

Medicine summary -paroxetine (to date)

			Case Group	Death Outcomes	Sole		
Case Count			1937	14	1530		
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		
		Blood and lymphatic system disorders			39	0	32
		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		35	0	32		
	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		
	Cardiac disorders			105	3	65	
	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		

Medicine summary -paroxetine (to date)

			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
		Gastroschisis	1	0	0
		Cleft palate	1	0	1
		Pierre Robin syndrome	2	0	2
		Congenital hand malformation	1	0	1
		Hip dysplasia	1	0	1
		Limb reduction defect	1	0	1
		Syndactyly	1	0	0
		Talipes	1	0	1
		Cerebellar hypoplasia	1	1	1
		Cerebral palsy	2	0	2
		Congenital hydrocephalus	1	0	1
		Congenital neurological disorder	1	1	1
		Tourette's disorder	1	0	1
		Renal aplasia	1	0	1
		Congenital, familial and genetic disorders	30	2	26
	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
		Ear and labyrinth disorders	64	0	55
	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
		Endocrine disorders	21	0	16
	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
		Periorbital oedema	5	0	5
		Glaucoma	4	0	4
		Conjunctival haemorrhage	2	0	2
		Conjunctivitis	1	0	0

Medicine summary -paroxetine (to date)

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Reaction Count	Eye disorders	Keratitis	1	0	1
		Ulcerative keratitis	1	0	1
		Blepharospasm	1	0	1
		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	5	0	5
		Visual impairment	33	0	24
		Eye disorders		102	0
	Gastrointestinal disorders	Rectal discharge	1	0	1
		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	4	0	3
		Gastrointestinal haemorrhage	2	0	2
Haematemesis		1	0	1	
Colitis		1	0	1	
Proctitis		1	0	0	
Diarrhoea		75	0	66	
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	37	0	34		
Abdominal pain upper	4	0	4		

Medicine summary -paroxetine (to date)

			Case Group	Death Outcomes	Sole		
Reaction Count	Gastrointestinal disorders	Abdominal discomfort	2	0	2		
		Dysphagia	14	0	10		
		Faecal incontinence	5	0	4		
		Nausea	237	1	210		
		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		
		Hypoaesthesia oral	1	0	1		
		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		
			Gastrointestinal disorders	560	2	478	
		Reaction Count	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	42			1	33		
Fatigue	57			0	50		
Malaise	35			0	25		
Gait disturbance	14			0	12		
Condition aggravated	4			0	3		
Developmental delay	1			0	1		
Ill-defined disorder	1			0	1		
Influenza like illness	3			0	3		
Irritability	4			0	4		
Face oedema	15			0	11		
Gravitational oedema	8			0	2		
Oedema	8			0	8		
Oedema peripheral	7			0	7		
Chest pain	22			0	19		

Medicine summary -paroxetine (to date)

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Reaction Count	General disorders and administration site conditions	Facial pain	1	0	0	
		Pain	20	0	18	
		Chest discomfort	3	0	3	
		Chills	17	0	10	
		Feeling abnormal	5	0	4	
		Feeling cold	1	0	1	
		Feeling hot	3	0	2	
		Feeling of body temperature change	2	0	2	
		Thirst	6	0	3	
		Alcohol interaction	1	1	0	
		Drug interaction	9	2	0	
		Drug ineffective	20	1	14	
		Therapeutic response unexpected	5	0	4	
		Therapeutic response unexpected with drug substitution	4	0	4	
		Drug withdrawal syndrome	16	0	16	
		Drug withdrawal syndrome neonatal	8	0	5	
		Product substitution issue	1	0	0	
			General disorders and administration site conditions	381	11	284
		Hepatobiliary disorders	Hepatitis cholestatic	1	0	0
			Jaundice	9	0	6
Hepatic function abnormal	28		1	19		
Hepatic failure	2		1	0		
Hepatosplenomegaly	1		0	0		
Hepatic necrosis	1		1	0		
Hepatic steatosis	1		0	0		
Hepatitis	6		1	3		
	Hepatobiliary disorders		49	4	28	
Immune system disorders	Hypersensitivity	1	0	0		
	Anaphylactoid reaction	1	0	0		
		Immune system disorders	2	0	0	
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		

Medicine summary -paroxetine (to date)

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Reaction Count	Infections and infestations	Urinary tract infection	2	0	2	
		Herpes simplex	1	0	1	
		Herpes zoster	2	0	2	
		Infections and infestations	24	1	20	
	Injury, poisoning and procedural complications	Limb injury	1	0	0	
		Drug toxicity	1	1	0	
		Drug exposure during pregnancy	9	1	7	
		Fall	4	0	1	
		Face injury	1	0	0	
		Contusion	5	0	4	
		Incorrect dose administered	1	0	0	
		Medication error	1	0	1	
		Intentional overdose	1	0	0	
		Multiple drug overdose	1	0	0	
		Overdose	3	1	1	
		Injury, poisoning and procedural complications	28	3	14	
		Investigations	Cardiac murmur	1	0	1
			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	
	International normalised ratio increased		1	0	0	
	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		
Blood glucose increased	1		0	1		
Apgar score low	1		0	1		
Body temperature increased	3		0	1		
Weight decreased	15		0	11		
Weight increased	45		1	39		

Medicine summary -paroxetine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Investigations	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
		Blood potassium increased	1	0	1
		Investigations	113	4	77
	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
		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	76	0	42
		Dehydration	6	0	4
		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
		Metabolism and nutrition disorders	171	1	107
	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		40	0	34	
Muscle spasms		16	0	13	
Muscle twitching		47	0	42	
Hypertonia neonatal		2	0	1	
Hypotonia neonatal		2	0	1	
Torticollis		4	0	3	

Medicine summary -paroxetine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Musculoskeletal and connective tissue disorders	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
		Musculoskeletal and connective tissue disorders	162	0	129
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal carcinoma	1	0	0
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0	0
	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	102	0	84
		Migraine	6	0	6
		Dementia	1	0	0
		Amnesia	19	0	15
		Memory impairment	1	0	0
		Disturbance in attention	20	0	17
		Akathisia	12	1	5
		Bradykinesia	1	0	1
		Dyskinesia	19	0	14
		Dyskinesia neonatal	1	0	0
		Extrapyramidal disorder	16	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		154	0	124	
Tremor neonatal		2	0	1	
Hyperreflexia	7	0	1		
Ataxia	28	0	20		

Medicine summary -paroxetine (to date)

		Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Balance disorder	2	0	2
		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	64	0	54
		Stupor	4	0	4
		Syncope	21	1	16
		Nervous system disorder	1	1	1
		Clonus	3	0	1
		Dizziness	175	1	151
		Meningism	2	0	2
		Myoclonus	6	0	4
		Crying	7	0	6
		Formication	2	0	2
		Hyperaesthesia	3	0	3
		Paraesthesia	86	0	76
		Ageusia	1	0	1
		Dysgeusia	9	0	7
		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	4	0	3
		Neuroleptic malignant syndrome	8	0	3
		Serotonin syndrome	36	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		

Medicine summary -paroxetine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Temporal lobe epilepsy	1	0	0
		Convulsion	45	0	32
		Epilepsy	1	0	1
		Tonic clonic movements	1	0	1
		Poor quality sleep	2	0	2
		Nervous system disorders	1096	6	835
	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 restriction	1	0	1
		Antepartum haemorrhage	1	0	1
		Postmature baby	1	0	1
		Jaundice neonatal	1	0	1
		Neonatal disorder	3	0	1
		Unintended pregnancy	2	0	0
		Pregnancy, puerperium and perinatal conditions	22	0	17
	Psychiatric disorders	Agitation	118	0	92
		Agitation neonatal	6	0	3
		Anxiety	75	1	56
		Nervousness	10	0	8
		Stress	1	0	1
		Agoraphobia	1	1	0
		Panic attack	9	0	7
		Panic disorder	1	0	1
		Neurosis	4	0	3
		Obsessive-compulsive disorder	1	0	0
		Restlessness	6	0	4
		Bruxism	11	0	11
		Tic	1	0	1
		Learning disorder	1	0	1
		Mutism	1	0	0
		Confusional state	61	0	40
Disorientation		6	0	2	
Delirium		16	0	5	
Depression		35	1	27	
Depressed mood		1	0	1	
Tearfulness	1	0	0		
Depersonalisation	29	0	24		
Dissociation	3	0	3		
Delusion	5	0	2		

Medicine summary -paroxetine (to date)

Reaction Count			Case Group	Death Outcomes	Sole
	Psychiatric disorders	Delusion of grandeur	1	0	0
		Hallucination	44	0	29
		Hallucination, auditory	3	0	2
		Hallucination, visual	3	0	3
		Thinking abnormal	17	0	15
		Hypomania	2	0	0
		Mania	25	0	17
		Affect lability	9	0	9
		Anger	7	0	6
		Dysphoria	1	0	1
		Emotional distress	1	0	1
		Euphoric mood	4	0	3
		Mood altered	3	0	3
		Mood swings	2	0	2
		Apathy	10	0	9
		Aggression	26	0	20
		Homicidal ideation	2	0	0
		Hostility	2	0	2
		Paranoia	6	0	4
		Personality change	3	0	1
		Violence-related symptom	1	0	0
		Personality disorder	1	0	0
		Abnormal behaviour	4	0	1
		Mental status changes	1	0	0
		Alcoholism	2	0	1
		Dependence	1	0	1
		Intentional drug misuse	1	0	0
		Withdrawal syndrome	175	0	169
		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	84	0	69
		Abnormal dreams	10	0	9
		Nightmare	37	0	31
		Somnambulism	4	0	3
		Sleep disorder	16	0	15
		Completed suicide	3	3	0
		Intentional self-injury	3	0	3
		Self injurious behaviour	6	1	4
		Self-injurious ideation	2	0	2

Medicine summary -paroxetine (to date)

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Reaction Count	Psychiatric disorders	Suicidal ideation	22	0	13	
		Suicide attempt	23	1	13	
		Psychiatric disorders	1059	8	826	
	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	4	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	
		Albuminuria	2	0	2	
		Chromaturia	1	0	1	
		Haematuria	6	0	4	
		Pyuria	1	0	1	
		Nocturia	2	0	2	
		Polyuria	5	0	5	
		Renal pain	1	0	0	
		Nephrolithiasis	1	0	0	
		Renal and urinary disorders	93	2	66	
		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		3	0	1	
	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	4		0	4		
Vulval disorder	1		0	0		
Reproductive system and breast disorders	140	0	116			

Medicine summary -paroxetine (to date)

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Reaction Count	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	21	0	14		
		Hyperventilation	6	0	4		
		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		
			Respiratory, thoracic and mediastinal disorders	93	4	73	
		Reaction Count	Skin and subcutaneous tissue disorders	Angioedema	8	0	6
				Urticaria	19	0	17
				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		

Medicine summary -paroxetine (to date)

			Case Group	Death Outcomes	Sole		
Reaction Count	Skin and subcutaneous tissue disorders	Eczema	4	0	4		
		Erythema	2	0	1		
		Rash erythematous	8	0	6		
		Dermatitis exfoliative	1	0	1		
		Skin exfoliation	1	0	0		
		Granuloma annulare	1	0	1		
		Rash papular	3	0	1		
		Photosensitivity reaction	9	0	6		
		Pruritus	61	0	49		
		Rash pruritic	3	0	3		
		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		
		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	130	0	109		
		Night sweats	6	0	5		
		Nail disorder	2	0	2		
		Hair colour changes	1	0	0		
		Purpura	63	0	49		
			Skin and subcutaneous tissue disorders		451	1	367
		Social circumstances		Physical assault	2	0	0
				Alcohol use	2	0	1
				Impaired work ability	1	0	1
Social circumstances	5			0	2		
Surgical and medical procedures		Abortion induced	1	0	1		
		Drug therapy changed	2	0	2		
		Off label use	1	0	1		
		Therapy regimen changed	2	0	2		
		Surgical and medical procedures	6	0	6		
Vascular disorders		Peripheral ischaemia	3	0	3		
		Circulatory collapse	1	0	1		
		Shock	2	0	1		

Medicine summary -paroxetine (to date)

			Case Group	Death Outcomes	Sole
Reaction Count	Vascular disorders	Hypotension	15	1	7
		Orthostatic hypotension	17	0	11
		Deep vein thrombosis	2	0	1
		Flushing	15	0	14
		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
		Vascular disorders	91	1	65
Reaction		4908	53	3782	