

**Medicine summary -paroxetine (to end January 2009)**

			Case Group	Death Outcomes	Sole	
Case Count			1881	14	1487	
Reaction Count	Blood and lymphatic system disorders	Anaemia vitamin B12 deficiency	1	0	1	
		Anaemia	3	0	3	
Hypochromic anaemia		2	0	2		
Pancytopenia		4	0	4		
Haemolytic anaemia		1	0	1		
Platelet disorder		2	0	1		
Thrombocytopenia		9	0	5		
Lymphadenopathy		1	0	1		
Eosinophilia		3	0	3		
Lymphocytosis		2	0	2		
Monocytosis		1	0	1		
Neutrophilia		1	0	1		
Leukopenia		5	0	5		
Neutropenia		4	0	2		
<b>Blood and lymphatic system disorders</b>			<b>39</b>	<b>0</b>	<b>32</b>	
Cardiac disorders		Atrioventricular block first degree	1	0	0	
	Bundle branch block	1	0	1		
	Arrhythmia	2	0	2		
	Bradycardia	6	0	3		
	Extrasystoles	4	0	3		
	Tachycardia	23	0	9		
	Atrial fibrillation	6	0	5		
	Sinus bradycardia	1	0	0		
	Cardiac arrest	4	0	2		
	Electromechanical dissociation	1	0	0		
	Torsade de pointes	1	0	1		
	Ventricular tachycardia	1	0	0		
	Cyanosis	2	1	1		
	Palpitations	31	0	28		
	Acute coronary syndrome	1	0	0		
	Angina pectoris	4	0	2		
	Myocardial infarction	3	0	1		
	Cardiac failure	3	1	1		
	Cardiomyopathy	5	1	2		
	Cardiomegaly	1	0	0		
<b>Cardiac disorders</b>			<b>101</b>	<b>3</b>	<b>61</b>	
Congenital, familial and genetic disorders	Pulmonary artery stenosis congenital	1	0	1		
	Heart disease congenital	2	0	2		
	Atrial septal defect	1	0	1		
	Cardiac septal defect	1	0	1		
	Ventricular septal defect	2	0	2		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Congenital, familial and genetic disorders	Patent ductus arteriosus	1	0	1	
		Multiple congenital abnormalities	4	0	2	
		Congenital eye disorder	1	0	1	
		Hernia congenital	1	0	1	
		Cleft palate	1	0	1	
		Pierre Robin syndrome	2	0	2	
		Congenital hand malformation	1	0	1	
		Limb reduction defect	1	0	1	
		Syndactyly	1	0	0	
		Talipes	1	0	1	
		Cerebellar hypoplasia	1	1	1	
		Cerebral palsy	1	0	1	
		Congenital hydrocephalus	1	0	1	
		Congenital neurological disorder	1	1	1	
		Tourette's disorder	1	0	1	
		Renal aplasia	1	0	1	
			<b>Congenital, familial and genetic disorders</b>	<b>27</b>	<b>2</b>	<b>24</b>
		Ear and labyrinth disorders	Ear pain	2	0	1
			Deafness	3	0	2
			Hyperacusis	3	0	3
			Tinnitus	36	0	32
			Vertigo	20	0	17
			<b>Ear and labyrinth disorders</b>	<b>64</b>	<b>0</b>	<b>55</b>
		Endocrine disorders	Hyperprolactinaemia	2	0	2
			Inappropriate antidiuretic hormone secretion	15	0	12
			Hyperparathyroidism	1	0	0
			Goitre	1	0	1
			Hyperthyroidism	1	0	1
			Hypothyroidism	1	0	0
			<b>Endocrine disorders</b>	<b>21</b>	<b>0</b>	<b>16</b>
		Eye disorders	Cataract	2	0	0
			Corneal opacity	1	0	1
			Xerophthalmia	1	0	1
			Lacrimal disorder	1	0	1
			Eye pain	3	0	3
			Retinal disorder	1	0	1
			Glaucoma	4	0	4
			Conjunctival haemorrhage	1	0	1
			Conjunctivitis	1	0	0
			Keratitis	1	0	1
			Ulcerative keratitis	1	0	1
			Blepharospasm	1	0	1

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			Case Group	Death Outcomes	Sole
Reaction Count	Eye disorders	Eyelid ptosis	2	0	2
		Oculogyric crisis	8	0	6
		Strabismus	1	0	1
		Mydriasis	11	0	8
		Pupillary reflex impaired	1	0	0
		Abnormal sensation in eye	1	0	1
		Photophobia	6	0	2
		Papilloedema	1	0	0
		Exophthalmos	1	0	1
		Accommodation disorder	5	0	4
		Diplopia	3	0	3
		Vision blurred	3	0	3
		Visual impairment	32	0	23
		<b>Eye disorders</b>	<b>93</b>	<b>0</b>	<b>69</b>
		Gastrointestinal disorders	Rectal discharge	1	0
	Dental caries		1	0	1
	Tooth disorder		2	0	2
	Toothache		1	0	1
	Gingivitis		1	0	1
	Gastrointestinal disorder		1	0	0
	Barrett's oesophagus		1	0	1
	Anal haemorrhage		1	0	1
	Rectal haemorrhage		3	0	2
	Gastrointestinal haemorrhage		2	0	2
	Haematemesis		1	0	1
	Colitis		1	0	1
	Proctitis		1	0	0
	Diarrhoea		69	0	60
	Diarrhoea haemorrhagic		1	0	1
	Constipation		18	0	13
	Gastrooesophageal reflux disease		2	0	1
	Gastrointestinal sounds abnormal		1	0	1
	Dyspepsia		5	0	4
Eructation	3		0	3	
Faeces pale	1		0	1	
Abdominal distension	1		0	1	
Flatulence	6		0	6	
Abdominal pain	36		0	33	
Abdominal pain upper	4		0	4	
Abdominal discomfort	1		0	1	
Dysphagia	14		0	10	
Faecal incontinence	5		0	4	

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			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Nausea	231	1	205
		Vomiting	61	0	44
		Vomiting neonatal	1	0	1
		Intestinal obstruction	1	0	0
		Gastric ulcer haemorrhage	1	0	1
		Lip swelling	1	0	0
		Mouth ulceration	5	0	5
		Stomatitis	1	0	0
		Ascites	2	1	1
		Dry mouth	35	0	32
		Salivary hypersecretion	3	0	1
		Salivary gland enlargement	2	0	2
		Glossitis	3	0	2
		Tongue disorder	1	0	1
		Tongue ulceration	1	0	1
		Swollen tongue	2	0	1
		Tongue oedema	9	0	9
	<b>Gastrointestinal disorders</b>	<b>544</b>	<b>2</b>	<b>463</b>	
	General disorders and administration site conditions	Hyperthermia malignant	1	0	0
		Hypothermia	3	1	2
		Fever neonatal	2	0	1
		Pyrexia	27	0	15
		Death	1	1	0
		Sudden death	4	4	1
		Asthenia	39	1	30
		Fatigue	57	0	50
		Malaise	32	0	22
Gait disturbance		14	0	12	
Condition aggravated		4	0	3	
Developmental delay		1	0	1	
Influenza like illness		3	0	3	
Irritability		3	0	3	
Face oedema		15	0	11	
Gravitational oedema		8	0	2	
Oedema		8	0	8	
Oedema peripheral		6	0	6	
Chest pain		20	0	18	
Facial pain	1	0	0		
Pain	20	0	18		
Chest discomfort	1	0	1		
Chills	17	0	10		
Feeling abnormal	4	0	4		

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			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	Feeling hot	3	0	2
		Feeling of body temperature change	2	0	2
		Thirst	6	0	3
		Alcohol interaction	1	1	0
		Drug interaction	7	2	0
		Drug ineffective	17	1	12
		Therapeutic response unexpected	4	0	3
		Therapeutic response unexpected with drug substitution	3	0	3
		Drug withdrawal syndrome	14	0	14
		Drug withdrawal syndrome neonatal	8	0	5
			<b>General disorders and administration site conditions</b>	<b>356</b>	<b>11</b>
Hepatobiliary disorders	Hepatitis cholestatic	1	0	0	
	Jaundice	9	0	6	
	Hepatic function abnormal	26	1	18	
	Hepatic failure	2	1	0	
	Hepatosplenomegaly	1	0	0	
	Hepatic necrosis	1	1	0	
	Hepatic steatosis	1	0	0	
	Hepatitis	6	1	3	
		<b>Hepatobiliary disorders</b>	<b>47</b>	<b>4</b>	<b>27</b>
Immune system disorders	Hypersensitivity	1	0	0	
	Anaphylactoid reaction	1	0	0	
		<b>Immune system disorders</b>	<b>2</b>	<b>0</b>	<b>0</b>
Infections and infestations	Folliculitis	1	0	1	
	Mastitis	1	0	0	
	Vaginal infection	2	0	2	
	Abscess	1	0	0	
	Pneumonia	4	1	3	
	Rash pustular	1	0	1	
	Pharyngitis	4	0	3	
	Rhinitis	3	0	3	
	Upper respiratory tract infection	1	0	1	
	Cystitis	1	0	1	
	Urinary tract infection	2	0	2	
	Herpes simplex	1	0	1	
	Herpes zoster	2	0	2	
		<b>Infections and infestations</b>	<b>24</b>	<b>1</b>	<b>20</b>
	Injury, poisoning and procedural complications	Limb injury	1	0	0
Drug toxicity		1	1	0	
Drug exposure during pregnancy		5	1	4	

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			Case Group	Death Outcomes	Sole
Reaction Count	Injury, poisoning and procedural complications	Fall	3	0	1
		Face injury	1	0	0
		Contusion	5	0	4
		Medication error	1	0	1
		Intentional overdose	1	0	0
		Overdose	3	1	1
		<b>Injury, poisoning and procedural complications</b>	<b>21</b>	<b>3</b>	<b>11</b>
	Investigations	Electrocardiogram QT prolonged	1	0	1
		Electrocardiogram abnormal	2	0	2
		Heart rate increased	1	0	1
		Blood pressure increased	5	0	2
		Blood prolactin increased	1	0	0
		Thyroid function test abnormal	1	0	1
		Blood creatine phosphokinase increased	5	0	1
		Bleeding time prolonged	2	0	1
		Prothrombin level decreased	5	0	1
		Red blood cell sedimentation rate increased	1	0	1
		Platelet aggregation abnormal	1	0	0
		Neutrophil count decreased	1	0	0
		White blood cell count decreased	1	0	0
		Alanine aminotransferase increased	2	0	2
		Aspartate aminotransferase increased	2	0	2
		Hepatic enzyme increased	1	0	1
		Liver function test abnormal	2	0	2
		Antinuclear antibody positive	2	0	2
		Apgar score low	1	0	1
		Body temperature increased	3	0	1
		Weight decreased	14	0	10
		Weight increased	44	1	38
		Blood creatinine increased	1	0	0
		Creatinine renal clearance decreased	1	0	0
		Urine analysis abnormal	1	0	1
		Drug level increased	6	3	1
	<b>Investigations</b>	<b>107</b>	<b>4</b>	<b>72</b>	
	Metabolism and nutrition disorders	Ketosis	1	0	0
		Lactic acidosis	1	1	0
Alkalosis		1	0	0	
Decreased appetite		32	0	30	
Increased appetite		5	0	4	
Feeding disorder neonatal		6	0	5	
Hypocalcaemia		2	0	0	

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			Case Group	Death Outcomes	Sole
Reaction Count	Metabolism and nutrition disorders	Tetany	5	0	4
		Hypomagnesaemia	2	0	1
		Hypophosphataemia	2	0	1
		Hypochloraemia	1	0	1
		Polydipsia	1	0	1
		Hypokalaemia	10	0	1
		Hyponatraemia	72	0	40
		Dehydration	5	0	3
		Alcohol intolerance	3	0	2
		Diabetes mellitus	7	0	2
		Hyperglycaemia	2	0	2
		Hypoglycaemia	3	0	3
		Hypoglycaemia neonatal	2	0	1
		Hypercholesterolaemia	2	0	2
		Hypertriglyceridaemia	1	0	1
		<b>Metabolism and nutrition disorders</b>	<b>166</b>	<b>1</b>	<b>104</b>
	Musculoskeletal and connective tissue disorders	Jaw disorder	1	0	1
		Pain in jaw	1	0	1
		Systemic lupus erythematosus	2	0	0
		Arthritis	6	0	4
Arthralgia		24	0	18	
Osteoarthritis		2	0	2	
Myositis		1	0	0	
Myalgia		39	0	33	
Muscle spasms		14	0	11	
Muscle twitching		45	0	40	
Hypertonia neonatal		2	0	1	
Hypotonia neonatal		2	0	1	
Torticollis		4	0	3	
Trismus		1	0	1	
Rhabdomyolysis		2	0	0	
Mobility decreased		1	0	1	
Sensation of heaviness		1	0	0	
Back pain		5	0	4	
Neck pain		1	0	1	
Pain in extremity		2	0	1	
Bursitis	1	0	1		
<b>Musculoskeletal and connective tissue disorders</b>	<b>157</b>	<b>0</b>	<b>124</b>		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal carcinoma	1	0	0	
	<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>1</b>	<b>0</b>	<b>0</b>	

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Reaction Count			Case Group	Death Outcomes	Sole
	Nervous system disorders	Cerebrovascular accident	1	0	0
		Parosmia	4	0	4
		Encephalopathy	1	0	0
		Encephalopathy neonatal	1	0	1
		Drug withdrawal headache	1	0	1
		Headache	97	0	79
		Migraine	5	0	5
		Dementia	1	0	0
		Amnesia	19	0	15
		Memory impairment	1	0	0
		Disturbance in attention	19	0	16
		Akathisia	12	1	5
		Bradykinesia	1	0	1
		Dyskinesia	18	0	13
		Dyskinesia neonatal	1	0	0
		Extrapyramidal disorder	15	0	9
		Hyperkinesia	21	0	18
		Hypokinesia	2	0	2
		Movement disorder	1	0	1
		Tardive dyskinesia	2	0	1
		Dystonia	35	0	23
		Opisthotonus	4	0	1
		Hemiparesis	1	0	0
		Paralysis	2	0	2
		Paresis	3	0	2
		Tremor	148	0	120
		Tremor neonatal	2	0	1
		Hyperreflexia	7	0	1
		Ataxia	27	0	19
		Balance disorder	1	0	1
		Coordination abnormal	7	0	5
		Nystagmus	1	0	0
		Coma	7	1	3
		Aphasia	4	0	3
		Altered state of consciousness	1	0	0
		Consciousness fluctuating	2	0	1
		Depressed level of consciousness	2	0	1
		Lethargy	8	0	5
		Loss of consciousness	3	0	1
		Sedation	1	0	1
	Somnolence	62	0	52	
	Stupor	3	0	3	



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			Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Syncope	20	1	15	
		Nervous system disorder	1	1	1	
		Clonus	3	0	1	
		Dizziness	170	1	146	
		Meningism	2	0	2	
		Myoclonus	5	0	3	
		Crying	4	0	3	
		Formication	2	0	2	
		Hyperaesthesia	3	0	3	
		Paraesthesia	82	0	72	
		Ageusia	1	0	1	
		Dysgeusia	8	0	6	
		Hypoaesthesia	22	0	18	
		Neuralgia	1	0	1	
		Restless legs syndrome	1	0	1	
		Sensory disturbance	11	0	10	
		Dysarthria	8	0	5	
		Speech disorder	9	0	9	
		Visual field defect	1	0	1	
		Anticholinergic syndrome	1	0	0	
		Hypertonia	36	0	26	
		Hypotonia	3	0	2	
		Neuroleptic malignant syndrome	5	0	2	
		Serotonin syndrome	35	1	7	
		Muscle contractions involuntary	1	0	1	
		Neuropathy peripheral	1	0	1	
		Petit mal epilepsy	1	0	1	
		Convulsion neonatal	3	0	3	
		Grand mal convulsion	12	0	6	
		Temporal lobe epilepsy	1	0	0	
		Convulsion	42	0	30	
		Epilepsy	1	0	1	
		Tonic clonic movements	1	0	1	
		Poor quality sleep	1	0	1	
			<b>Nervous system disorders</b>	<b>1052</b>	<b>6</b>	<b>798</b>
		Pregnancy, puerperium and perinatal conditions	Abortion	2	0	2
			Intra-uterine death	9	0	9
			Foetal disorder	1	0	1
			Foetal distress syndrome	1	0	0
			Foetal growth retardation	1	0	1
			Antepartum haemorrhage	1	0	1
			Postmature baby	1	0	1

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			Case Group	Death Outcomes	Sole
Reaction Count	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	1	0	1
		Neonatal disorder	3	0	1
Unintended pregnancy		2	0	0	
<b>Pregnancy, puerperium and perinatal conditions</b>		<b>22</b>	<b>0</b>	<b>17</b>	
Psychiatric disorders	Agitation	113	0	87	
	Agitation neonatal	6	0	3	
	Anxiety	72	1	53	
	Nervousness	10	0	8	
	Stress	1	0	1	
	Agoraphobia	1	1	0	
	Panic attack	8	0	6	
	Panic disorder	1	0	1	
	Neurosis	4	0	3	
	Restlessness	5	0	3	
	Bruxism	11	0	11	
	Tic	1	0	1	
	Learning disorder	1	0	1	
	Mutism	1	0	0	
	Confusional state	60	0	39	
	Disorientation	5	0	1	
	Delirium	16	0	5	
	Depression	35	1	27	
	Depressed mood	1	0	1	
	Tearfulness	1	0	0	
	Depersonalisation	28	0	23	
	Dissociation	3	0	3	
	Delusion	5	0	2	
	Delusion of grandeur	1	0	0	
	Hallucination	43	0	28	
	Hallucination, auditory	3	0	2	
	Hallucination, visual	3	0	3	
	Thinking abnormal	16	0	14	
	Hypomania	2	0	0	
	Mania	22	0	15	
	Affect lability	9	0	9	
	Anger	5	0	5	
	Dysphoria	1	0	1	
	Emotional distress	1	0	1	
Euphoric mood	4	0	3		
Mood altered	2	0	2		
Mood swings	2	0	2		

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			Case Group	Death Outcomes	Sole		
Reaction Count	Psychiatric disorders	Apathy	10	0	9		
		Aggression	23	0	18		
		Homicidal ideation	2	0	0		
		Hostility	1	0	1		
		Paranoia	6	0	4		
		Personality change	3	0	1		
		Violence-related symptom	1	0	0		
		Personality disorder	1	0	0		
		Abnormal behaviour	2	0	0		
		Mental status changes	1	0	0		
		Alcoholism	2	0	1		
		Intentional drug misuse	1	0	0		
		Withdrawal syndrome	172	0	166		
		Psychotic disorder	22	0	14		
		Anorgasmia	29	0	27		
		Libido decreased	34	0	30		
		Libido increased	2	0	1		
		Loss of libido	2	0	1		
		Insomnia	80	0	66		
		Abnormal dreams	7	0	6		
		Nightmare	35	0	29		
		Somnambulism	3	0	2		
		Sleep disorder	16	0	15		
		Completed suicide	3	3	0		
		Intentional self-injury	3	0	3		
		Self injurious behaviour	4	1	2		
		Self-injurious ideation	2	0	2		
		Suicidal ideation	18	0	9		
		Suicide attempt	23	1	13		
			<b>Psychiatric disorders</b>	<b>1011</b>	<b>8</b>	<b>784</b>	
		Reaction Count	Renal and urinary disorders	Tubulointerstitial nephritis	1	0	0
				Anuria	1	0	0
				Oliguria	2	0	0
				Renal failure acute	7	2	2
Renal impairment	3			0	1		
Urethral disorder	1			0	1		
Dysuria	7			0	7		
Enuresis	1			0	1		
Micturition disorder	10			0	7		
Pollakiuria	12			0	11		
Urinary incontinence	14			0	11		
Urinary retention	14			0	10		

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			Case Group	Death Outcomes	Sole
Reaction Count	Renal and urinary disorders	Albuminuria	2	0	2
		Chromaturia	1	0	1
		Haematuria	6	0	4
		Pyuria	1	0	1
		Nocturia	2	0	2
		Polyuria	4	0	4
		Renal pain	1	0	0
		Nephrolithiasis	1	0	0
		<b>Renal and urinary disorders</b>	<b>91</b>	<b>2</b>	<b>65</b>
	Reproductive system and breast disorders	Breast enlargement	2	0	1
		Gynaecomastia	3	0	2
		Breast pain	4	0	3
		Galactorrhoea	22	0	16
		Menstrual disorder	5	0	4
		Metrorrhagia	2	0	0
		Amenorrhoea	6	0	4
		Menorrhagia	7	0	6
		Penis disorder	2	0	2
		Perineal pain	1	0	1
		Ejaculation failure	49	0	45
		Erectile dysfunction	16	0	13
		Priapism	6	0	5
		Sexual dysfunction	8	0	8
		Testicular disorder	1	0	1
		Vaginal haemorrhage	3	0	3
		Vulval disorder	1	0	0
		<b>Reproductive system and breast disorders</b>	<b>138</b>	<b>0</b>	<b>114</b>
	Respiratory, thoracic and mediastinal disorders	Asthma	2	0	1
		Bronchospasm	2	0	2
		Pulmonary fibrosis	2	1	1
		Pulmonary oedema	2	0	2
		Cyanosis neonatal	1	0	1
		Infantile apnoeic attack	1	0	1
Neonatal hypoxia		1	0	1	
Neonatal respiratory distress syndrome		1	0	1	
Respiratory disorder neonatal		1	0	0	
Pleural fibrosis		1	0	1	
Pleural effusion		1	0	1	
Pulmonary embolism		3	1	2	
Apnoea		2	0	2	
Dyspnoea		20	0	14	
Hyperventilation		6	0	4	

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		Case Group	Death Outcomes	Sole	
Reaction Count	Respiratory, thoracic and mediastinal disorders	Respiratory arrest	1	1	1
		Cough	4	0	4
		Haemoptysis	1	0	1
		Respiratory failure	1	1	0
		Aspiration	1	0	1
		Respiratory disorder	2	0	1
		Choking	2	0	1
		Dry throat	1	0	1
		Dysphonia	4	0	3
		Throat irritation	1	0	1
		Throat tightness	5	0	4
		Yawning	17	0	16
		Epistaxis	5	0	4
		Oropharyngeal swelling	1	0	1
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>92</b>	<b>4</b>	<b>73</b>
	Skin and subcutaneous tissue disorders	Angioedema	8	0	6
		Periorbital oedema	5	0	5
		Urticaria	18	0	16
		Mechanical urticaria	1	0	1
		Blister	1	0	1
		Dermatitis bullous	3	0	3
		Erythema multiforme	4	0	3
		Dry skin	2	0	2
		Skin discolouration	2	0	2
		Skin disorder	1	0	1
		Swelling face	1	0	1
		Dermatitis	1	0	0
		Eczema	4	0	4
		Erythema	2	0	1
Rash erythematous		7	0	5	
Dermatitis exfoliative		1	0	1	
Skin exfoliation		1	0	0	
Rash papular		3	0	1	
Photosensitivity reaction		9	0	6	
Pruritus		58	0	46	
Dermatitis psoriasiform		2	0	2	
Psoriasis		2	0	2	
Fixed eruption		1	0	0	
Rash		50	0	41	
Rash maculo-papular	20	0	17		
Rash vesicular	3	0	3		

**Medicine summary -paroxetine (to end January 2009)**

			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	Systemic lupus erythematosus rash	1	0	0
		Skin depigmentation	1	0	1
		Erythema nodosum	1	0	1
		Skin ulcer	1	0	1
		Acne	5	0	5
		Alopecia	20	1	15
		Anhidrosis	1	0	1
		Cold sweat	5	0	4
		Hyperhidrosis	128	0	107
		Night sweats	4	0	3
		Nail disorder	2	0	2
		Hair colour changes	1	0	0
		Purpura	62	0	48
		<b>Skin and subcutaneous tissue disorders</b>	<b>442</b>	<b>1</b>	<b>358</b>
		Social circumstances	Physical assault	1	0
Alcohol use	2		0	1	
<b>Social circumstances</b>	<b>3</b>		<b>0</b>	<b>1</b>	
Surgical and medical procedures	Abortion induced	1	0	1	
	Drug therapy changed	2	0	2	
	Therapy regimen changed	2	0	2	
	<b>Surgical and medical procedures</b>	<b>5</b>	<b>0</b>	<b>5</b>	
Vascular disorders	Peripheral ischaemia	3	0	3	
	Circulatory collapse	1	0	1	
	Shock	2	0	1	
	Hypotension	14	1	7	
	Orthostatic hypotension	17	0	11	
	Deep vein thrombosis	2	0	1	
	Flushing	13	0	12	
	Hot flush	11	0	9	
	Pallor	2	0	1	
	Haematoma	1	0	1	
	Haemorrhage	3	0	2	
	Hypertension	17	0	12	
	Vasculitis	2	0	2	
	<b>Vascular disorders</b>	<b>88</b>	<b>1</b>	<b>63</b>	
	<b>Reaction</b>		<b>4714</b>	<b>53</b>	<b>3621</b>