

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

PAROXETINE HYDROCHLORIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		1845	12	1464
- Occurrences of Medicine		1865	12	1464
- Reactions Related to Medicine		4623	47	3576
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
Cardiac disorders	Atrioventricular block first degree	1	0	0
	Bundle branch block	1	0	1
	Arrhythmia	2	0	2
	Bradycardia	5	0	3
	Extrasystoles	4	0	3
	Tachycardia	23	0	9
	Atrial fibrillation	6	0	5
	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
	Angina pectoris	2	0	2



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Cardiac disorders	Myocardial infarction	2	0	1
	Cardiac failure	3	1	1
	Cardiomyopathy	5	1	2
	Cardiomegaly	1	0	0
Congenital, familial and genetic disorders	Pulmonary artery stenosis congenital	1	0	1
	Heart disease congenital	2	0	2
	Atrial septal defect	1	0	1
	Ventricular septal defect	2	0	2
	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
	Cerebral palsy	1	0	1
	Congenital hydrocephalus	1	0	1
	Tourette's disorder	1	0	1
	Renal aplasia	1	0	1
Ear and labyrinth disorders	Ear pain	2	0	1
	Deafness	3	0	2
	Hyperacusis	2	0	2
	Tinnitus	36	0	32
	Vertigo	20	0	17
Endocrine disorders	Hyperprolactinaemia	2	0	2
	Inappropriate antidiuretic hormone secretior	14	0	12
	Hyperparathyroidism	1	0	0
	Goitre	1	0	1
	Hyperthyroidism	1	0	1
	Hypothyroidism	1	0	0
Eye disorders	Cataract	2	0	0
	Corneal opacity	1	0	1

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Eye disorders	Xerophthalmia	1	0	1
	Lacrimonal 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
	Eyelid ptosis	2	0	2
	Oculogyration	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 disturbance	32	0	23	
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	3	0	2
	Gastrointestinal haemorrhage	2	0	2
	Haematemesis	1	0	1
	Colitis	1	0	1

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Gastrointestinal disorders	Proctitis	1	0	0
	Diarrhoea	69	0	60
	Diarrhoea haemorrhagic	1	0	1
	Constipation	18	0	13
	Gastrooesophageal reflux disease	1	0	1
	Bowel 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	3	0	3
	Dysphagia	14	0	10
	Faecal incontinence	5	0	4
	Stomach discomfort	1	0	1
	Nausea	228	1	204
	Vomiting	60	0	43
	Vomiting neonatal	1	0	1
	Intestinal obstruction	1	0	0
	Gastric ulcer haemorrhage	1	0	1
	Mouth ulceration	5	0	5
	Stomatitis	1	0	0
	Ascites	2	1	1
	Dry mouth	34	0	31
	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	1	0	1	
Tongue oedema	9	0	9	
General disorders and administration site conditions	Hyperthermia malignant	1	0	0
	Hypothermia	3	1	2
	Chills	16	0	10



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General disorders and administration site conditions	Feeling hot	2	0	2
	Feeling hot and cold	1	0	1
	Fever neonatal	2	0	1
	Pyrexia	26	0	15
	Sudden death	4	4	1
	Asthenia	40	1	31
	Fatigue	55	0	49
	Malaise	32	0	22
	Gait disturbance	14	0	12
	Chest discomfort	1	0	1
	Condition aggravated	4	0	3
	Developmental delay	1	0	1
	Feeling abnormal	3	0	3
	Influenza like illness	3	0	3
	Irritability	3	0	3
	Thirst	6	0	3
	Face oedema	16	0	12
	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	19	0	17
	Drug interaction	5	0	0
	Drug ineffective	16	1	12
	Drug withdrawal syndrome	179	0	173
	Drug withdrawal syndrome neonatal	7	0	4
	Therapeutic response unexpected	3	0	2
Therapeutic response unexpected with drug	2	0	2	
Hepatobiliary disorders	Hepatitis cholestatic	1	0	0
	Jaundice	9	0	6
	Hepatic function abnormal	25	1	17
	Hepatic failure	2	1	0
	Hepatosplenomegaly	1	0	0
	Hepatic necrosis	1	1	0



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Hepatobiliary disorders	Hepatic steatosis	1	0	0
	Hepatitis	6	1	3
Immune system disorders	Hypersensitivity	1	0	0
	Anaphylactoid reaction	1	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
	Urinary tract infection	2	0	2
	Herpes simplex	1	0	1
	Herpes zoster	2	0	2
	Injury, poisoning and procedural complications	Limb injury	1	0
Drug toxicity		1	1	0
Drug exposure during pregnancy		3	0	2
Fall		3	0	1
Face injury		1	0	0
Contusion		4	0	3
Medication error		1	0	1
Intentional overdose		1	0	0
Overdose		2	1	0
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	4	0	1
	Bleeding time prolonged	2	0	1
	Prothrombin level decreased	5	0	1

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Investigations	Red blood cell sedimentation rate increasec	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	13	0	9
	Weight increased	40	1	36
	Blood creatinine increased	1	0	0
	Creatinine renal clearance decreased	1	0	0
	Urine analysis abnormal	1	0	1
	Drug level increased	5	2	1
Metabolism and nutrition disorders	Ketosis	1	0	0
	Lactic acidosis	1	1	0
	Alkalosis	1	0	0
	Anorexia	31	0	30
	Increased appetite	5	0	4
	Feeding disorder neonatal	7	0	6
	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	9	0	1
	Hyponatraemia	71	0	40
	Dehydration	5	0	3
	Alcohol intolerance	3	0	2
	Diabetes mellitus	6	0	2
Hyperglycaemia	2	0	2	

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Metabolism and nutrition disorders	Hypoglycaemia	3	0	3
	Hypoglycaemia neonatal	2	0	1
	Hypercholesterolaemia	2	0	2
	Hypertriglyceridaemia	1	0	1
Musculoskeletal and connective tissue disorders	Jaw disorder	1	0	1
	Pain in jaw	1	0	1
	Systemic lupus erythematosus	2	0	0
	Arthritis	5	0	4
	Arthralgia	22	0	17
	Osteoarthritis	2	0	2
	Myositis	1	0	0
	Myalgia	38	0	32
	Muscle spasms	14	0	11
	Muscle twitching	44	0	39
	Hypertonia neonatal	2	0	1
	Hypotonia neonatal	2	0	1
	Torticollis	4	0	3
	Trismus	1	0	1
	Rhabdomyolysis	1	0	0
	Back pain	5	0	4
	Mobility decreased	1	0	1
	Neck pain	1	0	1
	Pain in extremity	1	0	1
	Sensation of heaviness	1	0	0
Bursitis	1	0	1	
Neoplasms benign, malignant and unspecified	Gastrointestinal carcinoma	1	0	0
Nervous system disorders	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

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Nervous system disorders	Disturbance in attention	19	0	16
	Akathisia	12	1	5
	Bradykinesia	1	0	1
	Dyskinesia	17	0	12
	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	147	0	119
	Tremor neonatal	2	0	1
	Hyperreflexia	7	0	1
	Balance disorder	1	0	1
	Coordination abnormal	34	0	24
	Nystagmus	1	0	0
	Coma	7	1	3
	Aphasia	3	0	3
	Consciousness fluctuating	3	0	2
	Depressed level of consciousness	1	0	1
	Lethargy	7	0	5
	Loss of consciousness	3	0	1
	Sedation	1	0	1
	Somnolence	62	0	52
	Stupor	3	0	3
	Syncope	21	1	16
	Clonus	2	0	0
	Dizziness	172	1	149
	Meningism	2	0	2
	Myoclonus	3	0	1

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Nervous system disorders	Formication	2	0	2
	Hyperaesthesia	3	0	3
	Hypoaesthesia	22	0	18
	Paraesthesia	82	0	72
	Ageusia	1	0	1
	Dysgeusia	8	0	6
	Neuralgia	1	0	1
	Sensory disturbance	10	0	9
	Dysarthria	8	0	5
	Dysphasia	1	0	0
	Speech disorder	9	0	9
	Visual field defect	1	0	1
	Anticholinergic syndrome	1	0	0
	Hypertonia	37	0	26
	Hypotonia	3	0	2
	Neuroleptic malignant syndrome	5	0	2
	Serotonin syndrome	32	1	6
	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	11	0	6
	Temporal lobe epilepsy	1	0	0
	Convulsion	43	0	30
	Epilepsy	1	0	1
	Tonic clonic movements	1	0	1
Poor quality sleep	1	0	1	
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
	Jaundice neonatal	1	0	1

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PAROXETINE HYDROCHLORIDE		Layer 1 of 1		
Pregnancy, puerperium and perinatal conditions	Neonatal disorder	3	0	1
	Unintended pregnancy	2	0	0
Psychiatric disorders	Neurosis	4	0	3
	Agitation	117	1	88
	Agitation neonatal	6	0	3
	Anxiety	70	2	51
	Nervousness	10	0	8
	Stress	1	0	1
	Panic disorder	1	0	1
	Panic attack	7	0	6
	Agoraphobia	1	1	0
	Restlessness	6	0	4
	Bruxism	11	0	11
	Tic	1	0	1
	Learning disorder	1	0	1
	Mutism	1	0	0
	Confusional state	60	0	38
	Disorientation	4	0	1
	Delirium	15	0	5
	Depression	35	1	26
	Depressed mood	1	0	1
	Tearfulness	1	0	0
	Depersonalisation	28	0	23
	Dissociation	3	0	3
	Delusion	4	0	2
	Delusion of grandeur	1	0	0
	Hallucination	43	0	28
	Hallucination, auditory	3	0	2
	Hallucination, visual	3	0	3
	Thinking abnormal	15	0	13
	Hypomania	2	0	0
	Mania	22	0	15
	Affect lability	9	0	9
	Anger	3	0	3
Crying	4	0	3	

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Psychiatric disorders	Dysphoria	1	0	1
	Emotional distress	1	0	1
	Euphoric mood	4	0	3
	Mood altered	1	0	1
	Mood swings	2	0	2
	Apathy	10	0	9
	Aggression	22	0	16
	Homicidal ideation	2	0	0
	Hostility	1	0	1
	Paranoia	5	0	4
	Personality change	2	0	1
	Violent ideation	1	0	0
	Personality disorder	1	0	0
	Abnormal behaviour	2	0	0
	Mental status changes	1	0	0
	Alcoholism	1	0	1
	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
	Sleep walking	3	0	2
	Sleep disorder	16	0	15
	Completed suicide	4	4	0
	Intentional self-injury	2	0	2
	Self injurious behaviour	4	1	2
	Self-injurious ideation	2	0	2
	Suicidal ideation	17	0	9
Suicide attempt	23	1	13	
Renal and urinary disorders	Nephritis interstitial	1	0	0
	Anuria	1	0	0
	Oliguria	2	0	0

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PAROXETINE HYDROCHLORIDE		Layer 1 of 1		
Renal and urinary disorders	Renal failure acute	7	2	2
	Renal impairment	3	0	1
	Urethral disorder	1	0	1
	Dysuria	7	0	7
	Micturition disorder	10	0	7
	Pollakiuria	12	0	11
	Urinary incontinence	15	0	12
	Urinary retention	13	0	10
	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
	Reproductive system and breast disorders	Breast enlargement	2	0
Gynaecomastia		3	0	2
Breast pain		4	0	3
Galactorrhoea		22	0	16
Menstrual disorder		5	0	4
Amenorrhoea		6	0	4
Menorrhagia		7	0	6
Metrorrhagia		2	0	0
Penis disorder		2	0	2
Perineal pain		1	0	1
Ejaculation failure		50	0	46
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	
Respiratory, thoracic and mediastinal disorders	Asthma	2	0	1
	Bronchospasm	2	0	2

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Respiratory, thoracic and mediastinal disorders	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
	Respiratory disorder neonatal	1	0	0
	Pleural fibrosis	1	0	1
	Pleural effusion	1	0	1
	Pulmonary embolism	3	1	2
	Apnoea	1	0	1
	Dyspnoea	20	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
	Skin and subcutaneous tissue disorders	Angioedema	8	0
Periorbital oedema		5	0	5
Dermographism		1	0	1
Urticaria		19	0	17
Blister		1	0	1
Dermatitis bullous		3	0	3
Erythema multiforme		4	0	3
Systemic lupus erythematosus rash		1	0	0
Dry skin		2	0	2

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Skin and subcutaneous tissue disorders	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
	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	126	0	106
	Night sweats	3	0	2
	Nail disorder	2	0	2
	Hair colour changes	1	0	0
	Purpura	63	0	49
Social circumstances	Physical assault	1	0	0
	Alcohol use	1	0	1
Surgical and medical procedures	Drug therapy changed	2	0	2
	Therapy regimen changed	2	0	2
Vascular disorders	Peripheral ischaemia	3	0	3



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Vascular disorders	Shock	3	0	2
	Hypotension	12	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