98	1	38
		Metabolism and nutrition disorders			
		Metabolic acidosis	1	0	1
		Acidosis	1	0	0
		Anorexia	28	1	23
		Increased appetite	5	0	4
		Feeding disorder neonatal	1	0	1
		Hyperchloraemia	1	0	0
		Hypokalaemia	3	0	1
		Hypernatraemia	1	0	1
		Hyponatraemia	57	1	42
		Dehydration	7	0	4
		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
		Metabolism and nutrition disorders	125	2	93
		Musculoskeletal and connective tissue disorders			
		Osteoporosis	1	0	1
		Systemic lupus erythematosus	1	0	1
		Arthritis	5	0	4
		Arthralgia	31	0	26
		Osteoarthritis	2	0	2
		Myositis	1	0	1
		Myalgia	24	0	16
		Muscle spasms	2	0	2
		Muscle twitching	16	0	14
		Nuchal rigidity	1	0	0
		Torticollis	1	0	0
		Trismus	3	0	2
		Muscular weakness	1	0	0
		Rhabdomyolysis	1	0	0
		Limb deformity	1	0	1
		Mobility decreased	1	0	0
		Musculoskeletal stiffness	2	0	0
		Back pain	8	0	3
		Bursitis	1	0	1

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				Case Group	Death Outcomes	Sole
Medicine	Reaction Count	Musculoskeletal and connective tissue disorders	Synovitis	1	0	1
			Musculoskeletal and connective tissue disorders	104	0	75
		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
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	2	3
			Nervous system disorders	Cerebral haemorrhage	1	1
		Cerebrovascular disorder		2	0	0
		Anosmia		1	0	1
		Headache		68	1	54
		Migraine		7	0	3
		Dementia		1	0	0
		Autism		2	0	2
		Amnesia		14	0	10
		Memory impairment		1	0	0
		Cognitive disorder		1	0	0
		Disturbance in attention		9	0	6
		Mental impairment		2	0	2
		Choreoathetosis		2	0	2
		Akathisia		10	1	5
		Dyskinesia		17	0	12
		Extrapyramidal disorder		9	1	4
		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
		Monoplegia		1	0	1
		Paralysis		2	0	2
		Paresis		3	0	3
		Quadriplegia		1	0	0
		Parkinsonism		1	0	0
		Tremor		72	0	50
		Hyperreflexia		5	0	1
		Reflexes abnormal		1	0	1
		Ataxia		12	1	6
		Balance disorder		2	0	2
		Coordination abnormal		8	0	3
		Coma		5	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Nervous system disorders	Consciousness fluctuating	2	1	0	
			Loss of consciousness	3	0	2	
			Sedation	2	0	0	
			Somnolence	46	1	23	
			Syncope	14	0	10	
			Central nervous system lesion	1	0	0	
			Dizziness	57	0	40	
			Meningism	1	0	1	
			Myoclonus	3	0	1	
			Neurological symptom	1	0	0	
			Crying	4	0	2	
			Hyperaesthesia	1	0	1	
			Paraesthesia	23	0	18	
			Ageusia	2	0	2	
			Dysgeusia	6	0	4	
			Hypoaesthesia	8	0	7	
			Sensory disturbance	2	0	2	
			Dysarthria	8	0	6	
			Speech disorder	9	0	4	
			Visual field defect	1	0	1	
			Cholinergic syndrome	1	0	0	
			Hypertonia	18	0	10	
			Hypotonia	2	0	2	
			Neuroleptic malignant syndrome	2	1	0	
			Serotonin syndrome	20	1	1	
			Neuropathy peripheral	2	0	2	
			Convulsion neonatal	2	0	2	
			Grand mal convulsion	12	0	3	
			Convulsion	35	0	20	
			Poor quality sleep	2	0	1	
			Nervous system disorders	588	9	359	
			Pregnancy, puerperium and perinatal conditions	Abortion	1	0	1
				Abortion missed	1	0	1
				Abortion spontaneous	3	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			
Pregnancy, puerperium and perinatal conditions	17	0	11				
Psychiatric disorders	Agitation	71	0	51			

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Medicine	Reaction Count	Psychiatric disorders	Case Group	Death Outcomes	Sole
		Agitation neonatal	3	0	3
		Anxiety	73	2	54
		Nervousness	13	0	10
		Stress	1	0	1
		Agoraphobia	1	1	0
		Fear	1	0	1
		Panic attack	5	0	2
		Panic disorder	1	0	1
		Panic reaction	1	0	1
		Neurosis	3	0	1
		Obsessive-compulsive disorder	1	0	1
		Restlessness	4	0	2
		Bruxism	6	0	3
		Change in sustained attention	1	0	0
		Mutism	1	0	0
		Dysphemia	1	0	0
		Confusional state	54	0	26
		Disorientation	3	0	0
		Delirium	14	0	5
		Depression	29	1	19
		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
		Dysphoria	1	0	0
		Euphoric mood	13	0	11
		Frustration	1	0	0
		Mood swings	3	0	1
		Apathy	5	0	4
		Aggression	32	0	18
		Homicidal ideation	5	0	3
		Paranoia	3	0	2

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Psychiatric disorders	Personality change	1	0	1
			Personality disorder	6	0	5
			Abnormal behaviour	2	0	0
			Hypervigilance	1	0	0
			Withdrawal syndrome	21	0	18
			Psychotic disorder	7	0	4
			Anorgasmia	7	0	7
			Libido decreased	14	0	13
			Libido increased	5	0	3
			Loss of libido	1	0	0
			Insomnia	69	1	55
			Abnormal dreams	3	0	3
			Abnormal sleep-related event	3	0	1
			Nightmare	12	0	9
			Sleep talking	1	0	1
			Somnambulism	3	0	2
			Sleep disorder	2	0	2
			Conversion disorder	1	0	1
			Somatoform disorder pregnancy	1	0	1
			Completed suicide	2	2	1
			Intentional self-injury	2	0	1
			Self injurious behaviour	4	1	0
			Suicidal behaviour	1	0	0
			Suicidal ideation	23	0	12
			Suicide attempt	53	4	28
			Psychiatric disorders	688	12	451
		Renal and urinary disorders	Tubulointerstitial nephritis	1	0	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	5	0	3
			Pyuria	1	0	0
			Nocturia	2	0	2
			Renal pain	1	0	1
			Renal and urinary disorders	51	0	29

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		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
			Menorrhagia	6	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
			Reproductive system and breast disorders	83	0	69
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	8	0	7
			Wheezing	1	0	1
			Lung infiltration	1	0	1
			Infantile apnoeic attack	2	0	0
			Pulmonary hypertension	1	0	0
			Pulmonary embolism	1	1	0
			Dyspnoea	16	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
			Oropharyngeal pain	1	0	0
			Throat irritation	1	0	1
			Throat tightness	1	0	1
			Yawning	2	0	2
			Laryngospasm	2	0	1
			Epistaxis	6	0	4
			Pharyngeal oedema	1	0	1
		Respiratory, thoracic and mediastinal disorders	55	1	37	
		Skin and subcutaneous tissue disorders	Angioedema	10	0	8
			Periorbital oedema	4	0	3
			Urticaria	55	0	43
			Lichenoid keratosis	1	0	1

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			Case Group	Death Outcomes	Sole		
Medicine	Reaction Count	Skin and subcutaneous tissue disorders	Skin hypertrophy	1	0	1	
			Dermatitis bullous	5	0	4	
			Erythema multiforme	2	0	1	
			Hypoaesthesia facial	1	0	1	
			Skin discolouration	3	0	3	
			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	
			Lichenification	1	0	0	
			Rash papular	1	0	1	
			Photosensitivity reaction	4	0	2	
			Pruritus	65	0	55	
			Rash pruritic	2	0	1	
			Dermatitis psoriasiform	1	0	1	
			Psoriasis	4	0	3	
			Fixed eruption	1	0	1	
			Rash	51	0	46	
			Rash generalised	1	0	1	
			Rash maculo-papular	30	0	27	
			Rash morbilliform	3	0	2	
			Rash vesicular	3	0	3	
			Systemic lupus erythematosus rash	1	0	1	
			Pityriasis	1	0	1	
			Chloasma	1	0	0	
			Acne	3	0	2	
			Alopecia	14	0	8	
			Hyperhidrosis	49	0	34	
			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	
			Skin and subcutaneous tissue disorders	377	1	303	
			Social circumstances	Physical assault	1	0	1
				Social circumstances	1	0	1
			Surgical and medical procedures	Drug therapy changed	2	0	2
				Therapy regimen changed	4	0	3
				Surgical and medical procedures	6	0	5
			Vascular disorders	Circulatory collapse	2	0	0

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Vascular disorders	Hypotension	15	0	7
			Orthostatic hypotension	8	0	4
			Vasodilatation	3	1	2
			Flushing	7	0	6
			Hot flush	5	0	3
			Pallor	4	0	3
			Haematoma	4	0	3
			Haemorrhage	1	0	0
			Hypertension	13	0	9
			Vasculitis	5	0	5
			Vascular disorders	67	1	42
		Reaction		3184	39	2147