

## Medicine summary -fluoxetine (to date)

			Case Group	Death Outcomes	Sole
Case Count			1411	25	998
Reaction Count	Blood and lymphatic system disorders	Normochromic normocytic anaemia	1	0	1
		Aplastic anaemia	1	0	0
		Thrombocytopenia	8	0	4
		Thrombocytopenia neonatal	1	0	1
		Thrombocytopenic purpura	2	0	1
		Thrombocytosis	1	0	0
		Lymphadenopathy	5	0	4
		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
	<b>Blood and lymphatic system disorders</b>		<b>47</b>	<b>0</b>	<b>24</b>
	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		
<b>Cardiac disorders</b>		<b>75</b>	<b>2</b>	<b>44</b>	
Congenital, familial and genetic disorders	Heart disease congenital	1	0	1	
	Ventricular septal defect	1	0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Congenital, familial and genetic disorders	Coarctation of the aorta	2	0	2
		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
		Disorder of sex development	1	0	1
		<b>Congenital, familial and genetic disorders</b>	<b>13</b>	<b>0</b>	<b>10</b>
	Ear and labyrinth disorders	Tinnitus	6	0	6
		Vertigo	7	0	3
		<b>Ear and labyrinth disorders</b>	<b>13</b>	<b>0</b>	<b>9</b>
	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
		<b>Endocrine disorders</b>	<b>25</b>	<b>2</b>	<b>19</b>
	Eye disorders	Cataract	2	0	0
		Pigment dispersion syndrome	1	0	1
		Eye pain	2	0	1
		Periorbital oedema	4	0	3
		Glaucoma	4	0	4
		Conjunctivitis	3	0	1
		Eye movement disorder	1	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
		<b>Eye disorders</b>	<b>53</b>	<b>0</b>	<b>34</b>
		Gastrointestinal disorders	Tooth disorder	2	0
	Toothache		1	0	1
	Gingivitis		1	0	1
	Gingival bleeding		1	0	1
	Pancreatitis		2	0	2
	Rectal haemorrhage		5	0	4

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			Case Group	Death Outcomes	Sole		
Reaction Count	Gastrointestinal disorders	Gastrointestinal haemorrhage	3	0	0		
		Melaena	1	0	1		
		Gastritis	1	0	1		
		Oesophagitis	1	0	1		
		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	26	0	22		
		Abdominal pain upper	1	0	1		
		Infantile colic	1	0	1		
		Dysphagia	6	0	3		
		Faecal incontinence	1	0	1		
		Nausea	116	0	90		
		Vomiting	43	0	26		
		Ileus	1	0	0		
		Gastritis erosive	1	0	0		
		Cheilitis	1	0	1		
		Lip swelling	1	0	1		
		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 disorder	1	0	1		
		Tongue ulceration	1	0	0		
		Tongue discolouration	1	0	1		
		Tongue oedema	3	0	2		
		Buccoglossal syndrome	1	0	1		
			<b>Gastrointestinal disorders</b>	<b>331</b>	<b>0</b>	<b>247</b>	
			General disorders and administration site conditions	Application site reaction	1	0	0
				Hypothermia	3	0	1
				Pyrexia	20	0	11
				Death	4	4	1
				Sudden death	2	2	0
Asthenia	11			1	8		
Fatigue	39			0	30		
Malaise	21			0	17		

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			Case Group	Death Outcomes	Sole	
Reaction Count	General disorders and administration site conditions	Gait disturbance	8	0	3	
		Condition aggravated	3	0	2	
		Influenza like illness	6	0	5	
		Irritability	4	0	2	
		Face oedema	13	0	8	
		Generalised oedema	1	0	1	
		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	16	0	10	
		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	5	0	0	
		Drug ineffective	54	1	46	
		Therapeutic response decreased	2	0	2	
		Therapeutic response unexpected	3	0	3	
		Therapeutic response unexpected with drug substitution	1	0	1	
		Drug withdrawal syndrome	2	0	0	
		Drug withdrawal syndrome neonatal	6	0	4	
		Product substitution issue	1	0	1	
			<b>General disorders and administration site conditions</b>	<b>288</b>	<b>8</b>	<b>200</b>
		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		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Hepatobiliary disorders	Hepatocellular injury	1	0	1	
		<b>Hepatobiliary disorders</b>	<b>58</b>	<b>0</b>	<b>28</b>	
	Immune system disorders	Hypersensitivity	4	0	3	
		Serum sickness	3	0	3	
		Anaphylactic reaction	1	0	1	
		Anaphylactoid reaction	2	0	1	
		<b>Immune system disorders</b>	<b>10</b>	<b>0</b>	<b>8</b>	
		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	
	<b>Infections and infestations</b>		<b>24</b>	<b>0</b>	<b>16</b>	
	Injury, poisoning and procedural complications		Drug toxicity	8	8	1
			Drug exposure during pregnancy	12	0	7
		Fall	2	0	1	
		Contusion	1	0	1	
		Drug administration error	1	0	1	
		Medication error	1	0	1	
		Drug exposure via breast milk	3	0	1	
		Intentional overdose	2	0	0	
		Overdose	1	0	0	
		<b>Injury, poisoning and procedural complications</b>	<b>31</b>	<b>8</b>	<b>13</b>	
	Investigations	Electrocardiogram QT prolonged	7	0	2	
		Heart rate increased	2	0	1	
		Blood pressure decreased	1	0	1	
		Blood pressure increased	1	0	1	
		Blood creatine phosphokinase increased	9	0	3	
		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	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Investigations	Platelet count decreased	1	0	1	
		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	23	1	11	
		Weight increased	16	0	8	
		C-reactive protein increased	2	0	1	
		C-reactive protein abnormal	1	0	1	
		Urine analysis abnormal	1	0	0	
		Semen analysis abnormal	1	0	1	
		Drug level above therapeutic	1	0	0	
		Drug level decreased	2	0	0	
		Drug level increased	12	0	0	
		Blood calcium abnormal	1	0	1	
		Blood magnesium abnormal	1	0	1	
		Blood phosphorus abnormal	1	0	1	
			<b>Investigations</b>	<b>107</b>	<b>1</b>	<b>46</b>
		Metabolism and nutrition disorders	Metabolic acidosis	1	0	1
			Acidosis	1	0	0
Decreased appetite	29		1	24		
Hyperphagia	1		0	1		
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		
Fluid retention	1		0	1		
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		

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			Case Group	Death Outcomes	Sole
Reaction Count	Metabolism and nutrition disorders	<b>Metabolism and nutrition disorders</b>	<b>128</b>	<b>2</b>	<b>96</b>
	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	2	0	2
		Myalgia	24	0	16
		Muscle spasms	2	0	2
		Muscle twitching	18	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
		Synovitis	1	0	1
		<b>Musculoskeletal and connective tissue disorders</b>	<b>107</b>	<b>0</b>	<b>76</b>
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer male	1	0	1
		Colon cancer	1	0	0
		Gastric cancer	1	1	1
		Angiocentric lymphoma	1	1	0
			<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>4</b>	<b>2</b>
Nervous system disorders	Cerebral haemorrhage	1	1	0	
	Cerebrovascular disorder	2	0	0	
	Anosmia	1	0	1	
	Headache	67	1	53	
	Migraine	7	0	3	
	Dementia	1	0	0	
	Autism	1	0	1	
	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		

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Reaction Count			Case Group	Death Outcomes	Sole
	Nervous system disorders	Akathisia	12	1	6
		Dyskinesia	17	0	12
		Extrapyramidal disorder	10	1	4
		Hyperkinesia	17	0	11
		Hypokinesia	1	0	1
		Psychomotor hyperactivity	3	0	2
		Tardive dyskinesia	2	0	1
		Dystonia	15	0	9
		Spasmodic dysphonia	3	0	0
		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	74	0	51
		Hyperreflexia	5	0	1
		Reflexes abnormal	1	0	1
		Ataxia	13	1	7
		Balance disorder	2	0	2
		Coordination abnormal	8	0	3
		Coma	5	0	1
		Consciousness fluctuating	2	1	0
		Loss of consciousness	4	0	3
		Sedation	2	0	0
		Somnolence	45	1	23
		Syncope	14	0	10
		Central nervous system lesion	1	0	0
		Dizziness	57	0	40
		Head discomfort	1	0	1
		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	10	0	5		



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			Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Visual field defect	1	0	1	
		Cholinergic syndrome	1	0	0	
		Hypertonia	18	0	10	
		Hypotonia	2	0	2	
		Neuroleptic malignant syndrome	3	2	0	
		Serotonin syndrome	27	3	2	
		Neuropathy peripheral	2	0	2	
		Convulsion neonatal	2	0	2	
		Grand mal convulsion	12	0	4	
		Convulsion	34	0	19	
		Poor quality sleep	2	0	1	
		<b>Nervous system disorders</b>		<b>607</b>	<b>12</b>	<b>366</b>
		Pregnancy, puerperium and perinatal conditions	Abortion	1	0	1
Abortion missed	1		0	1		
Abortion spontaneous	5		0	2		
Foetal growth restriction	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		
<b>Pregnancy, puerperium and perinatal conditions</b>			<b>19</b>	<b>0</b>	<b>12</b>	
Psychiatric disorders	Agitation	71	0	52		
	Agitation neonatal	3	0	3		
	Anxiety	74	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	5	0	3		
	Bruxism	6	0	3		
	Change in sustained attention	1	0	0		
	Mutism	1	0	0		
	Dysphemia	2	0	1		
	Confusional state	55	0	27		
	Disorientation	4	0	1		

**Medicine summary -fluoxetine (to date)**

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Delirium	13	0	5
		Depression	30	1	20
		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
		Impulsive behaviour	1	0	1
		Hypomania	3	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
		Hostility	1	0	1
		Paranoia	3	0	2
		Personality change	1	0	1
		Personality disorder	6	0	5
		Abnormal behaviour	3	0	1
		Hypervigilance	1	0	0
		Drug dependence	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	70	1	56		
Abnormal dreams	3	0	3		
Abnormal sleep-related event	3	0	1		
Nightmare	12	0	9		
Sleep talking	1	0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Somnambulism	4	0	3
		Sleep disorder	2	0	2
		Conversion disorder	2	0	2
		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	24	0	13
		Suicide attempt	52	4	28
		<b>Psychiatric disorders</b>	<b>701</b>	<b>12</b>	<b>464</b>
	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
		<b>Renal and urinary disorders</b>	<b>51</b>	<b>0</b>	<b>29</b>
		Reproductive system and breast disorders	Breast enlargement	8	0
	Gynaecomastia		7	0	6
	Breast pain		12	0	9
	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	10		0	9	
Sexual dysfunction	3		0	3	
Testicular disorder	2		0	1	
Vaginal haemorrhage	2		0	2	
Vulval disorder	1		0	0	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Reproductive system and breast disorders	<b>Reproductive system and breast disorders</b>	<b>81</b>	<b>0</b>	<b>67</b>	
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	8	0	7	
		Obstructive airways disorder	1	0	1	
		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	17	0	11	
		Hypoventilation	2	0	1	
		Orthopnoea	1	0	1	
		Respiratory distress	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	2	0	1	
		Sneezing	1	0	0	
		Throat irritation	1	0	1	
		Throat tightness	1	0	1	
		Yawning	2	0	2	
		Laryngospasm	2	0	1	
		Stridor	2	0	0	
		Epistaxis	7	0	5	
		Pharyngeal oedema	1	0	1	
			<b>Respiratory, thoracic and mediastinal disorders</b>	<b>65</b>	<b>1</b>	<b>41</b>
		Skin and subcutaneous tissue disorders	Angioedema	9	0	7
			Urticaria	54	0	42
			Lichenoid keratosis	1	0	1
	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	1		0	1		
Eczema	1		0	1		
Rash erythematous	14		0	10		
Dermatitis exfoliative	1		0	1		
Skin exfoliation	3		0	3		

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			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	Lichenification	1	0	0
		Rash papular	1	0	1
		Photosensitivity reaction	4	0	2
		Pruritus	64	0	54
		Rash pruritic	2	0	1
		Dermatitis psoriasiform	1	0	1
		Psoriasis	4	0	3
		Fixed eruption	1	0	1
		Rash	53	0	48
		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	50	0	34
		Night sweats	1	0	1
		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
			<b>Skin and subcutaneous tissue disorders</b>		<b>374</b>
Social circumstances		Physical assault	1	0	1
		Verbal abuse	1	0	1
		<b>Social circumstances</b>	<b>2</b>	<b>0</b>	<b>2</b>
Surgical and medical procedures		Drug therapy changed	2	0	2
		Therapy regimen changed	4	0	3
		<b>Surgical and medical procedures</b>	<b>6</b>	<b>0</b>	<b>5</b>
Vascular disorders		Circulatory collapse	2	0	0
		Hypotension	15	0	7
		Orthostatic hypotension	8	0	4
		Vasodilatation	3	1	2
		Flushing	6	0	5
		Hot flush	5	0	3
		Pallor	4	0	3
		Haematoma	4	0	3
		Haemorrhage	1	0	0

**Medicine summary -fluoxetine (to date)**

			Case Group	Death Outcomes	Sole
Reaction Count	Vascular disorders	Hypertension	13	0	9
		Vasculitis	5	0	5
		<b>Vascular disorders</b>	<b>66</b>	<b>1</b>	<b>41</b>
<b>Reaction</b>			<b>3288</b>	<b>52</b>	<b>2201</b>