

## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023  
Data Lock Date: 27-Jan-2023 14:00:04  
Earliest Reaction Date: 01-Mar-1980  
MedDRA Version: MedDRA 25.

All UK spontaneous suspected Adverse Drug Reaction reports received up to and including 27th January 2023 associated with SSRIs.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemia deficiencies</i></b>		
Anaemia vitamin B12 deficiency	1	0
Iron deficiency anaemia	4	0
<b><i>Anaemias NEC</i></b>		
Anaemia	54	0
Hypochromic anaemia	1	0
Microcytic anaemia	2	0
Normocytic anaemia	2	0
<b><i>Anaemias haemolytic NEC</i></b>		
Haemolytic anaemia	14	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	6	0
Coombs positive haemolytic anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Haemorrhagic diathesis	4	0
Haemorrhagic disorder	1	0
Increased tendency to bruise	130	0
<b><i>Coagulation factor deficiencies</i></b>		
Hypoprothrombinaemia	1	0
<b><i>Coagulopathies</i></b>		
Antiphospholipid syndrome	2	0
Coagulopathy	10	0
Disseminated intravascular coagulation	9	2
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	22	0
Hypereosinophilic syndrome	1	0
<b><i>Haematological disorders</i></b>		
Blood disorder	3	0
Bone marrow disorder	1	0
Bone marrow oedema syndrome	6	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	2	0
<b><i>Leukocytoses NEC</i></b>		
Granulocytosis	1	0
Leukaemoid reaction	1	0
Leukocytosis	8	0
Neutrophilia	3	0
<b><i>Leukopenias NEC</i></b>		
Leukopenia	35	1
Lymphopenia	5	0
<b><i>Lymphatic system disorders NEC</i></b>		
Hilar lymphadenopathy	1	0
Lymph node pain	3	0
Lymphadenopathy	17	0
Lymphadenopathy mediastinal	2	0
Lymphatic disorder	1	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplasia pure red cell	4	0
Aplastic anaemia	15	2
Bone marrow failure	1	0
Hypoplastic anaemia	1	1
Myelosuppression	1	0
Pancytopenia	33	1

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<b>Blood disorders</b> Blood disorders cont'd		
<i><b>Neutropenias</b></i>		
Agranulocytosis	16	0
Febrile neutropenia	3	0
Granulocytopenia	1	0
Neutropenia	112	0
<i><b>Platelet disorders NEC</b></i>		
Platelet disorder	3	0
<i><b>Polycythaemia (excl rubra vera)</b></i>		
Polycythaemia	5	0
<i><b>Red blood cell abnormal findings NEC</b></i>		
Macrocytosis	9	0
Microcytosis	1	0
Red blood cell abnormality	2	0
<i><b>Spleen disorders</b></i>		
Spleen congestion	2	0
Splenomegaly	7	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	13	0
Thrombocytopenia	141	0
Thrombocytopenic purpura	4	0
Thrombotic thrombocytopenic purpura	4	0
<i><b>White blood cell abnormal findings NEC</b></i>		
White blood cell disorder	1	0
<b>Blood disorders SOC TOTAL</b>	<b>733</b>	<b>7</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Aortic valvular disorders</b></i>		
Aortic valve disease	1	0
Aortic valve incompetence	1	0
<i><b>Cardiac conduction disorders</b></i>		
Adams-Stokes syndrome	3	0
Atrioventricular block	8	0
Atrioventricular block complete	12	0
Atrioventricular block first degree	9	0
Atrioventricular block second degree	4	0
Bundle branch block	1	0
Bundle branch block left	9	0
Bundle branch block right	4	0
Conduction disorder	3	0
Defect conduction intraventricular	1	0
Long QT syndrome	16	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	13	0
Cardiac ventricular thrombosis	1	0
Cardiotoxicity	5	0
Cardiovascular disorder	4	0
Cardiovascular insufficiency	1	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	1	1
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	1	0
Palpitations	811	0
<i><b>Cardiac valve disorders NEC</b></i>		
Heart valve incompetence	1	0
<i><b>Cardiomyopathies</b></i>		
Cardiac steatosis	1	0
Cardiomyopathy	7	2
Cardiomyopathy alcoholic	1	0
Congestive cardiomyopathy	4	0
Stress cardiomyopathy	1	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	13	4
Coronary artery disease	5	4
Coronary artery insufficiency	1	0
Coronary artery stenosis	2	0
Coronary artery thrombosis	4	3
<i><b>Heart failures NEC</b></i>		
Cardiac failure	27	9
Cardiac failure acute	5	3
Cardiac failure congestive	6	2
Cardiogenic shock	1	1
Cardiopulmonary failure	2	2
Ventricular failure	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	4	0
Acute myocardial infarction	15	3
Angina pectoris	29	0
Angina unstable	1	0
Arteriospasm coronary	2	0

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b> Cardiac disorders cont'd		
Myocardial infarction	58	25
Myocardial ischaemia	12	7
<b>Left ventricular failures</b>		
Left ventricular failure	10	4
<b>Mitral valvular disorders</b>		
Mitral valve incompetence	2	0
Mitral valve prolapse	3	0
<b>Myocardial disorders NEC</b>		
Cardiomegaly	6	0
Left ventricular dysfunction	7	0
Left ventricular hypertrophy	3	0
Myocardial fibrosis	3	0
Right ventricular hypertrophy	1	0
Ventricle rupture	1	0
Ventricular hypertrophy	1	0
<b>Noninfectious myocarditis</b>		
Myocarditis	5	2
<b>Noninfectious pericarditis</b>		
Pericarditis	4	0
<b>Pericardial disorders NEC</b>		
Pericardial effusion	3	0
Pericardial haemorrhage	1	1
<b>Pulmonary valvular disorders</b>		
Pulmonary valve stenosis	2	0
<b>Rate and rhythm disorders NEC</b>		
Agonal rhythm	1	0
Arrhythmia	59	8
Bradyarrhythmia	1	0
Bradycardia	105	1
Bradycardia foetal	1	0
Cardiac flutter	15	0
Extrasystoles	34	0
Foetal arrhythmia	1	0
Foetal heart rate deceleration abnormality	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachyarrhythmia	4	0
Tachycardia	236	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
<b>Right ventricular failures</b>		
Cor pulmonale	1	0
<b>Supraventricular arrhythmias</b>		
Arrhythmia supraventricular	5	0
Atrial fibrillation	58	0
Atrial flutter	7	0
Atrial tachycardia	2	0
Sinus arrest	1	0
Sinus arrhythmia	3	0
Sinus bradycardia	19	0
Sinus node dysfunction	2	0
Sinus tachycardia	31	0
Supraventricular extrasystoles	4	0
Supraventricular tachycardia	40	1

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	75	22
Cardio-respiratory arrest	4	3
Pulseless electrical activity	3	1
Torsade de pointes	24	2
Ventricular arrhythmia	4	0
Ventricular extrasystoles	16	0
Ventricular fibrillation	18	3
Ventricular tachycardia	47	1
<b>Cardiac disorders SOC TOTAL</b>	<b>1989</b>	<b>115</b>

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<b>Congenital disorders</b>		
<b><i>Anorectal disorders congenital</i></b>		
Anal atresia	2	0
<b><i>Anterior and posterior chamber disorders congenital</i></b>		
Anterior chamber cleavage syndrome	1	0
Posterior segment of eye anomaly congenital	1	0
<b><i>Arterial disorders congenital</i></b>		
Pulmonary artery stenosis congenital	4	1
<b><i>Autosomal chromosomal abnormalities</i></b>		
Trisomy 13	1	0
Trisomy 18	1	0
Trisomy 21	5	0
<b><i>Bladder disorders congenital</i></b>		
Congenital bladder anomaly	1	0
<b><i>Breast disorders congenital</i></b>		
Supernumerary nipple	1	0
<b><i>Cardiac disorders congenital NEC</i></b>		
Brugada syndrome	3	0
Heart disease congenital	15	2
<b><i>Cardiac hypoplasias congenital</i></b>		
Hypoplastic left heart syndrome	4	0
Ventricular hypoplasia	2	0
<b><i>Cardiac malpositions congenital</i></b>		
Dextrocardia	3	0
Ectopia cordis	1	0
<b><i>Cardiac septal defects congenital</i></b>		
Atrial septal defect	8	0
Atrioventricular septal defect	3	0
Cardiac septal defect	4	0
Hypertrophic cardiomyopathy	2	0
Univentricular heart	1	0
Ventricular septal defect	15	0
<b><i>Cardiac valve disorders congenital</i></b>		
Congenital pulmonary valve atresia	4	1
Congenital pulmonary valve disorder	1	0
Mitral valve hypoplasia	1	0
<b><i>Cardiovascular disorders congenital NEC</i></b>		
Congenital cardiovascular anomaly	2	0
<b><i>Central nervous system disorders congenital NEC</i></b>		
Brain malformation	1	0
Congenital central hypoventilation syndrome	1	0
Congenital central nervous system anomaly	4	1
Encephalocele	1	0
Meningocele	2	0
Meningomyelocele	4	0
Neural tube defect	2	0
Spina bifida	9	0
Spina bifida occulta	2	0
<b><i>Cerebellar disorders congenital</i></b>		
Arnold-Chiari malformation	2	0
Cerebellar hypoplasia	1	0
<b><i>Cerebral disorders congenital</i></b>		
Anencephaly	13	0
Cerebral palsy	1	0

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<b>Congenital disorders</b> Congenital disorders cont'd		
Congenital brain damage	4	2
Congenital choroid plexus cyst	1	0
Congenital hydrocephalus	6	0
Schizencephaly	1	0
<b>Chromosomal abnormalities NEC</b>		
Cytogenetic abnormality	1	0
Foetal chromosome abnormality	2	0
<b>Congenital disorders NEC</b>		
Congenital anomaly	33	0
Foetal malformation	3	1
Heterotaxia	1	0
Multiple congenital abnormalities	7	0
Teratogenicity	1	0
<b>Connective tissue disorders congenital</b>		
Ehlers-Danlos syndrome	1	0
<b>Corneal and scleral disorders congenital</b>		
Corneal opacity congenital	2	0
<b>Diaphragmatic disorders congenital</b>		
Congenital diaphragmatic anomaly	1	0
Congenital diaphragmatic hernia	2	0
<b>Ear disorders congenital NEC</b>		
Ear malformation	4	0
<b>Endocrine disorders congenital NEC</b>		
Congenital hypoparathyroidism	1	0
<b>External ear disorders congenital</b>		
Anotia	1	0
Low set ears	1	0
<b>Gastrointestinal tract disorders congenital NEC</b>		
Abdominal transposition	1	0
Exomphalos	2	0
Gastrointestinal disorder congenital	1	0
Gastrointestinal malformation	2	0
Gastroschisis	7	0
Hernia congenital	3	0
<b>Genetic mitochondrial abnormalities NEC</b>		
Neuropathy, ataxia, retinitis pigmentosa syndrome	1	0
<b>Genetic polymorphisms</b>		
CYP3A4 polymorphism	1	0
<b>Great vessel disorders congenital</b>		
Aorta hypoplasia	2	0
Coarctation of the aorta	2	0
Congenital aortic atresia	1	0
Congenital great vessel anomaly	1	0
Double outlet right ventricle	2	0
Interruption of aortic arch	1	0
Right aortic arch	1	0
Transposition of the great vessels	6	1
Truncus arteriosus persistent	1	0
<b>Haematological disorders congenital NEC</b>		
Congenital thrombocytopenia	1	0
<b>Hair and nail disorders congenital</b>		
Congenital nail disorder	1	0
<b>Hearing disorders congenital</b>		



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<b>Congenital disorders</b> Congenital disorders cont'd		
Deafness congenital	2	0
<b>Hepatobiliary abnormalities congenital</b>		
Congenital absence of bile ducts	1	0
<b>Immune system abnormalities congenital</b>		
Congenital thymus absence	1	0
DiGeorge's syndrome	1	0
<b>Inborn errors of bilirubin metabolism</b>		
Gilbert's syndrome	1	0
<b>Inborn errors of carbohydrate metabolism (excl glucose)</b>		
Galactosaemia	1	0
<b>Inborn errors of porphyrin metabolism</b>		
Porphyria	1	0
Porphyria acute	5	0
<b>Intestinal disorders congenital</b>		
Duodenal atresia	1	0
Intestinal atresia	1	0
<b>Iris and choroid disorders congenital</b>		
Choroidal coloboma	1	0
Iris coloboma	3	0
<b>Laryngeal and tracheal disorders congenital</b>		
Tracheo-oesophageal fistula	1	0
<b>Lens disorders congenital</b>		
Cataract congenital	1	0
<b>Lymphatic system disorders congenital</b>		
Cystic lymphangioma	2	0
<b>Lysosomal storage disorders</b>		
Lipidosis	1	0
Niemann-Pick disease	1	0
<b>Male reproductive tract disorders congenital</b>		
Cryptorchism	1	0
Epispadias	1	0
Hydrocele	2	0
Hypospadias	5	0
Phimosis	1	0
<b>Multiple cardiac abnormalities congenital</b>		
Fallot's tetralogy	6	0
Multiple cardiac defects	1	1
<b>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</b>		
Cleft lip	6	0
Hypertelorism	1	0
<b>Musculoskeletal and connective tissue disorders of limbs congenital</b>		
Congenital hand malformation	9	0
Congenital musculoskeletal disorder of limbs	8	0
Developmental hip dysplasia	2	0
Ectrodactyly	2	0
Limb reduction defect	4	0
Poland's syndrome	1	0
Polydactyly	2	0
Syndactyly	1	0
Talipes	15	0
<b>Musculoskeletal and connective tissue disorders of skull congenital</b>		
Congenital absence of cranial vault	1	0

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<b>Congenital disorders</b> Congenital disorders cont'd		
Congenital musculoskeletal disorder of skull	1	0
Craniorachischisis	1	0
Craniosynostosis	1	0
Macrocephaly	1	0
Microcephaly	1	0
Plagiocephaly	2	0
<b>Musculoskeletal and connective tissue disorders of spine congenital</b>		
Caudal regression syndrome	1	0
Congenital musculoskeletal disorder of spine	2	0
<b>Musculoskeletal and connective tissue disorders of trunk congenital (excl spine)</b>		
Synostosis	2	0
<b>Musculoskeletal disorders congenital NEC</b>		
Congenital multiplex arthrogryposis	1	0
Congenital musculoskeletal disorder	5	0
Dysmorphism	8	0
Otospondylomegaepiphyseal dysplasia	1	0
<b>Neurological disorders congenital NEC</b>		
Congenital nystagmus	2	0
Huntington's disease	2	0
Prader-Willi syndrome	1	0
Tourette's disorder	9	0
<b>Non-site specific cartilage disorders congenital</b>		
Osteochondrodysplasia	2	0
<b>Non-site specific muscle disorders congenital</b>		
Congenital floppy infant	2	0
Familial tremor	1	0
<b>Ocular disorders congenital NEC</b>		
Blindness congenital	1	0
Coloboma	2	0
Colour blindness	4	0
Congenital eye disorder	5	0
Congenital visual acuity reduced	1	0
Microphthalmos	2	0
<b>Oesophageal disorders congenital</b>		
Oesophageal atresia	1	0
<b>Optic nerve and optic disc disorders congenital</b>		
Congenital optic nerve anomaly	1	0
Optic nerve hypoplasia	1	0
Septo-optic dysplasia	1	0
<b>Palate disorders congenital</b>		
Cleft lip and palate	1	0
Cleft palate	16	0
<b>Persistent foetal circulation disorders</b>		
Newborn persistent pulmonary hypertension	3	0
Patent ductus arteriosus	4	0
<b>Pharyngeal disorders congenital</b>		
Choanal atresia	1	0
<b>Pulmonary and bronchial disorders congenital</b>		
Congenital pulmonary airway malformation	1	0
Pulmonary hypoplasia	4	1
Pulmonary malformation	2	1
<b>Renal and urinary tract disorders congenital NEC</b>		

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<b>Congenital disorders</b> Congenital disorders cont'd		
Congenital hydronephrosis	2	0
Urinary tract malformation	1	0
<b><i>Renal disorders congenital</i></b>		
Kidney duplex	1	0
Potter's syndrome	1	0
Renal aplasia	2	0
Renal dysplasia	3	0
<b><i>Reproductive tract disorders congenital NEC</i></b>		
Genitalia external ambiguous	1	0
<b><i>Respiratory tract disorders congenital NEC</i></b>		
Congenital pulmonary hypertension	1	0
Respiratory tract malformation	2	0
<b><i>Retinal disorders congenital</i></b>		
Retinal coloboma	2	0
<b><i>Sex chromosomal abnormalities</i></b>		
Klinefelter's syndrome	1	0
<b><i>Skin and subcutaneous tissue disorders congenital NEC</i></b>		
Abnormal palmar/plantar creases	3	0
Congenital acrochordon	1	0
Congenital pigmentation disorder	1	0
Congenital skin dimples	1	0
Naevus flammeus	1	0
<b><i>Thyroid disorders congenital</i></b>		
Congenital hypothyroidism	3	0
<b><i>Tongue disorders congenital</i></b>		
Ankyloglossia congenital	2	0
<b><i>Vascular anomalies congenital NEC</i></b>		
Arteriovenous malformation	1	0
Congenital cerebrovascular anomaly	1	0
<b><i>Venous disorders congenital</i></b>		
Anomalous pulmonary venous connection	2	1
<b>Congenital disorders SOC TOTAL</b>	<b>463</b>	<b>13</b>

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<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	4	0
Ear discomfort	12	0
Ear disorder	3	0
Ear haemorrhage	2	0
Ear pain	33	0
Ear swelling	2	0
Otorrhoea	2	0
Ototoxicity	2	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube dysfunction	2	0
Eustachian tube obstruction	1	0
<i><b>Hearing disorders NEC</b></i>		
Autophony	1	0
<i><b>Hearing losses</b></i>		
Deafness	24	0
Deafness bilateral	1	0
Deafness neurosensory	8	0
Deafness transitory	3	0
Deafness unilateral	2	0
Hypoacusis	29	0
Presbycusis	1	0
Sudden hearing loss	2	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	62	0
<i><b>Inner ear disorders NEC</b></i>		
Inner ear disorder	4	0
Meniere's disease	7	0
Vestibular disorder	2	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	18	0
Tinnitus	431	0
Vertigo	326	0
Vertigo labyrinthine	1	0
Vertigo positional	6	0
<b>Ear disorders SOC TOTAL</b>	<b>991</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenal insufficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	2	0
Adrenomegaly	1	0
<i>Adrenal medulla disorders</i>		
Pseudophaeochromocytoma	1	0
<i>Anterior pituitary hyperfunction</i>		
Hyperprolactinaemia	72	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	2	0
<i>Ectopic endocrine disorders</i>		
Carcinoid syndrome	2	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine disorders NEC</i>		
Endocrine disorder	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	1	0
Hyperparathyroidism primary	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	1	0
<i>Posterior pituitary disorders</i>		
Antidiuretic hormone abnormality	2	0
Diabetes insipidus	3	0
Inappropriate antidiuretic hormone secretion	215	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
Thyroid disorder	5	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	20	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	32	0
<b>Endocrine disorders SOC TOTAL</b>	<b>370</b>	<b>0</b>

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<b>Eye disorders</b>		
<b><i>Amblyopic vision impairment</i></b>		
Amblyopia	1	0
<b><i>Anterior chamber structural change, deposit and degeneration</i></b>		
Flat anterior chamber of eye	1	0
<b><i>Cataract conditions</i></b>		
Cataract	11	0
Cataract nuclear	1	0
<b><i>Choroid and vitreous haemorrhages and vascular disorders</i></b>		
Vitreous haemorrhage	1	0
<b><i>Choroid and vitreous structural change, deposit and degeneration</i></b>		
Vitreous detachment	3	0
Vitreous floaters	26	0
<b><i>Colour blindness (incl acquired)</i></b>		
Dyschromatopsia	1	0
<b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>		
Conjunctival haemorrhage	8	0
Corneal neovascularisation	1	0
<b><i>Conjunctival infections, irritations and inflammations</i></b>		
Conjunctival hyperaemia	5	0
Conjunctival irritation	1	0
Conjunctival oedema	2	0
Conjunctivitis allergic	2	0
<b><i>Corneal infections, oedemas and inflammations</i></b>		
Corneal oedema	4	0
Keratitis	1	0
Punctate keratitis	1	0
Ulcerative keratitis	1	0
<b><i>Corneal structural change, deposit and degeneration</i></b>		
Cornea verticillata	1	0
Corneal deposits	2	0
Corneal erosion	1	0
Corneal scar	1	0
Keratoconus	1	0
Keratopathy	3	0
Xerophthalmia	3	0
<b><i>Eyelid movement disorders</i></b>		
Blepharospasm	28	0
Excessive eye blinking	3	0
Eyelid myoclonus	1	0
Eyelid ptosis	5	0
Lid lag	1	0
<b><i>Glaucomas (excl congenital)</i></b>		
Angle closure glaucoma	56	0
Glaucoma	27	0
Ocular hypertension	1	0
Open angle glaucoma	1	0
<b><i>Iris and ciliary body structural change, deposit and degeneration</i></b>		
Eye colour change	2	0
Iris disorder	1	0
<b><i>Iris and uveal tract infections, irritations and inflammations</i></b>		
Iridocyclitis	1	0
Iritis	6	0
Uveitis	3	0

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**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
<b><i>Lacrimation disorders</i></b>		
Dry eye	57	0
Lacrimal disorder	2	0
Lacrimation decreased	4	0
Lacrimation increased	18	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Blepharitis	3	0
Eczema eyelids	1	0
Erythema of eyelid	1	0
Eyelid oedema	6	0
Swelling of eyelid	24	0
<b><i>Lid, lash and lacrimal structural disorders</i></b>		
Entropion	1	0
Eyelid retraction	2	0
<b><i>Ocular bleeding and vascular disorders NEC</i></b>		
Eye haemorrhage	12	0
<b><i>Ocular disorders NEC</i></b>		
Dark circles under eyes	2	0
Eye disorder	23	0
Eye oedema	1	0
Eye pain	106	0
Eye swelling	50	0
Eyelid disorder	1	0
Eyelid pain	1	0
Eyelids pruritus	1	0
Ocular discomfort	8	0
Periorbital oedema	52	0
Periorbital swelling	5	0
Vitreous disorder	1	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		
Eye allergy	1	0
Eye irritation	26	0
Eye pruritus	13	0
Ocular hyperaemia	22	0
<b><i>Ocular nerve and muscle disorders</i></b>		
Eye movement disorder	38	0
Gaze palsy	2	0
Oculogyric crisis	40	0
Ophthalmoplegia	4	0
Strabismus	5	0
<b><i>Ocular sensation disorders</i></b>		
Abnormal sensation in eye	7	0
Asthenopia	10	0
Contact lens intolerance	1	0
Foreign body sensation in eyes	3	0
Hypoaesthesia eye	2	0
Photophobia	79	0
<b><i>Optic disc abnormalities NEC</i></b>		
Optic disc disorder	1	0
Papilloedema	9	0
<b><i>Optic nerve bleeding and vascular disorders</i></b>		
Optic ischaemic neuropathy	17	0
<b><i>Pupil disorders</i></b>		

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Anisocoria	31	0
Cycloplegia	3	0
Holmes-Adie pupil	1	0
Miosis	6	0
Mydriasis	242	0
Pupil fixed	7	0
Pupillary disorder	5	0
Pupillary reflex impaired	6	0
<b><i>Refractive and accommodative disorders</i></b>		
Accommodation disorder	16	0
Altered visual depth perception	4	0
Astigmatism	2	0
Hypermetropia	1	0
Myopia	5	0
Presbyopia	1	0
<b><i>Retinal bleeding and vascular disorders (excl retinopathy)</i></b>		
Retinal artery occlusion	2	0
Retinal haemorrhage	5	0
Retinal vascular disorder	2	0
Retinal vein occlusion	11	0
Retinal vein thrombosis	5	0
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Disruption of the photoreceptor inner segment-outer segment	3	0
Macular degeneration	3	0
Maculopathy	37	0
Retinal detachment	2	0
Retinal drusen	1	0
Retinal pigment epitheliopathy	3	0
Retinal pigmentation	2	0
Vitreoretinal traction syndrome	1	0
<b><i>Retinal, choroid and vitreous infections and inflammations</i></b>		
Cystoid macular oedema	1	0
Macular oedema	3	0
<b><i>Retinopathies NEC</i></b>		
Central serous chorioretinopathy	1	0
Retinopathy	2	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	1	0
<b><i>Scleral structural change, deposit and degeneration</i></b>		
Scleral discolouration	1	0
<b><i>Structural change, deposit and degeneration of eye NEC</i></b>		
Exophthalmos	6	0
<b><i>Visual colour distortions</i></b>		
Chromatopsia	1	0
<b><i>Visual disorders NEC</i></b>		
Delayed dark adaptation	1	0
Diplopia	82	0
Loss of visual contrast sensitivity	1	0
Metamorphopsia	4	0
Photopsia	45	0
Scintillating scotoma	1	0
Vision blurred	488	0
Visual brightness	1	0



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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Visual snow syndrome	3	0
<b>Visual field disorders</b>		
Visual field defect	26	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Amaurosis fugax	1	0
Blindness	28	0
Blindness transient	12	0
Blindness unilateral	5	0
Central vision loss	5	0
Night blindness	1	0
Sudden visual loss	1	0
Visual acuity reduced	22	0
Visual acuity reduced transiently	1	0
Visual impairment	391	0
<b>Visual pathway disorders</b>		
Optic nerve disorder	2	0
Optic neuropathy	2	0
<b>Eye disorders SOC TOTAL</b>	<b>2427</b>	<b>0</b>

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	3	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall disorder	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	2	0
Pancreatitis	47	2
Pancreatitis acute	37	3
Pancreatitis chronic	2	0
Pancreatitis haemorrhagic	1	0
Pancreatitis necrotising	2	1
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
Anorectal disorder	2	0
<i>Anal and rectal pains</i>		
Levator syndrome	2	0
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anal spasm	1	0
Anorectal discomfort	1	0
Rectal discharge	1	0
Rectal tenesmus	1	0
<i>Anal and rectal stenosis and obstruction</i>		
Anal stenosis	1	0
<i>Benign neoplasms gastrointestinal (excl oral cavity)</i>		
Large intestine polyp	1	0
<i>Colitis (excl infective)</i>		
Allergic colitis	1	0
Colitis	17	0
Colitis microscopic	16	0
Colitis ulcerative	10	0
Crohn's disease	6	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	2	0
Necrotising colitis	1	0
<i>Cystic pancreatic disorders</i>		
Pancreatic cyst	1	0
Pancreatic pseudocyst	2	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	4	0
<i>Dental disorders NEC</i>		
Tooth disorder	11	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	10	0
Toothache	28	0
<i>Dental surface disorders</i>		
Enamel anomaly	1	0
Tooth discolouration	6	0
<i>Diaphragmatic hernias</i>		
Diaphragmatic hernia	1	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Hiatus hernia	5	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	2021	0
Diarrhoea haemorrhagic	8	0
<b><i>Duodenal and small intestinal stenosis and obstruction</i></b>		
Duodenal stenosis	1	0
Small intestinal obstruction	3	0
<b><i>Duodenal ulcers and perforation</i></b>		
Duodenal perforation	2	0
Duodenal ulcer	30	0
Duodenal ulcer haemorrhage	8	1
Duodenal ulcer perforation	12	0
Erosive duodenitis	3	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	446	0
Epigastric discomfort	19	0
Eructation	30	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	8	0
Faecaloma	6	0
Faeces discoloured	28	0
Faeces pale	1	0
Faeces soft	1	0
Mucous stools	3	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	83	0
Aerophagia	1	0
Flatulence	123	0
<b><i>Gastric and oesophageal haemorrhages</i></b>		
Gastric haemorrhage	11	0
Mallory-Weiss syndrome	3	0
Oesophageal haemorrhage	2	0
Oesophageal varices haemorrhage	2	0
<b><i>Gastric and pyloric stenosis and obstruction</i></b>		
Obstruction gastric	1	0
<b><i>Gastric ulcers and perforation</i></b>		
Gastric ulcer	25	0
Gastric ulcer haemorrhage	13	3
Gastric ulcer perforation	2	0
Gastritis erosive	9	1
<b><i>Gastritis (excl infective)</i></b>		
Chronic gastritis	1	0
Gastritis	64	0
Gastritis haemorrhagic	1	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal pain	528	0
Abdominal pain lower	12	0
Abdominal pain upper	321	0
Abdominal tenderness	5	0
Gastrointestinal pain	9	0
Oesophageal pain	10	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	238	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Duodenogastric reflux	1	0
Gastric dilatation	3	0
Gastrointestinal hypomotility	2	0
Gastrooesophageal reflux disease	90	0
Infrequent bowel movements	2	0
Intestinal dilatation	3	0
Intestinal pseudo-obstruction	3	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Functional gastrointestinal disorder	7	0
Gastric disorder	16	0
Gastrointestinal disorder	50	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	4	0
Change of bowel habit	13	0
Dyskinesia oesophageal	2	0
Gastrointestinal motility disorder	4	0
<b><i>Gastrointestinal fistulae</i></b>		
Anal fistula	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Duodenitis	12	0
Enteritis	2	0
Gastrointestinal inflammation	1	0
Gastrointestinal tract irritation	1	0
Necrotising enterocolitis neonatal	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Barrett's oesophagus	3	0
Gastrointestinal mucosal disorder	1	0
Hyperchlorhydria	4	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	192	0
Anal incontinence	39	0
Breath odour	10	0
Dumping syndrome	1	0
Dysphagia	124	0
Odynophagia	7	0
Oesophageal discomfort	3	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	3	0
Frequent bowel movements	24	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	33	0
Oesophageal spasm	6	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	11	0
Intestinal strangulation	2	0
<b><i>Gastrointestinal ulcers and perforation, site unspecified</i></b>		
Diverticular perforation	1	0
Gastrointestinal perforation	1	0
Gastrointestinal ulcer	7	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	3	0
Mesenteric artery thrombosis	1	0
Mesenteric vascular occlusion	1	1

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival atrophy	3	0
Gingival blister	1	0
Gingival disorder	3	0
Gingival hypertrophy	1	0
Gingival pain	14	0
Gingival recession	2	0
Gingival swelling	2	0
Gingivitis ulcerative	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	36	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoids	9	0
<b><i>Inguinal hernias</i></b>		
Inguinal hernia	2	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	3	0
Large intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	3	0
Rectal haemorrhage	69	0
Small intestinal haemorrhage	2	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	2	1
Intestinal ulcer	2	0
Large intestinal ulcer	1	0
<b><i>Large intestinal stenosis and obstruction</i></b>		
Large intestinal stenosis	1	0
<b><i>Malabsorption syndromes</i></b>		
Bile acid malabsorption	1	0
Coeliac disease	2	0
Malabsorption	2	0
Short-bowel syndrome	1	0
Steatorrhoea	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Infantile vomiting	1	0
Nausea	4474	0
Regurgitation	2	0
Retching	66	0
Vomiting	1744	0
Vomiting projectile	2	0
<b><i>Non-mechanical ileus</i></b>		
Ileus paralytic	5	0
Megacolon	1	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Chronic gastrointestinal bleeding	1	0
Gastrointestinal haemorrhage	168	13
Haematemesis	126	0
Haematochezia	22	0
Intra-abdominal haemorrhage	1	0
Melaena	92	1
Upper gastrointestinal haemorrhage	64	3
<b><i>Oesophageal disorders NEC</i></b>		
Oesophageal disorder	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oesophageal ulcers and perforation</i></b>		
Oesophageal perforation	2	0
Oesophageal ulcer	7	0
Oesophageal ulcer haemorrhage	1	0
Oesophagitis ulcerative	1	0
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophageal irritation	2	0
Oesophagitis	39	0
<b><i>Oral dryness and saliva altered</i></b>		
Aptyalism	1	0
Dry mouth	540	0
Lip dry	10	0
Saliva altered	3	0
Salivary hypersecretion	66	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Chapped lips	2	0
Cheilitis	5	0
Lip blister	6	0
Lip disorder	1	0
Oral disorder	3	0
Oral lichen planus	5	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Lip haemorrhage	1	0
Mouth haemorrhage	5	0
<b><i>Oral soft tissue infections</i></b>		
Angular cheilitis	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	50	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	4	0
Oral discomfort	35	0
Oral mucosal blistering	9	0
Oral mucosal eruption	1	0
Oral mucosal exfoliation	4	0
Oral pain	38	0
Oral pruritus	1	0
Paraesthesia oral	23	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip oedema	6	0
Lip swelling	106	0
Mouth swelling	27	0
Palatal oedema	2	0
<b><i>Pancreatic disorders NEC</i></b>		
Pancreatic fibrosis	1	0
Pancreatic mass	1	0
<b><i>Peptic ulcers and perforation</i></b>		
Peptic ulcer	6	0
Peptic ulcer haemorrhage	1	0
Peptic ulcer perforation	1	0
<b><i>Peritoneal and retroperitoneal disorders</i></b>		
Ascites	6	0
Retroperitoneal effusion	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Peritoneal and retroperitoneal fibrosis and adhesions</i></b>		
Retroperitoneal fibrosis	4	0
<b><i>Peritoneal and retroperitoneal haemorrhages</i></b>		
Haemoperitoneum	2	1
<b><i>Rectal inflammations NEC</i></b>		
Proctitis	2	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	3	0
Salivary gland enlargement	3	0
<b><i>Salivary gland stenosis and obstruction</i></b>		
Salivary duct obstruction	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	9	0
Lip ulceration	5	0
Mouth ulceration	123	0
Stomatitis	16	0
<b><i>Tongue disorders</i></b>		
Glossitis	14	0
Plicated tongue	2	0
Tongue disorder	11	0
Tongue geographic	2	0
Tongue haemorrhage	2	0
Tongue ulceration	11	0
<b><i>Tongue signs and symptoms</i></b>		
Buccoglossal syndrome	8	0
Glossodynia	24	0
Stiff tongue	1	0
Swollen tongue	110	0
Tongue blistering	5	0
Tongue coated	5	0
Tongue discolouration	12	0
Tongue discomfort	5	0
Tongue dry	2	0
Tongue eruption	3	0
Tongue erythema	2	0
Tongue movement disturbance	5	0
Tongue oedema	3	0
Tongue pruritus	1	0
Tongue spasm	8	0
<b><i>Tooth missing</i></b>		
Tooth loss	2	0
<b><i>Umbilical hernias</i></b>		
Umbilical hernia	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>13393</b>	<b>31</b>

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Adverse effect absent</b></i>		
No adverse event	4	0
<i><b>Application and instillation site reactions</b></i>		
Application site rash	1	0
<i><b>Asthenic conditions</b></i>		
Asthenia	399	0
Chronic fatigue syndrome	10	0
Decreased activity	2	0
Fatigue	1099	0
Malaise	983	0
Sluggishness	6	0
<i><b>Body temperature altered</b></i>		
Hyperthermia	9	0
Hypothermia	16	2
Temperature regulation disorder	5	0
<i><b>Complications associated with device NEC</b></i>		
Phantom shocks	1	0
<i><b>Death and sudden death</b></i>		
Accidental death	1	1
Brain death	1	0
Death	50	49
Drowning	2	0
Sudden cardiac death	7	6
Sudden death	47	47
Sudden infant death syndrome	2	2
Sudden unexplained death in epilepsy	1	1
<i><b>Febrile disorders</b></i>		
Fever neonatal	1	0
Hyperpyrexia	12	1
Pyrexia	231	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	234	0
Early satiety	1	0
Feeling abnormal	702	0
Feeling cold	99	0
Feeling drunk	45	0
Feeling hot	139	0
Feeling jittery	92	0
Feeling of body temperature change	59	0
Hangover	21	0
Hunger	8	0
Sensation of foreign body	18	0
Temperature intolerance	11	0
Thirst	79	0
Thirst decreased	3	0
<i><b>Fibrosis NEC</b></i>		
Fibrosis	2	0
Pelvic fibrosis	1	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	185	0
Gait inability	16	0
Loss of control of legs	9	0
<i><b>General signs and symptoms NEC</b></i>		



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Condition aggravated	295	0
Critical illness	1	0
Crying	204	0
Developmental delay	12	0
Disease progression	3	0
Disease recurrence	9	0
Energy increased	13	0
Exercise tolerance decreased	4	0
Fat tissue increased	2	0
Foaming at mouth	7	0
General physical health deterioration	18	0
High-pitched crying	3	0
Idiopathic environmental intolerance	1	0
Ill-defined disorder	30	0
Illness	187	0
Impaired self-care	5	0
Influenza like illness	204	0
Multiple organ dysfunction syndrome	11	6
Nonspecific reaction	3	0
Organ failure	2	0
Performance status decreased	7	0
Peripheral swelling	116	0
Pre-existing condition improved	1	0
Screaming	21	0
Swelling	42	0
Swelling face	175	0
Symptom masked	3	0
Terminal state	2	0
Unevaluable event	16	0
<b>Healing abnormal NEC</b>		
Impaired healing	1	0
<b>Hernias NEC</b>		
Hernia	3	0
<b>Implant and catheter site reactions</b>		
Implant site extravasation	1	0
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	12	0
Polyserositis	1	0
Systemic inflammatory response syndrome	1	0
<b>Injection site reactions</b>		
Injection site discomfort	1	0
Injection site rash	1	0
Injection site reaction	1	0
<b>Interactions</b>		
Alcohol interaction	107	0
Drug interaction	726	3
Food interaction	19	0
Inhibitory drug interaction	42	0
Potentiating drug interaction	59	0
<b>Mass conditions NEC</b>		
Cyst	2	0
Mass	4	0

## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<b><i>Mucosal findings abnormal</i></b>		
Mucosal disorder	1	0
Mucosal dryness	3	0
Mucosal haemorrhage	1	0
Mucosal inflammation	2	0
Polyp	1	0
<b><i>Necrosis NEC</i></b>		
Necrosis	2	0
<b><i>Oedema NEC</i></b>		
Face oedema	57	0
Generalised oedema	14	0
Gravitational oedema	2	0
Localised oedema	3	0
Oedema	50	0
Oedema peripheral	69	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	1	0
Chest discomfort	151	0
Chest pain	316	0
Discomfort	34	0
Facial discomfort	2	0
Facial pain	18	0
Non-cardiac chest pain	4	0
Pain	267	0
Tenderness	9	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	125	0
Adverse event	14	0
Drug effective for unapproved indication	1	0
Drug ineffective	394	0
Drug ineffective for unapproved indication	5	0
Drug intolerance	26	0
Drug resistance	3	0
Drug tolerance	1	0
Drug tolerance decreased	3	0
Idiosyncratic drug reaction	1	0
Inadequate analgesia	1	0
Paradoxical drug reaction	3	0
Tachyphylaxis	1	0
Therapeutic product effect decreased	8	0
Therapeutic product effect delayed	1	0
Therapeutic product effect incomplete	7	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	6	0
Therapeutic reaction time decreased	1	0
Therapeutic response changed	1	0
Therapeutic response decreased	9	0
Therapeutic response unexpected	46	0
Therapy non-responder	7	0
Therapy partial responder	1	0
Treatment failure	1	0
Treatment noncompliance	22	0
<b><i>Trophic disorders</i></b>		

## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Calcinosis	1	0
Hyperplasia	1	0
<b><i>Ulcers NEC</i></b>		
Perforated ulcer	1	0
Ulcer	5	0
<b><i>Withdrawal and rebound effects</i></b>		
Antidepressant discontinuation syndrome	1	0
Drug withdrawal syndrome	841	0
Drug withdrawal syndrome neonatal	50	0
Rebound effect	2	0
Withdrawal syndrome	2306	0
<b>General disorders SOC TOTAL</b>	<b>11897</b>	<b>118</b>

## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	1	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	4	0
Cholecystitis acute	1	0
Cholelithiasis	11	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	14	0
Cholestasis of pregnancy	4	0
Hepatitis cholestatic	12	0
Hyperbilirubinaemia	5	0
Jaundice	153	1
Jaundice cholestatic	18	0
Jaundice hepatocellular	3	0
Ocular icterus	3	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder cholesterolosis	1	0
Gallbladder disorder	2	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Hepatic mass	1	0
Liver disorder	13	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	52	2
Hypertransaminasaemia	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	9	2
Hepatic failure	29	12
Hepatorenal failure	3	1
Hepatorenal syndrome	4	0
Subacute hepatic failure	1	0
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	6	2
Hepatic fibrosis	1	0
<i><b>Hepatic vascular disorders</b></i>		
Congestive hepatopathy	1	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	5	0
Hepatomegaly	7	0
Liver tenderness	2	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Acute fatty liver of pregnancy	2	0
Autoimmune hepatitis	2	0
Drug-induced liver injury	19	0
Granulomatous liver disease	2	0
Hepatic necrosis	7	5
Hepatic steatosis	25	0
Hepatitis	78	1
Hepatitis acute	12	0
Hepatitis chronic active	3	0
Hepatitis fulminant	1	0
Hepatocellular injury	2	0
Hepatotoxicity	10	0

# Case Series Drug Analysis Print

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Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b> Hepatic disorders cont'd		
Liver injury	9	1
<b>Hepatic disorders SOC TOTAL</b>	<b>540</b>	<b>27</b>

## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergy to animal	1	0
Hypersensitivity	182	0
Multiple allergies	2	0
Serum sickness	1	0
Serum sickness-like reaction	1	0
Type I hypersensitivity	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	1	0
Allergy to chemicals	1	0
Drug hypersensitivity	18	0
Food allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	8	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	68	0
Anaphylactic shock	9	0
Anaphylactoid reaction	6	0
<i>Atopic disorders</i>		
Seasonal allergy	3	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	1	0
Immune system disorder	4	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>315</b>	<b>0</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Abdominal infection	1	0
Anal abscess	1	0
Anal infection	1	0
Appendicitis	2	0
Diarrhoea infectious	1	0
Diverticulitis	3	0
Dysentery	1	0
Gastroenteritis	10	0
Gastrointestinal infection	1	0
Haemorrhoid infection	1	0
Peritonitis	2	0
<b><i>Bacterial infections NEC</i></b>		
Bacterial infection	1	0
Bacterial vaginosis	2	0
Cellulitis	4	0
Folliculitis	3	0
Gangrene	2	0
Gangrene neonatal	1	0
Periorbital cellulitis	1	0
Peritonitis bacterial	1	0
<b><i>Breast infections</i></b>		
Breast abscess	1	0
Mastitis	2	0
<b><i>Campylobacter infections</i></b>		
Campylobacter gastroenteritis	1	0
<b><i>Candida infections</i></b>		
Candida infection	17	0
Gastrointestinal candidiasis	1	0
Oral candidiasis	4	0
Vulvovaginal candidiasis	5	0
<b><i>Cardiac infections</i></b>		
Endocarditis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	4	0
Meningitis	1	0
<b><i>Clostridia infections</i></b>		
Clostridium difficile colitis	1	0
<b><i>Coronavirus infections</i></b>		
COVID-19	2	1
Coronavirus infection	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	7	0
Parotitis	1	0
Sialoadenitis	1	0
Tooth abscess	2	0
Tooth infection	1	0
<b><i>Ear infections</i></b>		
Ear infection	2	0
Labyrinthitis	10	0
Otitis media	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	11	0

## Case Series Drug Analysis Print

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Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Eye abscess	1	0
Eye infection	2	0
Retinitis	1	0
<b>Female reproductive tract infections</b>		
Amniotic cavity infection	2	0
Vaginal infection	2	0
Vulvitis	1	0
<b>Fungal infections NEC</b>		
Fungal infection	2	0
Onychomycosis	2	0
Oropharyngitis fungal	1	0
<b>Helicobacter infections</b>		
Helicobacter gastritis	1	0
Helicobacter infection	2	0
<b>Hepatitis virus infections</b>		
Hepatitis C	1	0
<b>Herpes viral infections</b>		
Herpes simplex	1	0
Herpes zoster	6	0
Oral herpes	3	0
Varicella zoster virus infection	1	0
<b>Infections NEC</b>		
Abscess	3	0
Abscess limb	1	0
Groin abscess	1	0
Implant site infection	1	0
Infection	13	0
Purulent discharge	2	0
Respiratory tract infection	2	0
Wound infection	1	0
<b>Influenza viral infections</b>		
H1N1 influenza	6	0
Influenza	60	0
<b>Lower respiratory tract and lung infections</b>		
Atypical pneumonia	1	0
Bronchitis	1	0
Infective exacerbation of bronchiectasis	1	0
Infective exacerbation of chronic obstructive airways disease	2	0
Lower respiratory tract infection	27	0
Pneumonia	44	7
Pneumonia aspiration	12	2
<b>Male reproductive tract infections</b>		
Epididymitis	2	0
Genital infection male	1	0
Orchitis	2	0
<b>Muscle and soft tissue infections</b>		
Psoas abscess	1	0
<b>Retroviral infections</b>		
HIV infection	1	0
<b>Rhinoviral infections</b>		
Rhinovirus infection	1	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Neutropenic sepsis	1	0



## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Sepsis	21	2
Sepsis neonatal	1	0
Septic rash	1	0
Septic shock	3	0
Urosepsis	1	0
Viraemia	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Acne pustular	1	0
Blister infected	1	0
Eczema infected	1	0
Impetigo	1	0
Infected skin ulcer	1	0
Rash pustular	8	0
Skin infection	2	0
Subcutaneous abscess	2	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	9	0
Staphylococcal infection	1	1
Staphylococcal sepsis	1	0
<b><i>Streptococcal infections</i></b>		
Alpha haemolytic streptococcal infection	1	0
Pharyngitis streptococcal	1	0
Streptococcal infection	1	0
<b><i>Tinea infections</i></b>		
Tinea infection	1	0
Tinea pedis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Croup infectious	1	0
Laryngitis	2	0
Nasal vestibulitis	1	0
Nasopharyngitis	26	0
Pharyngitis	22	0
Rhinitis	11	0
Sinusitis	18	0
Tonsillitis	3	0
Tracheitis	1	0
Upper respiratory tract infection	1	0
<b><i>Urinary tract infections</i></b>		
Cystitis	10	0
Kidney infection	3	0
Pyelonephritis	1	0
Pyelonephritis acute	2	0
Urinary tract infection	40	0
Urinary tract infection neonatal	1	0
<b><i>Vascular infections</i></b>		
Lymphangitis	1	0
<b><i>Viral infections NEC</i></b>		
Bronchiolitis	1	0
Bronchitis viral	1	0
Encephalitis viral	1	0
Gastroenteritis viral	2	0
Post viral fatigue syndrome	8	0
Vestibular neuronitis	3	0

# Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Viral infection	7	0
<b>Infections SOC TOTAL</b>	<b>560</b>	<b>13</b>

## Case Series Drug Analysis Print

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Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Oesophageal injury	1	0
Splenic rupture	1	0
Tongue injury	1	0
Tooth fracture	4	0
Tooth injury	3	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	3	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Delayed recovery from anaesthesia	3	0
Sedation complication	14	0
<b><i>Atmospheric pressure injuries</i></b>		
Decompression sickness	1	0
<b><i>Cardiac and vascular procedural complications</i></b>		
Vasoplegia syndrome	2	0
<b><i>Cerebral injuries NEC</i></b>		
Concussion	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
<b><i>Chemical injuries</i></b>		
Chemical burn	1	0
Meningitis chemical	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Foreign body aspiration	1	1
Foreign body in respiratory tract	1	0
Foreign body in throat	5	0
Pulmonary contusion	1	0
Tracheal injury	1	0
Traumatic lung injury	1	0
<b><i>Ear injuries NEC</i></b>		
Deafness traumatic	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Drug exposure before pregnancy	2	0
Exposure during pregnancy	55	0
Exposure via breast milk	16	0
Foetal exposure during pregnancy	85	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	14	0
Maternal exposure during pregnancy	44	0
Maternal exposure timing unspecified	1	0
Paternal exposure during pregnancy	1	0
<b><i>Eye injuries NEC</i></b>		
Corneal abrasion	2	0
Eye contusion	2	0
Eye injury	1	0
Retinal injury	1	0
<b><i>Foetal and neonatal conditions associated with product exposure</i></b>		
Paternal drugs affecting foetus	1	0
<b><i>Fractures and dislocations NEC</i></b>		
Compression fracture	1	0
Fracture	8	0
Joint dislocation	6	0
Multiple fractures	1	0

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Dental restoration failure	1	0
Procedural nausea	1	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat exhaustion	3	0
Heat stroke	3	0
<b><i>Intentional product misuses</i></b>		
Intentional device misuse	1	0
Intentional product misuse	19	0
<b><i>Intentional product use issues</i></b>		
Intentional dose omission	1	0
Intentional product use issue	3	0
<b><i>Limb fractures and dislocations</i></b>		
Ankle fracture	5	0
Clavicle fracture	2	0
Femoral neck fracture	15	0
Femur fracture	6	0
Forearm fracture	1	0
Hip fracture	4	0
Humerus fracture	1	0
Lower limb fracture	3	0
Scapula fracture	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Circumstance or information capable of leading to medication error	3	0
Drug titration error	2	0
Medication error	109	0
Prescription drug used without a prescription	2	0
Product use complaint	6	0
Product use in unapproved indication	27	0
Product use issue	9	0
Wrong technique in product usage process	14	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	1	0
Ligament sprain	2	0
Muscle rupture	2	0
Tendon rupture	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	2	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Agitation postoperative	1	0
Confusion postoperative	1	0
Mental status changes postoperative	1	0
Procedural dizziness	1	0
<b><i>Non-occupational environmental exposures</i></b>		
Exposure to chemical pollution	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Electric shock	35	0
Fall	219	2
Foreign body	1	0
Gun shot wound	2	1
Injury	6	0
Multiple injuries	2	1
Road traffic accident	18	4

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Wound haemorrhage	2	0
Wound secretion	1	0
<b>Non-site specific procedural complications</b>		
Infusion related reaction	2	0
Post procedural haemorrhage	7	0
Postoperative hypertension	1	0
Procedural haemorrhage	3	0
Procedural pain	1	0
Wound dehiscence	1	0
<b>Off label uses</b>		
Off label use	61	0
<b>Overdoses NEC</b>		
Intentional overdose	260	15
Overdose	468	38
Prescribed overdose	19	1
<b>Peripheral nerve injuries</b>		
Injury to brachial plexus due to birth trauma	1	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	21	3
Carbon monoxide poisoning	1	0
Metal poisoning	1	0
Poisoning	4	0
Poisoning deliberate	1	0
Toxicity to various agents	106	58
<b>Product administration errors and issues</b>		
Accidental overdose	36	4
Accidental underdose	2	0
Contraindicated product administered	10	0
Drug dose titration not performed	5	0
Expired product administered	2	0
Inappropriate schedule of product administration	3	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	13	0
Incorrect product administration duration	2	0
Incorrect route of product administration	8	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	4	0
Product administration error	14	0
Product dose omission in error	3	0
Product dose omission issue	25	0
Wrong patient received product	8	0
Wrong product administered	12	0
<b>Product confusion errors and issues</b>		
Product label confusion	2	0
Product name confusion	1	0
Product packaging confusion	1	0
<b>Product dispensing errors and issues</b>		
Drug dispensed to wrong patient	8	0
Product dispensing error	53	0
<b>Product monitoring errors and issues</b>		
Documented hypersensitivity to administered product	2	0
Drug monitoring procedure not performed	4	0
Labelled drug-drug interaction issue	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Labelled drug-drug interaction medication error	14	0
Product monitoring error	2	0
<b>Product prescribing errors and issues</b>		
Product prescribing error	15	0
Product prescribing issue	2	0
<b>Product selection errors and issues</b>		
Product selection error	1	0
<b>Product storage errors and issues in the product use system</b>		
Product storage error	2	0
<b>Radiation injuries</b>		
Sunburn	16	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
<b>Site specific injuries NEC</b>		
Back injury	1	0
Head injury	10	0
Limb injury	8	0
<b>Skin injuries NEC</b>		
Contusion	426	0
Dermatitis artefacta	1	0
Scar	7	0
Scratch	3	0
Skin abrasion	2	0
Skin injury	1	0
Skin laceration	8	0
<b>Skull fractures, facial bone fractures and dislocations</b>		
Jaw fracture	1	0
Skull fracture	3	1
<b>Spinal fractures and dislocations</b>		
Cervical vertebral fracture	2	0
Spinal compression fracture	3	0
Spinal fracture	1	0
Thoracic vertebral fracture	1	0
<b>Stoma complications</b>		
Gastrointestinal stoma complication	1	0
Stoma site haemorrhage	1	0
<b>Thermal burns</b>		
Burn oesophageal	2	0
Burn oral cavity	1	0
Burns second degree	1	0
Thermal burn	2	0
<b>Underdoses NEC</b>		
Intentional underdose	1	0
Underdose	2	0
<b>Injuries SOC TOTAL</b>	<b>2561</b>	<b>129</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal cortex tests</i></b>		
Blood cortisol	1	0
Cortisol abnormal	1	0
Cortisol decreased	2	0
Cortisol increased	1	0
Dehydroepiandrosterone decreased	1	0
<b><i>Adrenal medulla tests</i></b>		
Blood catecholamines decreased	1	0
Epinephrine decreased	1	0
<b><i>Autoimmunity analyses</i></b>		
Antinuclear antibody positive	3	0
Antiphospholipid antibodies	1	0
<b><i>Blood counts NEC</i></b>		
Full blood count abnormal	3	0
Full blood count decreased	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Anion gap increased	1	0
Blood bicarbonate abnormal	1	0
Blood bicarbonate decreased	1	0
Blood lactic acid	1	0
Blood lactic acid increased	3	0
Blood pH abnormal	1	0
Blood pH increased	1	0
Carbon dioxide abnormal	1	0
Oxygen saturation decreased	10	0
Oxygen saturation increased	1	0
PCO2 abnormal	1	0
PCO2 increased	1	0
<b><i>Bone marrow and immune tissue histopathology procedures</i></b>		
Megakaryocytes decreased	1	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose abnormal	1	0
Blood glucose decreased	14	0
Blood glucose fluctuation	4	0
Blood glucose increased	19	0
Glycosylated haemoglobin increased	3	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	5	0
Cardiac murmur functional	2	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Ejection fraction decreased	2	0
<b><i>Central nervous system imaging procedures</i></b>		
Brain scan abnormal	1	0
Dopamine transporter scintigraphy abnormal	1	0
<b><i>Cerebrospinal fluid tests (excl microbiology)</i></b>		
CSF glucose decreased	1	0
CSF test abnormal	1	0
CSF white blood cell count increased	1	0
CSF white blood cell count positive	1	0
<b><i>Chemistry analyses NEC</i></b>		
Inflammatory marker increased	1	0
Serum serotonin	1	0
Serum serotonin decreased	1	0

## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Serum serotonin increased	4	0
<b>Cholesterol analyses</b>		
Blood cholesterol increased	18	0
Low density lipoprotein increased	1	0
<b>Coagulation and bleeding analyses</b>		
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time abnormal	2	0
Activated partial thromboplastin time prolonged	8	0
Bleeding time prolonged	4	0
Blood fibrinogen decreased	2	0
Blood thromboplastin increased	1	0
Capillary fragility increased	1	0
Coagulation test abnormal	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	1	0
Fibrin D dimer increased	1	0
International normalised ratio decreased	2	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	65	0
Prothrombin level abnormal	1	0
Prothrombin level increased	1	0
Prothrombin time abnormal	1	0
Prothrombin time prolonged	11	0
<b>Digestive enzymes</b>		
Amylase increased	7	0
Pancreatic enzymes decreased	1	0
<b>ECG investigations</b>		
Electrocardiogram PR prolongation	3	0
Electrocardiogram QRS complex prolonged	11	0
Electrocardiogram QT interval	2	0
Electrocardiogram QT interval abnormal	3	0
Electrocardiogram QT prolonged	264	0
Electrocardiogram QT shortened	2	0
Electrocardiogram ST segment abnormal	3	0
Electrocardiogram ST segment elevation	4	0
Electrocardiogram T wave abnormal	2	0
Electrocardiogram T wave biphasic	1	0
Electrocardiogram T wave inversion	4	0
Electrocardiogram T wave peaked	1	0
Electrocardiogram abnormal	13	0
Electrocardiogram change	5	0
QRS axis abnormal	1	0
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	1	0
Insulin-like growth factor increased	1	0
<b>Faecal analyses NEC</b>		
Faecal calprotectin increased	1	0
Occult blood positive	1	0
<b>Fertility analyses</b>		
Semen analysis abnormal	2	0
Semen viscosity decreased	1	0
Semen volume decreased	4	0
Sperm concentration abnormal	1	0



## Case Series Drug Analysis Print

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Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Sperm concentration decreased	5	0
Spermatozoa abnormal	2	0
Spermatozoa morphology abnormal	1	0
Spermatozoa progressive motility decreased	1	0
<b> Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate abnormal	1	0
<b> Foetal and neonatal imaging procedures</b>		
Foetal gastrointestinal tract imaging abnormal	1	0
<b> Gastrointestinal function diagnostic procedures</b>		
Gastric pH decreased	7	0
Gastric pH increased	1	0
<b> Haem metabolism analyses</b>		
Haptoglobin increased	1	0
<b> Haematological analyses NEC</b>		
Red blood cell sedimentation rate increased	16	0
<b> Heart rate and pulse investigations</b>		
Heart rate	3	0
Heart rate abnormal	11	0
Heart rate decreased	20	0
Heart rate increased	142	0
Heart rate irregular	32	0
Pulse abnormal	6	0
Pulse absent	2	0
Pulse pressure decreased	1	0
Sinus rhythm	1	0
<b> Hepatobiliary function diagnostic procedures</b>		
Alanine aminotransferase increased	54	0
Ammonia increased	1	0
Aspartate aminotransferase increased	18	0
Blood bilirubin increased	28	0
Gamma-glutamyltransferase abnormal	2	0
Gamma-glutamyltransferase increased	30	0
Hepatic enzyme	1	0
Hepatic enzyme abnormal	3	0
Hepatic enzyme increased	21	0
Liver function test abnormal	247	0
Liver function test increased	64	0
Transaminases abnormal	1	0
Transaminases increased	4	0
<b> Imaging procedures NEC</b>		
Computerised tomogram abnormal	1	0
<b> Immune response protein analyses NEC</b>		
Complement factor decreased	1	0
<b> Immunoglobulin analyses</b>		
Blood immunoglobulin E increased	1	1
Blood immunoglobulin M decreased	1	0
Blood immunoglobulin M increased	1	0
Immunoglobulins increased	2	0
<b> Immunology analyses NEC</b>		
Tryptase decreased	1	0
<b> Investigations NEC</b>		
Quality of life decreased	10	0
<b> Lipoprotein and lipid tests NEC</b>		

## Case Series Drug Analysis Print

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Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Lipids abnormal	1	0
Lipids increased	2	0
<b>Metabolism tests NEC</b>		
Blood uric acid increased	1	0
Brain natriuretic peptide increased	1	0
<b>Mineral and electrolyte analyses</b>		
Blood calcium decreased	6	0
Blood calcium increased	4	0
Blood copper decreased	1	0
Blood iron decreased	1	0
Blood magnesium decreased	10	0
Blood phosphorus decreased	2	0
Blood phosphorus increased	1	0
Blood potassium decreased	15	0
Blood potassium increased	7	0
Blood sodium decreased	99	0
Blood sodium increased	5	0
Serum ferritin decreased	2	0
Serum ferritin increased	1	0
Urine sodium increased	1	0
<b>Musculoskeletal and soft tissue imaging procedures</b>		
Bone density decreased	2	0
<b>Neurologic diagnostic procedures</b>		
Coma scale	1	0
Coma scale abnormal	18	0
Electroencephalogram abnormal	7	0
Nerve conduction studies abnormal	1	0
Neurotransmitter level altered	2	0
Romberg test positive	1	0
Sensory level abnormal	1	0
<b>Ophthalmic function diagnostic procedures</b>		
Intraocular pressure increased	9	0
Intraocular pressure test	1	0
Pupillary light reflex tests abnormal	3	0
<b>Physical examination procedures and organ system status</b>		
Body temperature abnormal	1	0
Body temperature decreased	5	0
Body temperature fluctuation	10	0
Body temperature increased	39	0
Breath sounds abnormal	2	0
General physical condition abnormal	3	0
Grip strength decreased	2	0
Head circumference abnormal	1	0
Intelligence test abnormal	1	0
Menstruation normal	1	0
Neurological examination abnormal	1	0
Ophthalmological examination	1	0
Product residue present	1	0
Respiratory rate decreased	7	0
Respiratory rate increased	11	0
Skin turgor decreased	1	0
Weight	1	0
Weight decreased	270	0

## Case Series Drug Analysis Print

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Report Run Date: 30-Jan-2023

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Weight increased	347	0
<b><i>Pituitary analyses anterior</i></b>		
Blood corticotrophin decreased	1	0
Blood follicle stimulating hormone increased	3	0
Blood gonadotrophin abnormal	1	0
Blood luteinising hormone increased	2	0
Blood prolactin decreased	1	0
Blood prolactin increased	51	0
Blood thyroid stimulating hormone abnormal	1	0
Blood thyroid stimulating hormone decreased	2	0
Blood thyroid stimulating hormone increased	12	0
<b><i>Pituitary analyses posterior</i></b>		
Blood antidiuretic hormone increased	2	0
<b><i>Platelet analyses</i></b>		
Platelet aggregation abnormal	1	0
Platelet count abnormal	1	0
Platelet count decreased	54	0
Platelet count increased	8	0
Platelet function test abnormal	2	0
<b><i>Protein analyses NEC</i></b>		
Alpha 1 foetoprotein increased	1	0
Blood albumin decreased	3	0
Blood albumin increased	1	0
C-reactive protein increased	15	0
Ceruloplasmin decreased	1	0
Globulins increased	1	0
Protein total decreased	2	0
<b><i>Red blood cell analyses</i></b>		
Haematocrit increased	1	0
Haemoglobin decreased	36	0
Haemoglobin increased	2	0
Mean cell haemoglobin concentration decreased	1	0
Mean cell haemoglobin increased	1	0
Mean cell volume increased	2	0
Red blood cell count decreased	3	0
Red cell distribution width increased	1	0
<b><i>Renal function analyses</i></b>		
Blood creatinine abnormal	1	0
Blood creatinine increased	18	0
Blood urea abnormal	1	0
Blood urea decreased	1	0
Blood urea increased	7	0
Glomerular filtration rate decreased	4	0
Renal function test abnormal	1	0
<b><i>Reproductive hormone analyses</i></b>		
Blood testosterone decreased	3	0
Blood testosterone increased	1	0
Oestradiol decreased	1	0
Oestradiol increased	1	0
Progesterone decreased	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Peak expiratory flow rate decreased	5	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 30-Jan-2023

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood creatine phosphokinase increased	63	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin increased	6	0
<b>Therapeutic drug monitoring analyses</b>		
Anticonvulsant drug level increased	1	0
Antidepressant drug clearance decreased	1	0
Antidepressant drug clearance increased	1	0
Antidepressant drug level above therapeutic	1	0
Antidepressant drug level increased	3	0
Antipsychotic drug level above therapeutic	2	0
Antipsychotic drug level decreased	3	0
Antipsychotic drug level increased	31	2
Drug level above therapeutic	2	0
Drug level increased	28	0
<b>Thyroid analyses</b>		
Thyroid function test abnormal	2	0
Thyroxine decreased	8	0
Thyroxine free increased	2	0
Thyroxine increased	1	0
Tri-iodothyronine increased	1	0
<b>Tissue enzyme analyses NEC</b>		
Blood alkaline phosphatase increased	29	0
Blood lactate dehydrogenase abnormal	1	0
Blood lactate dehydrogenase increased	2	0
<b>Toxicology laboratory analyses</b>		
Blood caffeine increased	1	0
Blood cannabinoids increased	1	0
Blood ethanol increased	1	0
Drug screen false positive	2	0
Drug screen positive	1	0
Postmortem blood drug level increased	1	0
Urine amphetamine positive	1	0
<b>Triglyceride analyses</b>		
Blood triglycerides increased	4	0
<b>Urinalysis NEC</b>		
Blood urine present	10	0
Crystal urine present	1	0
Glucose urine present	1	0
Urine analysis abnormal	5	0
White blood cells urine positive	1	0
pH urine decreased	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output decreased	19	0
Urine output increased	3	0
<b>Vascular auscultatory investigations</b>		
Carotid bruit	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	2	0
Blood pressure decreased	27	0
Blood pressure diastolic increased	1	0
Blood pressure increased	57	0
Blood pressure orthostatic abnormal	1	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood pressure systolic decreased	2	0
Blood pressure systolic increased	2	0
<b><i>Virus identification and serology</i></b>		
Epstein-Barr virus antibody positive	1	0
<b><i>Vitamin analyses</i></b>		
Blood folate decreased	2	0
Vitamin D decreased	1	0
<b><i>Water and electrolyte analyses NEC</i></b>		
Blood osmolarity decreased	3	0
Osmolar gap abnormal	1	0
Urine osmolarity increased	1	0
<b><i>White blood cell analyses</i></b>		
Basophil count increased	1	0
Differential white blood cell count abnormal	6	0
Eosinophil count abnormal	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count decreased	2	0
Lymphocyte count increased	1	0
Macrophages increased	1	0
Monocyte count increased	2	0
Neutrophil count abnormal	2	0
Neutrophil count decreased	19	0
Neutrophil count increased	15	0
White blood cell count decreased	23	0
White blood cell count increased	31	0
<b>Investigations SOC TOTAL</b>	<b>2942</b>	<b>3</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	28	0
Decreased appetite	756	1
Eating disorder symptom	1	0
Food craving	16	0
Hyperphagia	12	0
Hypophagia	8	0
Increased appetite	70	0
Salt craving	1	0
<b><i>Calcium metabolism disorders</i></b>		
Calcium deficiency	1	0
Hypercalcaemia	2	0
Hypocalcaemia	10	0
Tetany	6	0
<b><i>Chloride imbalance</i></b>		
Hypochloraemia	3	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Decreased insulin requirement	1	0
Diabetes mellitus	27	0
Diabetes mellitus inadequate control	28	0
Increased insulin requirement	1	0
Type 1 diabetes mellitus	6	0
Type 2 diabetes mellitus	8	0
<b><i>Diabetic complications NEC</i></b>		
Diabetic ketoacidosis	3	0
<b><i>Diabetic complications neurological</i></b>		
Hyperglycaemic hyperosmolar nonketotic syndrome	1	0
<b><i>Disorders of purine metabolism</i></b>		
Gout	12	0
<b><i>Electrolyte imbalance NEC</i></b>		
Electrolyte depletion	1	0
Electrolyte imbalance	10	0
Hyperosmolar state	1	0
<b><i>Elevated cholesterol</i></b>		
Hypercholesterolaemia	10	0
<b><i>Elevated triglycerides</i></b>		
Hypertriglyceridaemia	1	0
<b><i>Fat soluble vitamin deficiencies and disorders</i></b>		
Vitamin D deficiency	5	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	4	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	24	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Alcohol intolerance	15	0
Food intolerance	7	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal loss of weight	51	0
Abnormal weight gain	87	0
Cachexia	2	0
Failure to thrive	3	0
Feeding disorder	17	0
Food aversion	4	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Obesity	7	0
Overweight	1	0
Poor feeding infant	22	0
Underweight	2	0
Weight fluctuation	5	0
Weight gain poor	5	0
Weight loss poor	5	0
<b>Hyperglycaemic conditions NEC</b>		
Hyperglycaemia	18	0
Insulin resistance	1	0
Metabolic syndrome	1	0
<b>Hyperlipidaemias NEC</b>		
Hyperlipidaemia	4	0
<b>Hypoglycaemic conditions NEC</b>		
Hypoglycaemia	152	0
Hypoglycaemia neonatal	4	0
Hypoglycaemia unawareness	7	0
<b>Iron excess</b>		
Haemosiderosis	1	0
<b>Iron metabolism disorders NEC</b>		
Iron metabolism disorder	1	0
<b>Magnesium metabolism disorders</b>		
Hypomagnesaemia	3	0
Magnesium deficiency	2	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Ketoacidosis	4	1
Lactic acidosis	1	0
Metabolic acidosis	40	0
<b>Metabolic alkaloses</b>		
Alkalosis	1	0
Metabolic alkalosis	1	0
<b>Metabolic disorders NEC</b>		
Hypermetabolism	1	0
Hypometabolism	1	0
Metabolic disorder	2	0
<b>Mixed acid-base disorders</b>		
Acidosis	6	0
<b>Potassium imbalance</b>		
Hyperkalaemia	17	2
Hypokalaemia	94	1
<b>Protein metabolism disorders NEC</b>		
Hyperammonaemia	3	0
Hyperproteinaemia	1	0
Hypoproteinaemia	1	0
<b>Sodium imbalance</b>		
Hypernatraemia	7	0
Hyponatraemia	1146	3
Hyponatraemic syndrome	6	0
<b>Sugar intolerance (excl glucose intolerance)</b>		
Carbohydrate intolerance	1	0
Lactose intolerance	1	0
<b>Total fluid volume decreased</b>		
Dehydration	58	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Hypovolaemia	1	0
<b>Total fluid volume increased</b>		
Fluid retention	27	0
Hypervolaemia	2	0
Water intoxication	2	0
<b>Water soluble vitamin deficiencies</b>		
Folate deficiency	3	0
Vitamin B complex deficiency	2	0
Vitamin B12 deficiency	4	0
<b>Metabolic disorders SOC TOTAL</b>	<b>2917</b>	<b>8</b>



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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	29	0
Arthropathy	20	0
Palindromic rheumatism	1	0
Polyarthritis	13	0
Seronegative arthritis	3	0
<i><b>Bone disorders NEC</b></i>		
Exostosis	1	0
Jaw disorder	9	0
Osteonecrosis	2	0
Osteonecrosis of jaw	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	10	0
Pain in jaw	90	0
Spinal pain	3	0
<i><b>Bursal disorders</b></i>		
Bursitis	2	0
<i><b>Connective tissue disorders NEC</b></i>		
Scleroderma	3	0
Sjogren's syndrome	1	0
Systemic scleroderma	1	0
<i><b>Extremity deformities</b></i>		
Foot deformity	2	0
Hand deformity	1	0
<i><b>Fractures NEC</b></i>		
Pathological fracture	1	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc degeneration	1	0
<i><b>Joint related disorders NEC</b></i>		
Joint hyperextension	2	0
Temporomandibular joint syndrome	8	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	443	0
Jaw clicking	4	0
Joint effusion	3	0
Joint noise	1	0
Joint stiffness	82	0
Joint swelling	94	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	4	0
<i><b>Metabolic bone disorders</b></i>		
Osteopenia	4	0
Osteoporosis	6	0
<i><b>Muscle infections and inflammations</b></i>		
Antisynthetase syndrome	1	0
Myositis	10	0
Polymyositis	1	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	7	0
Myalgia	362	0
Myalgia intercostal	1	0
Myofascial pain syndrome	1	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Muscle related signs and symptoms NEC</i></b>		
Haematoma muscle	1	0
Muscle atrophy	5	0
Muscle disorder	14	0
Muscle fatigue	5	0
Muscle spasms	405	0
Muscle tightness	91	0
Muscle twitching	356	0
Myokymia	1	0
<b><i>Muscle tone abnormalities</i></b>		
Floppy infant	2	0
Hypertonia neonatal	1	0
Hypotonia neonatal	7	1
Muscle rigidity	80	0
Nuchal rigidity	2	0
Torticollis	17	0
Trismus	87	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	133	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Back disorder	3	0
Growth retardation	1	0
Infantile back arching	2	0
Limb mass	1	0
Mobility decreased	27	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	120	0
Posture abnormal	4	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Head deformity	2	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	96	0
Flank pain	1	0
Limb discomfort	23	0
Musculoskeletal chest pain	5	0
Musculoskeletal discomfort	9	0
Musculoskeletal pain	5	0
Neck pain	46	0
Pain in extremity	186	0
<b><i>Myopathies</i></b>		
Compartment syndrome	1	0
Myopathy	10	0
Myopathy toxic	1	0
Rhabdomyolysis	28	2
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	10	0
Spinal osteoarthritis	1	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	1	0
<b><i>Rheumatoid arthropathies</i></b>		

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	9	0
<b>Soft tissue disorders NEC</b>		
Clubbing	1	0
Groin pain	5	0
Neck mass	1	0
<b>Spine and neck deformities</b>		
Neck deformity	1	0
Scoliosis	1	0
Spinal deformity	1	0
<b>Spondyloarthropathies</b>		
Arthritis reactive	2	0
<b>Synovial disorders</b>		
Synovitis	5	0
<b>Tendon disorders</b>		
Tendonitis	3	0
Tenosynovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>3053</b>	<b>3</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Adrenal neoplasms benign</i>		
Adrenal adenoma	1	0
<i>Adult T-cell lymphomas/leukaemias</i>		
Hepatosplenic T-cell lymphoma	1	1
<i>B-cell lymphomas NEC</i>		
Follicular lymphoma	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
Fibroadenoma of breast	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	12	0
Breast cancer male	2	0
Breast cancer metastatic	1	0
Breast cancer recurrent	1	0
Lobular breast carcinoma in situ	1	0
<i>Carcinoid tumours</i>		
Carcinoid tumour	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Colorectal neoplasms malignant</i>		
Rectal cancer	1	0
<i>Endocrine neoplasms benign NEC</i>		
Parathyroid tumour benign	1	0
Pituitary tumour benign	5	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Pituitary tumour	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	2	1
Gastric cancer stage IV	1	0
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	1	1
<i>Germ cell neoplasms site unspecified NEC</i>		
Germ cell cancer	1	0
<i>Gliomas benign</i>		
Astrocytoma, low grade	1	0
<i>Hepatic neoplasms malignant</i>		
Hepatic cancer metastatic	1	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hormone secreting pituitary neoplasms</i>		
Prolactin-producing pituitary tumour	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Phaeochromocytoma	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	4	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	1	0
<i>Leukaemias chronic myeloid</i>		
Chronic myeloid leukaemia	1	0
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	4	1

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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
<b><i>Neoplasms malignant site unspecified NEC</i></b>		
Adenocarcinoma	2	0
Malignant neoplasm progression	3	2
Neoplasm malignant	2	0
Squamous cell carcinoma	2	0
<b><i>Nervous system neoplasms benign NEC</i></b>		
Brain neoplasm benign	1	0
<b><i>Nervous system neoplasms malignant NEC</i></b>		
Neuroblastoma	1	0
<b><i>Nervous system neoplasms unspecified malignancy NEC</i></b>		
Brain neoplasm	2	0
<b><i>Non-Hodgkin's lymphomas NEC</i></b>		
Non-Hodgkin's lymphoma	1	0
<b><i>Non-small cell neoplasms malignant of the respiratory tract cell type specified</i></b>		
Lung adenocarcinoma	1	0
Non-small cell lung cancer	1	0
<b><i>Oesophageal neoplasms malignant</i></b>		
Oesophageal carcinoma	1	0
<b><i>Ovarian neoplasms malignant (excl germ cell)</i></b>		
Ovarian cancer	1	0
<b><i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i></b>		
Pancreatic carcinoma	1	0
<b><i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i></b>		
Lung cancer metastatic	1	0
Lung neoplasm malignant	2	1
<b><i>Skin melanomas (excl ocular)</i></b>		
Malignant melanoma	1	0
Melanoma recurrent	1	0
<b><i>Skin neoplasms benign</i></b>		
Melanocytic naevus	2	0
Skin papilloma	1	0
<b><i>Skin neoplasms malignant and unspecified (excl melanoma)</i></b>		
Basal cell carcinoma	1	0
Neoplasm skin	2	0
Skin cancer	1	0
<b><i>Soft tissue neoplasms benign NEC</i></b>		
Benign muscle neoplasm	1	0
<b>Neoplasms SOC TOTAL</b>	<b>89</b>	<b>7</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Extensor plantar response	5	0
Hyperreflexia	48	0
Hyporeflexia	5	0
Poor sucking reflex	1	0
Reflexes abnormal	2	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	8	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	31	0
<i><b>Acute polyneuropathies</b></i>		
Guillain-Barre syndrome	2	0
<i><b>Alzheimer's disease (incl subtypes)</b></i>		
Mixed dementia	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Adrenergic syndrome	2	0
Anticholinergic syndrome	6	0
Autonomic nervous system imbalance	1	0
<i><b>Central nervous system aneurysms and dissections</b></i>		
Intracranial aneurysm	3	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Brain stem haemorrhage	2	0
Brain stem ischaemia	1	0
Cerebellar infarction	1	0
Cerebral artery embolism	1	0
Cerebral haematoma	1	0
Cerebral haemorrhage	31	9
Cerebral infarction	7	2
Cerebrovascular accident	67	14
Embolic stroke	1	0
Haemorrhage intracranial	9	3
Haemorrhagic stroke	4	0
Intraventricular haemorrhage	2	0
Ischaemic stroke	1	0
Lacunar infarction	1	0
Lacunar stroke	1	0
Subarachnoid haemorrhage	23	9
<i><b>Central nervous system vascular disorders NEC</b></i>		
Central nervous system vasculitis	3	0
Cerebral amyloid angiopathy	1	1
Cerebral congestion	1	0
Cerebral vasoconstriction	3	0
Cerebrovascular disorder	3	0
Dural arteriovenous fistula	1	0
Reversible cerebral vasoconstriction syndrome	9	0
<i><b>Choreiform movements</b></i>		
Athetosis	2	0
Chorea	20	0
Choreoathetosis	19	0
<i><b>Chronic polyneuropathies</b></i>		
Diabetic neuropathy	1	0
<i><b>Coma states</b></i>		
Coma	32	1

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Coma hepatic	1	1
Diabetic coma	2	1
<b>Coordination and balance disturbances</b>		
Ataxia	104	0
Balance disorder	323	0
Cerebellar ataxia	3	0
Cerebellar syndrome	3	0
Coordination abnormal	102	0
Dysdiadochokinesis	1	0
Dysmetria	1	0
Dysstasia	19	0
Hand-eye coordination impaired	2	0
Nystagmus	41	0
<b>Cortical dysfunction NEC</b>		
Agnosia	2	0
Aphasia	70	0
Apraxia	5	0
Dysgraphia	3	0
Dyslexia	5	0
Dyspraxia	5	0
Neurologic neglect syndrome	1	0
Prosopagnosia	1	0
<b>Cranial nerve disorders NEC</b>		
Cranial nerve disorder	1	0
<b>Dementia (excl Alzheimer's type)</b>		
Dementia	14	0
Frontotemporal dementia	1	0
Progressive supranuclear palsy	1	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	1	0
Osmotic demyelination syndrome	5	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	15	0
Apallic syndrome	2	0
Consciousness fluctuating	1	0
Depressed level of consciousness	62	3
Lethargy	437	0
Loss of consciousness	272	0
Postictal state	2	0
Sedation	104	0
Somnolence	1012	0
Somnolence neonatal	2	0
Stupor	12	0
Syncope	357	0
<b>Disturbances in sleep phase rhythm</b>		
Circadian rhythm sleep disorder	1	0
Irregular sleep wake rhythm disorder	1	0
Non-24-hour sleep-wake disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	170	0
Akinesia	2	0
Ballismus	2	0
Bradykinesia	8	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Clumsiness	26	0
Dyskinesia	495	0
Dyskinesia neonatal	1	0
Extrapyramidal disorder	149	0
Fine motor skill dysfunction	3	0
Gross motor delay	2	0
Hyperkinesia	23	0
Hypokinesia	18	0
Motor dysfunction	5	0
Movement disorder	47	0
Psychomotor hyperactivity	112	0
Rabbit syndrome	1	0
Tardive dyskinesia	59	0
<b><i>Dystonias</i></b>		
Dystonia	410	0
Opisthotonus	13	0
Oromandibular dystonia	8	0
Pharyngeal dystonia	3	0
Pleurothotonus	4	0
Spasmodic dysphonia	6	0
<b><i>Encephalitis NEC</i></b>		
Encephalitis autoimmune	1	0
<b><i>Encephalopathies NEC</i></b>		
Encephalopathy	9	1
Hypertensive encephalopathy	2	0
Leukoencephalopathy	1	0
<b><i>Encephalopathies toxic and metabolic</i></b>		
Hepatic encephalopathy	2	0
Toxic encephalopathy	1	0
<b><i>Eye movement disorders</i></b>		
IIIrd nerve paralysis	1	0
VIth nerve paralysis	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	17	0
Facial nerve disorder	1	0
Facial paralysis	26	0
Facial paresis	4	0
Facial spasm	23	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	338	2
<b><i>Glossopharyngeal nerve disorders</i></b>		
Glossopharyngeal neuralgia	1	0
<b><i>Headaches NEC</i></b>		
Cluster headache	6	0
Drug withdrawal headache	28	0
Headache	2405	0
Menstrual headache	1	0
Sinus headache	10	0
Tension headache	31	0
<b><i>Hydrocephalic conditions</i></b>		
Hydrocephalus	4	0
<b><i>Increased intracranial pressure disorders</i></b>		
Brain oedema	9	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	9	0
<b>Intellectual disabilities</b>		
Intellectual disability	7	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	2	0
<b>Memory loss (excl dementia)</b>		
Amnesia	327	0
Anterograde amnesia	1	0
Memory impairment	331	0
Retrograde amnesia	1	0
Transient global amnesia	5	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	68	0
Disturbance in attention	559	0
Judgement impaired	10	0
Mental impairment	66	0
<b>Migraine headaches</b>		
Basilar migraine	1	0
Hemiplegic migraine	2	0
Migraine	335	0
Migraine with aura	13	0
Migraine without aura	2	0
Typical aura without headache	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	12	0
Mononeuropathy multiplex	1	0
Nerve compression	2	0
Peroneal nerve palsy	10	0
Pudendal canal syndrome	1	0
Radial nerve palsy	2	0
Ulnar nerve palsy	1	0
<b>Motor neurone diseases</b>		
Lower motor neurone lesion	1	0
Upper motor neurone lesion	1	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis	10	0
Multiple sclerosis relapse	4	0
Radiologically isolated syndrome	1	0
<b>Muscle tone abnormal</b>		
Drop attacks	7	0
Hypertonia	55	0
Hypotonia	29	0
Myotonia	1	0
Neuroleptic malignant syndrome	67	6
Serotonin syndrome	349	5
<b>Myelitis (incl infective)</b>		
Myelitis transverse	2	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	1	0
Hypersomnia	50	0
Narcolepsy	7	0
<b>Nervous system cysts and polyps</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Arachnoid cyst	1	0
<b><i>Nervous system disorders NEC</i></b>		
Central nervous system lesion	3	0
Cerebral disorder	8	0
Nervous system disorder	12	0
Neurotoxicity	5	0
Psychomotor skills impaired	2	0
<b><i>Neurologic visual problems NEC</i></b>		
Hemianopia	2	0
Hemianopia heteronymous	1	0
Hemianopia homonymous	3	0
Tunnel vision	17	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Agitation neonatal	17	0
Clonus	17	0
Dizziness	2815	0
Dizziness exertional	3	0
Dizziness postural	44	0
Drooling	17	0
Exaggerated startle response	1	0
Grimacing	2	0
Head discomfort	55	0
Hyporesponsive to stimuli	8	0
Meningism	3	0
Myoclonus	167	0
Neurological decompensation	1	0
Neurological symptom	10	0
Patient elopement	3	0
Presyncope	40	0
Slow response to stimuli	6	0
Tongue biting	14	0
Unresponsive to stimuli	45	0
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	27	0
Muscle spasticity	6	0
Neuromyopathy	1	0
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis	6	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	20	0
Hyposmia	2	0
Parosmia	36	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	12	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Anaesthesia	1	0
Burning sensation	184	0
Dysaesthesia	5	0
Formication	34	0
Hyperaesthesia	22	0
Hypoaesthesia	366	0
Paraesthesia	885	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Diplegia	2	0
Hemiparesis	20	0
Hemiplegia	15	0
Locked-in syndrome	1	0
Monoparesis	1	0
Monoplegia	6	0
Paralysis	24	0
Paraparesis	1	0
Paresis	4	0
Quadriparesis	2	0
Quadriplegia	2	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Cogwheel rigidity	27	0
Parkinson's disease	27	1
Parkinsonian gait	1	0
Parkinsonian rest tremor	2	0
Parkinsonism	70	0
Reduced facial expression	4	0
<b><i>Partial complex seizures</i></b>		
Dreamy state	1	0
Focal dyscognitive seizures	12	0
Temporal lobe epilepsy	2	0
<b><i>Partial simple seizures NEC</i></b>		
Simple partial seizures	4	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuritis	2	0
Neuropathy peripheral	20	0
Peripheral motor neuropathy	1	0
Peripheral sensory neuropathy	5	0
Polyneuropathy	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Acquired epileptic aphasia	2	0
Atonic seizures	1	0
Change in seizure presentation	1	0
Clonic convulsion	2	0
Convulsions local	1	0
Convulsive threshold lowered	15	0
Drug withdrawal convulsions	9	0
Epilepsy	200	4
Epileptic aura	6	0
Hypoglycaemic seizure	1	0
Hyponatraemic seizure	10	0
Infantile spasms	2	0
Myoclonic epilepsy	2	0
Neonatal seizure	15	0
Partial seizures	13	0
Psychogenic seizure	7	0
Seizure	667	3
Seizure anoxic	1	0
Seizure like phenomena	2	0
Status epilepticus	24	0
Tonic clonic movements	4	0
Tonic convulsion	5	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	40	0
Allodynia	1	0
Aura	5	0
Dysgeusia	89	0
Electric shock sensation	530	0
Hypogeusia	2	0
Neuralgia	24	0
Persistent genital arousal disorder	9	0
Phantom limb syndrome	1	0
Restless arm syndrome	1	0
Restless legs syndrome	180	0
Sensory disturbance	92	0
Sensory loss	30	0
Taste disorder	88	0
Vibratory sense increased	1	0
<b><i>Sleep disturbances NEC</i></b>		
Periodic limb movement disorder	3	0
Sleep deficit	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	155	0
Incoherent	9	0
Language disorder	5	0
Repetitive speech	2	0
Slow speech	4	0
Speech disorder	149	0
Speech disorder developmental	3	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Myelopathy	1	0
<b><i>Structural brain disorders NEC</i></b>		
Brain injury	22	4
Cerebral atrophy	5	0
Hippocampal sclerosis	1	0
Intracranial mass	1	0
White matter lesion	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	10	0
<b><i>Tremor (excl congenital)</i></b>		
Action tremor	3	0
Asterixis	1	0
Essential tremor	6	0
Head titubation	8	0
Intention tremor	7	0
Resting tremor	5	0
Tremor	2418	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal nerve disorder	2	0
Trigeminal neuralgia	6	0
<b>Nervous system disorders SOC TOTAL</b>	<b>20309</b>	<b>70</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortion related conditions and complications</b></i>		
Anembryonic gestation	3	0
Retained products of conception	2	0
<i><b>Abortions not specified as induced or spontaneous</b></i>		
Abortion	2	0
Abortion late	1	0
Abortion missed	16	0
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	107	0
Habitual abortion	1	0
<i><b>Amniotic fluid and cavity disorders of pregnancy NEC</b></i>		
Meconium in amniotic fluid	1	0
Meconium stain	1	0
Oligohydramnios	8	0
Polyhydramnios	3	0
<i><b>Foetal complications NEC</b></i>		
Foetal cardiac disorder	1	0
Foetal damage	1	0
Foetal disorder	5	0
Foetal distress syndrome	11	0
Foetal hypokinesia	4	0
Hydrops foetalis	1	0
<i><b>Foetal growth complications</b></i>		
Foetal growth abnormality	1	0
Foetal growth restriction	11	0
<i><b>Gestational age and weight conditions</b></i>		
Low birth weight baby	7	0
Poor weight gain neonatal	1	0
Premature baby	38	0
Small for dates baby	6	0
Weight decrease neonatal	1	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	4	0
<i><b>Hypertension associated disorders of pregnancy</b></i>		
Gestational hypertension	2	0
Pre-eclampsia	16	0
<i><b>Labour onset and length abnormalities</b></i>		
Induced labour	3	0
Premature delivery	4	0
Premature labour	12	0
Premature rupture of membranes	1	0
Prolonged labour	1	0
Threatened labour	1	0
<i><b>Maternal complications of delivery NEC</b></i>		
Retained placenta or membranes	1	0
<i><b>Maternal complications of labour NEC</b></i>		
Abnormal labour	1	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Complication of pregnancy	1	0
Ectopic pregnancy	12	0
Hyperemesis gravidarum	2	0
Morning sickness	1	0

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b> <small>Pregnancy conditions cont'd</small>		
Somatic symptom disorder of pregnancy	1	0
Uterine irritability	2	0
<b>Multiple pregnancies</b>		
Multiple pregnancy	1	0
<b>Neonatal hepatobiliary disorders</b>		
Jaundice neonatal	10	0
<b>Newborn complications NEC</b>		
Neonatal disorder	2	0
<b>Normal newborn status</b>		
Normal newborn	2	0
<b>Normal pregnancy, labour and delivery</b>		
Delivery	3	0
Live birth	6	0
Pregnancy	10	0
Uterine contractions during pregnancy	1	0
<b>Placental abnormalities (excl neoplasms)</b>		
Foetal vascular malperfusion	3	0
Placenta praevia	4	0
Placental disorder	3	0
Placental insufficiency	1	0
<b>Postpartum complications NEC</b>		
Postpartum haemorrhage	3	0
<b>Pregnancy complicated by maternal disorders</b>		
Gestational diabetes	6	0
<b>Stillbirth and foetal death</b>		
Foetal death	26	21
Stillbirth	15	11
<b>Umbilical cord complications</b>		
Umbilical cord abnormality	1	1
Umbilical cord vascular disorder	1	0
<b>Unintended pregnancies</b>		
Pregnancy on oral contraceptive	9	0
Pregnancy with injectable contraceptive	1	0
Unintended pregnancy	7	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>416</b>	<b>33</b>

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Reaction Name	Total	Fatal
<b><i>Counterfeit, falsified and substandard products</i></b>		
Suspected counterfeit product	9	0
<b><i>Device physical property and chemical issues</i></b>		
Device colour issue	1	0
<b><i>Product distribution and storage issues</i></b>		
Product distribution issue	1	0
<b><i>Product label issues</i></b>		
Product label issue	3	0
Product lot number issue	3	0
<b><i>Product packaging issues</i></b>		
Product commingling	1	0
Product outer packaging issue	1	0
Product packaging quantity issue	1	0
<b><i>Product physical issues</i></b>		
Product after taste	1	0
Product coating issue	2	0
Product colour issue	1	0
Product odour abnormal	1	0
Product physical issue	10	0
Product size issue	3	0
Product solubility abnormal	5	0
Product taste abnormal	4	0
<b><i>Product quality issues NEC</i></b>		
Product adhesion issue	1	0
Product complaint	6	0
Product design issue	1	0
Product formulation issue	1	0
Product quality issue	13	0
Product substitution issue	180	0
Suspected product quality issue	1	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	5	0
<b>null SOC TOTAL</b>	<b>255</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	170	0
Behaviour disorder	41	0
Breath holding	1	0
Regressive behaviour	2	0
Sexually inappropriate behaviour	3	0
Staring	10	0
<b><i>Abnormal food elimination</i></b>		
Self-induced vomiting	1	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder	3	0
Adjustment disorder with depressed mood	5	0
Adjustment disorder with mixed anxiety and depressed mood	2	0
Adjustment disorder with mixed disturbance of emotion and conduct	2	0
Grief reaction	2	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	74	0
Blunted affect	16	0
Flat affect	40	0
Inappropriate affect	33	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	1	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	16	0
Anxiety disorder due to a general medical condition	1	0
Generalised anxiety disorder	3	0
Neurosis	2	0
Selective mutism	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1612	0
Anticipatory anxiety	1	0
Anxiety	1997	0
Nervousness	195	0
Stress	58	0
Tension	79	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	4	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	930	0
Antisocial behaviour	20	0
Asocial behaviour	2	0
Aversion	1	0
Disinhibition	50	0
Disturbance in social behaviour	11	0
Grandiosity	6	0
Homicidal ideation	38	0
Hostility	13	0
Impatience	5	0
Indifference	14	0
Negativism	6	0
Overconfidence	2	0
Paranoia	271	0
Personality change	97	0



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Social avoidant behaviour	80	0
Soliloquy	1	0
Stubbornness	1	0
Suggestibility	1	0
Suspiciousness	2	0
Violence-related symptom	57	0
<b>Bipolar disorders</b>		
Bipolar I disorder	8	0
Bipolar II disorder	4	0
Bipolar disorder	18	0
<b>Brief psychotic disorder</b>		
Brief psychotic disorder with marked stressors	1	0
Brief psychotic disorder, with postpartum onset	1	0
Transient psychosis	2	0
<b>Cognitive and attention disorders and disturbances NEC</b>		
Daydreaming	4	0
Distractibility	2	0
Executive dysfunction	1	0
Mental fatigue	8	0
<b>Communications disorders</b>		
Communication disorder	15	0
Mutism	6	0
Speech sound disorder	1	0
<b>Confusion and disorientation</b>		
Confusional state	1118	1
Disorientation	272	0
<b>Decreased physical activity levels</b>		
Catatonia	20	2
<b>Deliria</b>		
Delirium	61	0
<b>Delusional disorders</b>		
Delusional disorder, unspecified type	1	0
<b>Delusional symptoms</b>		
Delusion	81	0
Delusion of grandeur	1	0
Delusion of parasitosis	1	0
Delusion of replacement	1	0
Persecutory delusion	8	0
Somatic delusion	1	0
Thought broadcasting	1	0
Thought insertion	4	0
<b>Dementia NEC</b>		
Pseudodementia	1	0
<b>Depressive disorders</b>		
Agitated depression	4	0
Depression	866	0
Depression suicidal	43	1
Major depression	15	0
Mixed anxiety and depressive disorder	4	0
Perinatal depression	1	0
Persistent depressive disorder	3	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	178	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Dissociation	143	0
Dissociative amnesia	8	0
Dissociative disorder	16	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	15	0
Insomnia	1637	0
Middle insomnia	10	0
Terminal insomnia	20	0
<b><i>Dyssomnias</i></b>		
Dyssomnia	4	0
Poor quality sleep	145	0
<b><i>Eating disorders NEC</i></b>		
Anorexia nervosa	1	0
Binge eating	6	0
Bulimia nervosa	5	0
Eating disorder	27	0
Mercyism	1	0
Pica	3	0
Selective eating disorder	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	237	0
Dysphoria	16	0
Emotional disorder	119	0
Emotional distress	123	0
Emotional poverty	48	0
Euphoric mood	119	0
Frustration tolerance decreased	21	0
Irritability	456	0
Mood altered	94	0
<b><i>Factitious disorders</i></b>		
Factitious disorder	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Acrophobia	1	0
Agoraphobia	52	0
Autophobia	2	0
Claustrophobia	8	0
Fear	130	0
Fear of crowded places	2	0
Fear of death	1	0
Fear of weight gain	1	0
Nocturnal fear	1	0
Nosophobia	2	0
Phobia	10	0
Phonophobia	1	0
Social anxiety disorder	10	0
Social fear	2	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	331	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	496	0
Hallucination, auditory	132	0
Hallucination, olfactory	9	0
Hallucination, tactile	3	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Hallucination, visual	255	0
Hallucinations, mixed	84	0
Somatic hallucination	1	0
<b><i>Impulse control disorders</i></b>		
Impulsive behaviour	48	0
Kleptomania	1	0
Pyromania	2	0
Pyromania	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	371	0
<b><i>Infancy, childhood and adolescence psychiatric disorders NEC</i></b>		
Reactive attachment disorder	1	0
<b><i>Learning disorders</i></b>		
Learning disorder	2	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	68	0
Mental status changes	11	0
<b><i>Mental disorders due to a general medical condition NEC</i></b>		
Neuropsychiatric symptoms	1	0
Organic brain syndrome	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Anhedonia	32	0
Decreased interest	37	0
Depressed mood	370	0
Depressive symptom	17	0
Feeling guilty	4	0
Feeling of despair	44	0
Feelings of worthlessness	13	0
Negative thoughts	35	0
Psychomotor retardation	2	0
Tearfulness	198	0
<b><i>Mood alterations with manic symptoms</i></b>		
Hypomania	189	0
Mania	248	0
<b><i>Mood disorders NEC</i></b>		
Affective disorder	25	0
Apathy	111	0
Boredom	2	0
Listless	7	0
Mood disorder due to a general medical condition	1	0
<b><i>Narcolepsy and associated conditions</i></b>		
Hypnopompic hallucination	1	0
Sleep attacks	2	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Body dysmorphic disorder	3	0
Compulsions	2	0
Compulsive lip biting	1	0
Compulsive shopping	3	0
Dermatillomania	2	0
Obsessive rumination	1	0
Obsessive thoughts	27	0
Obsessive-compulsive disorder	64	0
Trichotillomania	4	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<b><i>Orgasmic disorders and disturbances</i></b>		
Anorgasmia	270	0
Female orgasmic disorder	30	0
Male orgasmic disorder	16	0
Orgasm abnormal	96	0
Orgasmic sensation decreased	21	0
Premature ejaculation	17	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	577	0
Panic disorder	32	0
Panic reaction	186	0
<b><i>Paraphilias and paraphilic disorders</i></b>		
Exhibitionism	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	375	0
Abnormal sleep-related event	5	0
Loss of dreaming	3	0
Nightmare	788	0
Parasomnia	3	0
Rapid eye movements sleep abnormal	2	0
Sleep sex	1	0
Sleep talking	7	0
Sleep terror	21	0
Sleep-related eating disorder	1	0
Somnambulism	48	0
<b><i>Perception disturbances NEC</i></b>		
Autoscopy	8	0
Deja vu	5	0
Derealisation	89	0
Flashback	17	0
Illusion	28	0
Near death experience	2	0
<b><i>Personality disorders NEC</i></b>		
Personality disorder	29	0
Self esteem decreased	18	0
<b><i>Personality disorders with anxious behaviour (Cluster C)</i></b>		
Avoidant personality disorder	1	0
Dependent personality disorder	1	0
Obsessive-compulsive personality disorder	3	0
<b><i>Personality disorders with dramatic behaviour (Cluster B)</i></b>		
Antisocial personality disorder	5	0
Borderline personality disorder	3	0
Histrionic personality disorder	2	0
Psychopathic personality	1	0
<b><i>Personality disorders with eccentric behaviour (Cluster A)</i></b>		
Paranoid personality disorder	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	10	1
Neurodevelopmental disorder	2	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	36	0
<b><i>Psychiatric symptoms NEC</i></b>		
Abulia	2	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Decreased eye contact	2	0
Helplessness	3	0
Hypervigilance	24	0
Neglect of personal appearance	1	0
Psychiatric symptom	47	0
Psychological trauma	2	0
Trance	2	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	33	0
Alcoholic psychosis	1	0
Hysterical psychosis	2	0
Psychotic behaviour	13	0
Psychotic disorder	175	0
Rebound psychosis	2	0
Shared psychotic disorder	1	0
Substance-induced psychotic disorder	6	0
<b>Schizoaffective and schizophreniform disorders</b>		
Schizoaffective disorder	2	0
Schizophreniform disorder	5	0
<b>Schizophrenia NEC</b>		
Schizophrenia	26	0
<b>Sexual and gender identity disorders NEC</b>		
Gender dysphoria	2	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	57	0
Sexual inhibition	5	0
<b>Sexual desire disorders</b>		
Excessive sexual fantasies	1	0
Hypersexuality	6	0
Libido decreased	241	0
Libido disorder	4	0
Libido increased	35	0
Loss of libido	273	0
<b>Sexual dysfunction NEC</b>		
Genito-pelvic pain/penetration disorder	3	0
<b>Sleep disorders NEC</b>		
Sleep disorder	427	0
Sopor	1	0
<b>Somatic symptom disorders</b>		
Conversion disorder	11	0
Illness anxiety disorder	3	0
Polydipsia psychogenic	2	0
Somatic symptom disorder	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	3	0
Logorrhoea	10	0
<b>Speech articulation and rhythm disturbances</b>		
Coprolalia	2	0
Dysphemia	48	0
Pressure of speech	4	0
<b>Stereotypies and automatisms</b>		
Automatism	1	0
Bruxism	371	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <sup>Psychiatric disorders cont'd</sup>		
Head banging	4	0
Posturing	2	0
Stereotypy	1	0
<b><i>Stress disorders</i></b>		
Acute stress disorder	3	0
Burnout syndrome	2	0
Post-traumatic stress disorder	17	0
<b><i>Substance related and addictive disorders</i></b>		
Alcohol abuse	42	0
Alcohol problem	5	0
Alcohol use disorder	2	0
Alcohol withdrawal syndrome	3	0
Alcoholism	93	0
Dependence	57	0
Drug abuse	22	0
Drug dependence	104	0
Drug use disorder	1	0
Gambling disorder	3	0
Neonatal complications of substance abuse	1	0
Nicotine dependence	2	0
Substance abuse	2	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Completed suicide	355	352
Intentional self-injury	274	1
Self-injurious ideation	155	0
Suicidal behaviour	79	0
Suicidal ideation	1426	0
Suicide attempt	435	1
Suicide threat	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	10	0
Confabulation	3	0
Flight of ideas	5	0
Illogical thinking	1	0
Impaired reasoning	2	0
Intrusive thoughts	28	0
Morbid thoughts	25	0
Perseveration	1	0
Tachyphrenia	28	0
Tangentiality	1	0
Thinking abnormal	131	0
Thought blocking	3	0
<b><i>Tic disorders</i></b>		
Chronic tic disorder	1	0
Secondary tic	1	0
Tic	63	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>23517</b>	<b>359</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	4	0
Bladder irritation	6	0
Bladder pain	7	0
Bladder spasm	1	0
Dysuria	81	0
Incontinence	48	0
Micturition disorder	24	0
Micturition frequency decreased	1	0
Micturition urgency	35	0
Pollakiuria	137	0
Strangury	2	0
Stress urinary incontinence	4	0
Urethral pain	1	0
Urethral syndrome	1	0
Urge incontinence	9	0
Urinary hesitation	30	0
Urinary incontinence	90	0
Urinary retention	167	0
Urine flow decreased	8	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	8	0
Bladder neck obstruction	1	0
Bladder obstruction	2	0
Urinary bladder haemorrhage	2	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis haemorrhagic	1	0
Cystitis noninfective	1	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Urinary tract disorder	2	0
Urogenital disorder	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis acute	1	0
Glomerulonephritis membranous	1	0
Nephrotic syndrome	3	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Atonic urinary bladder	5	0
Bladder dysfunction	3	0
Hypertonic bladder	9	0
Loss of bladder sensation	2	0
<i><b>Nephritis NEC</b></i>		
Nephritis	2	0
Tubulointerstitial nephritis	7	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephrogenic diabetes insipidus	1	0
Renal tubular acidosis	1	0
Renal tubular dysfunction	1	0
<i><b>Renal disorders NEC</b></i>		
Kidney fibrosis	1	0
Renal disorder	3	0
Renal haemorrhage	1	0
<i><b>Renal failure and impairment</b></i>		

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
Renal & urinary disorders cont'd		
Acute kidney injury	62	4
Anuria	3	0
Chronic kidney disease	3	0
Oliguria	6	0
Renal failure	27	1
Renal failure neonatal	1	0
Renal impairment	31	0
Renal injury	1	0
<b>Renal lithiasis</b>		
Nephrocalcinosis	1	0
Nephrolithiasis	3	0
<b>Renal obstructive disorders</b>		
Hydronephrosis	4	0
<b>Renal structural abnormalities and trauma</b>		
Pyelocaliectasis	1	0
<b>Renal vascular and ischaemic conditions</b>		
Ischaemic nephropathy	1	0
Renal papillary necrosis	1	0
<b>Urethral disorders NEC</b>		
Urethral discharge	4	0
Urethral disorder	1	0
Urethral haemorrhage	2	0
<b>Urethral infections and inflammations</b>		
Urethritis noninfective	1	0
<b>Urinary abnormalities</b>		
Albuminuria	2	0
Choluria	1	0
Chromaturia	15	0
Crystalluria	2	0
Glycosuria	3	0
Haematuria	33	0
Ketonuria	1	0
Proteinuria	10	0
Urine abnormality	1	0
<b>Urinary tract lithiasis (excl renal)</b>		
Ureterolithiasis	1	0
<b>Urinary tract signs and symptoms NEC</b>		
Haemorrhage urinary tract	2	0
Nocturia	43	0
Polyuria	30	0
Renal colic	2	0
Renal pain	13	0
Urinary tract discomfort	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1029</b>	<b>5</b>



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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	1	0
Breast hyperplasia	1	0
<i><b>Breast disorders NEC</b></i>		
Breast disorder	2	0
Breast enlargement	33	0
Breast mass	8	0
Gynaecomastia	72	0
Nipple disorder	3	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	18	0
Breast discomfort	2	0
Breast engorgement	4	0
Breast haemorrhage	1	0
Breast pain	42	0
Breast swelling	5	0
Breast tenderness	46	0
Nipple exudate bloody	2	0
Nipple pain	4	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation delayed	116	0
Ejaculation disorder	69	0
Ejaculation failure	235	0
Erectile dysfunction	413	0
Erection increased	8	0
Nocturnal emission	4	0
Organic erectile dysfunction	1	0
Painful ejaculation	3	0
Painful erection	3	0
Priapism	45	0
Retrograde ejaculation	8	0
Spontaneous ejaculation	1	0
Spontaneous penile erection	10	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	242	0
Lactation disorder	4	0
Lactation puerperal increased	5	0
Suppressed lactation	8	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	6	0
Premature menopause	4	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	8	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	1	0
Abnormal withdrawal bleeding	1	0
Dysmenorrhoea	11	0
Intermenstrual bleeding	53	0
Menstrual disorder	19	0
Menstruation irregular	63	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Premenstrual pain	1	0
Premenstrual syndrome	8	0
<b><i>Menstruation with decreased bleeding</i></b>		
Amenorrhoea	62	0
Hypomenorrhoea	4	0
Menstruation delayed	15	0
Oligomenorrhoea	10	0
<b><i>Menstruation with increased bleeding</i></b>		
Heavy menstrual bleeding	80	0
Menometrorrhagia	2	0
Polymenorrhagia	1	0
Polymenorrhoea	7	0
<b><i>Ovarian and fallopian tube cysts and neoplasms</i></b>		
Ovarian cyst	1	0
<b><i>Ovarian and fallopian tube disorders NEC</i></b>		
Ovarian failure	1	0
Ovulation pain	1	0
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Pelvic adhesions	1	0
<b><i>Penile and scrotal infections and inflammations</i></b>		
Balanoposthitis	3	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Penile burning sensation	1	0
Penile discharge	1	0
Penile exfoliation	1	0
Penile haemorrhage	2	0
Penile oedema	1	0
Penile pain	4	0
Penile size reduced	2	0
Penile swelling	2	0
Penis disorder	5	0
Peyronie's disease	6	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	3	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatic disorder	1	0
Prostatism	4	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Female reproductive tract disorder	1	0
Genital anaesthesia	4	0
Genital haemorrhage	1	0
Genital hypoaesthesia	22	0
Genital paraesthesia	4	0
Male reproductive tract disorder	2	0
<b><i>Reproductive tract infections and inflammations NEC</i></b>		
Genital tract inflammation	1	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
Genital burning sensation	4	0
Genital discharge	1	0
Genital discolouration	1	0
Genital pain	5	0
Genital rash	1	0
Genital swelling	4	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Pelvic pain	3	0
Perineal pain	5	0
Pruritus genital	5	0
<b>Scrotal disorders NEC</b>		
Scrotal oedema	1	0
Scrotal pain	2	0
<b>Sexual function and fertility disorders NEC</b>		
Dyspareunia	1	0
Female sexual arousal disorder	3	0
Female sexual dysfunction	17	0
Infertility	4	0
Infertility female	1	0
Infertility male	1	0
Male sexual dysfunction	22	0
Sexual dysfunction	215	0
<b>Spermatogenesis and semen disorders</b>		
Asthenospermia	1	0
Azoospermia	1	0
Haematospermia	3	0
Oligospermia	2	0
Semen discolouration	2	0
Teratospermia	1	0
<b>Testicular and epididymal disorders NEC</b>		
Epididymal tenderness	1	0
Testicular disorder	2	0
Testicular pain	20	0
Testicular retraction	1	0
Testicular swelling	2	0
<b>Uterine disorders NEC</b>		
Endometrial hyperplasia	1	0
Endometriosis	2	0
Uterine haemorrhage	3	0
Uterine pain	2	0
<b>Vulvovaginal cysts and neoplasms</b>		
Vaginal polyp	1	0
<b>Vulvovaginal disorders NEC</b>		
Vaginal haemorrhage	112	0
Vulval disorder	1	0
<b>Vulvovaginal signs and symptoms</b>		
Coital bleeding	1	0
Inadequate lubrication	1	0
Vaginal discharge	6	0
Vulval oedema	3	0
Vulvovaginal discomfort	7	0
Vulvovaginal dryness	18	0
Vulvovaginal erythema	2	0
Vulvovaginal pain	5	0
Vulvovaginal pruritus	2	0
Vulvovaginal swelling	2	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>2353</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	2	0
Apnoeic attack	3	0
Bradypnoea	1	0
Central sleep apnoea syndrome	1	0
Dyspnoea	490	0
Dyspnoea at rest	1	0
Dyspnoea exertional	11	0
Grunting	4	0
Hyperventilation	60	0
Hypopnoea	8	0
Hypoventilation	3	0
Irregular breathing	1	0
Obstructive sleep apnoea syndrome	2	1
Orthopnoea	2	0
Pickwickian syndrome	1	0
Respiration abnormal	3	0
Respiratory arrest	18	1
Respiratory depression	12	2
Respiratory distress	10	0
Sleep apnoea syndrome	7	0
Tachypnoea	12	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	64	0
Asthma exercise induced	1	0
Bronchospasm	29	1
Chronic obstructive pulmonary disease	8	2
Obstructive airways disorder	7	0
Status asthmaticus	1	0
Wheezing	63	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Anoxia	1	0
Asphyxia	9	3
Hypoxia	18	0
Respiratory acidosis	5	0
Respiratory alkalosis	2	0
Respiratory gas exchange disorder	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	144	0
Haemoptysis	24	0
Productive cough	6	0
Sputum discoloured	1	0
<i><b>Diaphragmatic disorders</b></i>		
Diaphragmatic disorder	2	0
Diaphragmatic paralysis	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngeal oedema	3	1
Laryngeal stenosis	1	0
Laryngospasm	3	0
Stridor	6	0

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Lower respiratory tract inflammatory and immunologic conditions</i></b>		
Alveolitis	7	0
Eosinophilic pneumonia	8	0
Eosinophilic pneumonia chronic	1	0
Hypersensitivity pneumonitis	20	0
Pneumonitis	7	2
Pulmonary eosinophilia	4	0
Pulmonary sarcoidosis	1	0
Pulmonary vasculitis	3	0
<b><i>Lower respiratory tract signs and symptoms</i></b>		
Hiccups	17	0
Pleuritic pain	4	0
Pulmonary haemorrhage	1	0
<b><i>Nasal congestion and inflammations</i></b>		
Nasal congestion	25	0
Nasal inflammation	1	0
Rhinitis allergic	4	0
Rhinitis perennial	1	0
<b><i>Nasal disorders NEC</i></b>		
Epistaxis	139	0
Nasal disorder	1	0
Nasal dryness	4	0
Nasal odour	1	0
Nasal pruritus	3	0
<b><i>Neonatal hypoxic conditions</i></b>		
Cyanosis neonatal	1	0
Hypoventilation neonatal	2	0
Infantile apnoea	3	0
Neonatal asphyxia	1	0
Neonatal respiratory arrest	1	0
Neonatal respiratory distress	2	0
Neonatal respiratory distress syndrome	12	1
Neonatal respiratory failure	1	0
<b><i>Newborn respiratory disorders NEC</i></b>		
Immature respiratory system	1	0
Meconium aspiration syndrome	1	0
Neonatal tachypnoea	1	0
Respiratory disorder neonatal	1	0
Transient tachypnoea of the newborn	1	0
<b><i>Paranasal sinus disorders (excl infections and neoplasms)</i></b>		
Sinonasal obstruction	2	0
Sinus congestion	4	0
Sinus disorder	3	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Alveolar proteinosis	1	0
Atelectasis	1	0
Emphysema	1	0
Idiopathic pulmonary fibrosis	3	0
Interstitial lung disease	33	0
Lung consolidation	1	0
Lung infiltration	2	0
Organising pneumonia	3	0
Pulmonary fibrosis	29	0

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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Oropharyngeal spasm	1	0
Oropharyngeal swelling	1	0
Pharyngeal erythema	1	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	4	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	50	0
Pharyngeal ulceration	1	0
<b><i>Pleural conditions NEC</i></b>		
Pleural disorder	1	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Haemothorax	1	0
Pleural effusion	10	0
Pneumothorax	5	0
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary arterial hypertension	1	0
Pulmonary hypertension	7	0
<b><i>Pulmonary oedemas</i></b>		
Acute lung injury	1	0
Acute pulmonary oedema	3	2
Acute respiratory distress syndrome	9	1
Pulmonary congestion	7	1
Pulmonary oedema	30	2
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary embolism	35	13
Pulmonary infarction	1	0
Pulmonary microemboli	1	0
Pulmonary thrombosis	1	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Acute respiratory failure	1	0
Respiratory failure	23	4
<b><i>Respiratory signs and symptoms NEC</i></b>		
Diaphragmalgia	1	0
Respiratory symptom	1	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
<b><i>Respiratory tract disorders NEC</i></b>		
Aspiration	9	2
Lung disorder	6	1
Respiratory disorder	8	1
Respiratory tract congestion	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	3	0
Choking	8	3
Choking sensation	16	0
Dry throat	14	0
Dysphonia	26	0
Nasal discomfort	5	0
Nasal obstruction	1	0
Oropharyngeal blistering	1	0
Oropharyngeal pain	88	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Paranasal sinus discomfort	2	0
Rhinalgia	2	0
Rhinorrhoea	33	0
Sinus pain	5	0
Sneezing	22	0
Snoring	7	0
Throat irritation	41	0
Throat tightness	62	0
Upper-airway cough syndrome	1	0
Yawning	177	0
<b><i>Vascular pulmonary disorders NEC</i></b>		
Pulmonary artery dilatation	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>2161</b>	<b>44</b>

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	54	0
Acne cystic	3	0
Dermatitis acneiform	7	0
<b><i>Alopecias</i></b>		
Alopecia	440	0
Alopecia areata	16	0
Alopecia totalis	5	0
Androgenetic alopecia	1	0
Diffuse alopecia	4	0
Madarosis	5	0
<b><i>Angioedemas</i></b>		
Angioedema	200	0
Circumoral oedema	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	1	0
Cold sweat	66	0
Hidradenitis	3	0
Hyperhidrosis	1739	0
Hypohidrosis	2	0
Miliaria	11	0
Night sweats	276	0
Sweat discolouration	2	0
<b><i>Bullous conditions</i></b>		
Blister	69	0
Blood blister	6	0
Dermatitis bullous	34	0
Erythema multiforme	77	0
Pemphigoid	5	0
Pemphigus	2	0
Stevens-Johnson syndrome	32	0
Toxic epidermal necrolysis	10	4
<b><i>Connective tissue disorders</i></b>		
Dermatomyositis	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	48	0
Excessive skin	1	0
Pain of skin	11	0
Papule	6	0
Scab	5	0
Sensitive skin	2	0
Skin burning sensation	41	0
Skin discolouration	25	0
Skin discomfort	1	0
Skin disorder	18	0
Skin fissures	1	0
Skin laxity	1	0
Skin lesion	16	0
Skin necrosis	1	0
Skin odour abnormal	17	0
Skin reaction	9	0
Skin sensitisation	2	0
Skin swelling	3	0



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Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin texture abnormal	1	0
Skin tightness	2	0
Skin warm	5	0
Target skin lesion	1	0
Yellow skin	9	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	27	0
Dermatitis allergic	80	0
Dermatitis atopic	2	0
Dermatitis contact	2	0
Dyshidrotic eczema	2	0
Eczema	72	0
Hand dermatitis	2	0
Neurodermatitis	2	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	3	0
Skin irritation	31	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	11	0
Drug reaction with eosinophilia and systemic symptoms	4	1
Fixed eruption	8	0
Toxic skin eruption	7	0
<b><i>Erythemas</i></b>		
Erythema	80	0
Palmar erythema	5	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	11	0
Dermatitis exfoliative generalised	4	0
Exfoliative rash	3	0
Skin exfoliation	60	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Granuloma annulare	3	0
<b><i>Hyperkeratoses</i></b>		
Keratosis pilaris	1	0
Lichenoid keratosis	8	0
<b><i>Hyperpigmentation disorders</i></b>		
Chloasma	2	0
Ephelides	1	0
Skin hyperpigmentation	12	0
<b><i>Hypertrichoses</i></b>		
Hirsutism	8	0
Hypertrichosis	4	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	4	0
Vitiligo	2	0
<b><i>Lipodystrophies</i></b>		
Lipoatrophy	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail bed disorder	1	0
Nail discolouration	2	0
Nail disorder	16	0
Nail dystrophy	2	0
Nail growth abnormal	1	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Nail pigmentation	1	0
Nail pitting	1	0
Nail ridging	1	0
Onychalgia	1	0
Onychoclasia	16	0
Onycholysis	6	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	25	0
Panniculitis	1	0
Panniculitis lobular	1	0
<b><i>Papulosquamous conditions</i></b>		
Erythema annulare	2	0
Erythema marginatum	1	0
Lichen planus	3	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Chronic actinic dermatitis	1	0
Photodermatosis	1	0
Photosensitivity reaction	198	0
Polymorphic light eruption	5	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	14	0
<b><i>Pilar disorders NEC</i></b>		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	19	0
Hair texture abnormal	10	0
Piloerection	2	0
Trichorrhexis	3	0
<b><i>Pruritus NEC</i></b>		
Pruritus	824	0
Pruritus allergic	3	0
<b><i>Psoriatic conditions</i></b>		
Dermatitis psoriasiform	1	0
Erythrodermic psoriasis	1	0
Guttate psoriasis	5	0
Psoriasis	41	0
Pustular psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Chronic pigmented purpura	1	0
Ecchymosis	68	0
Henoch-Schonlein purpura	1	0
Petechiae	39	0
Purpura	96	0
<b><i>Pustular conditions</i></b>		
Acute generalised exanthematous pustulosis	2	0
Rash follicular	2	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	1	0
Erythema toxicum neonatorum	1	0
Rash	940	0
Rash erythematous	167	0
Rash macular	121	0
Rash maculo-papular	164	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash morbilliform	9	0
Rash neonatal	1	0
Rash papular	76	0
Rash pruritic	202	0
Rash vesicular	17	0
Systemic lupus erythematosus rash	3	0
<b>Rosaceas</b>		
Rosacea	8	0
<b>Scaly conditions</b>		
Dandruff	3	0
Pityriasis	1	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	6	0
<b>Skin and subcutaneous conditions NEC</b>		
Skin mass	4	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Ischaemic skin ulcer	1	0
Skin erosion	2	0
Skin ulcer	7	0
<b>Skin cysts and polyps</b>		
Dermal cyst	1	0
<b>Skin dystrophies</b>		
Skin wrinkling	2	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	2	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	1	0
Skin striae	3	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	7	0
Vasculitic rash	48	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	1	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	2	0
Telangiectasia	1	0
<b>Urticarias</b>		
Cold urticaria	2	0
Idiopathic urticaria	1	0
Mechanical urticaria	7	0
Solar urticaria	1	0
Urticaria	904	0
Urticaria papular	4	0
Urticarial vasculitis	2	0
<b>Skin disorders SOC TOTAL</b>	<b>7914</b>	<b>5</b>

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Alcohol product use</b></i>		
Alcohol use	20	0
Alcoholic	2	0
<i><b>Bereavement issues</b></i>		
Death of relative	1	0
<i><b>Crime victims</b></i>		
Victim of abuse	1	0
<i><b>Criminal activity</b></i>		
Child neglect	1	0
Crime	1	0
Homicide	29	0
Imprisonment	6	0
Legal problem	4	0
Physical assault	30	0
Sexual abuse	3	0
Shoplifting	3	0
Theft	2	0
Verbal abuse	5	0
<i><b>Disability issues</b></i>		
Bedridden	7	0
Disability	6	0
Housebound	1	0
Immobile	12	0
Impaired driving ability	11	0
Impaired work ability	14	0
Loss of personal independence in daily activities	27	0
Mental disability	1	0
Sight disability	2	0
<i><b>Drug and chemical abuse</b></i>		
Drug abuser	1	0
<i><b>Economic circumstances</b></i>		
Economic problem	2	0
<i><b>Educational issues</b></i>		
Failed examinations	2	0
<i><b>Employment issues</b></i>		
Job dissatisfaction	6	0
Loss of employment	10	0
Stress at work	2	0
<i><b>Family and partner issues</b></i>		
Divorced	1	0
Family stress	1	0
Marital problem	1	0
Parent-child problem	2	0
Partner stress	3	0
Sexual relationship change	4	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Water pollution	1	0
<i><b>Sexuality issues</b></i>		
High risk sexual behaviour	2	0
Promiscuity	2	0
<i><b>Social issues NEC</b></i>		
Contraindication to medical treatment	1	0
Gambling	1	0

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Reaction Name	Total	Fatal
<b>Social circumstances</b> <small>Social circumstances cont'd</small>		
Impaired quality of life	2	0
Patient dissatisfaction with treatment	2	0
Patient uncooperative	1	0
Personal relationship issue	1	0
Poor personal hygiene	1	0
Refusal of treatment by patient	2	0
Social problem	8	0
Substance use	5	0
<b>Tobacco use</b>		
Ex-tobacco user	1	0
Tobacco user	2	0
<b>Social circumstances SOC TOTAL</b>	<b>256</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i><b>Anaesthesia and allied procedures</b></i>		
Local anaesthesia	1	0
<i><b>Cardiac therapeutic procedures NEC</b></i>		
Cardiac operation	1	0
<i><b>Cardiac valve therapeutic procedures</b></i>		
Heart valve replacement	1	0
<i><b>Dental and gingival therapeutic procedures</b></i>		
Tooth extraction	1	0
<i><b>Dietary and nutritional therapies</b></i>		
Enteral nutrition	1	0
<i><b>Drug withdrawal therapies</b></i>		
Drug withdrawal maintenance therapy	2	0
<i><b>Fallopian tube therapeutic procedures</b></i>		
Salpingo-oophorectomy unilateral	1	0
<i><b>Gastric therapeutic procedures</b></i>		
Gastrectomy	1	0
Gastric bypass	4	0
Gastric operation	1	0
Gastric stapling	1	0
<i><b>Gastrointestinal therapeutic procedures NEC</b></i>		
Gastrointestinal tube insertion	2	0
Intestinal resection	1	0
<i><b>Haematological therapeutic procedures NEC</b></i>		
Bone marrow transplant	1	0
<i><b>Hormonal therapeutic procedures NEC</b></i>		
Antiandrogen therapy	1	0
<i><b>Induced abortions</b></i>		
Abortion induced	9	0
<i><b>Iris and ciliary body therapeutic procedures</b></i>		
Iridotomy	1	0
<i><b>Joint therapeutic procedures</b></i>		
Hip arthroplasty	1	0
Hip surgery	1	0
<i><b>Large intestine therapeutic procedures</b></i>		
Appendectomy	1	0
<i><b>Laryngeal therapeutic procedures</b></i>		
Laryngectomy	1	0
<i><b>Limb therapeutic procedures</b></i>		
Limb immobilisation	1	0
<i><b>Nervous system therapeutic procedures NEC</b></i>		
Central nervous system stimulation	2	0
<i><b>Obstetric therapeutic procedures</b></i>		
Caesarean section	5	0
Forceps delivery	1	0
<i><b>Prophylactic procedures NEC</b></i>		
Prophylaxis	1	0
<i><b>Psychiatric therapies</b></i>		
Electroconvulsive therapy	1	0
<i><b>Renal therapeutic procedures</b></i>		
Dialysis	1	0
<i><b>Skull and brain therapeutic procedures</b></i>		
Leukotomy	2	0
<i><b>Small intestine therapeutic procedures</b></i>		

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Ileostomy	2	0
<b>Therapeutic procedures NEC</b>		
Drug titration	1	0
Hospitalisation	12	0
Life support	1	0
Patient isolation	2	0
Self-medication	2	0
Surgery	1	0
Therapy cessation	5	0
Therapy change	1	0
Therapy interrupted	1	0
<b>Thyroid therapeutic procedures</b>		
Thyroidectomy	2	0
<b>Tracheal therapeutic procedures</b>		
Endotracheal intubation	3	0
<b>Vascular therapeutic procedures NEC</b>		
Angioplasty	1	0
Vasodilation procedure	2	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>84</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Accelerated hypertension	1	0
Hypertensive crisis	3	0
Malignant hypertension	1	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Aneurysm	1	0
<b><i>Aortic aneurysms and dissections</i></b>		
Aortic aneurysm	1	0
Aortic dissection	1	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic thrombosis	1	0
<b><i>Aortic necrosis and vascular insufficiency</i></b>		
Aortic arteriosclerosis	2	0
<b><i>Arterial infections and inflammations</i></b>		
Giant cell arteritis	2	0
Kawasaki's disease	1	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	16	0
Blood pressure inadequately controlled	1	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	168	2
Hypoperfusion	1	0
Hypovolaemic shock	2	0
Shock	7	0
Shock symptom	4	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	1	0
Haematoma	11	0
Haemorrhage	36	0
Internal haemorrhage	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	5	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Embolism	2	0
Thrombosis	5	0
Venous thrombosis	1	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arteriosclerosis	5	0
Ischaemia	2	0
Peripheral venous disease	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Haemodynamic instability	1	0
Superficial vein prominence	1	0
Vascular pain	1	0
Vasodilatation	1	0
Vein disorder	1	0
Visceral congestion	1	1
<b><i>Peripheral embolism and thrombosis</i></b>		
Axillary vein thrombosis	1	0
Deep vein thrombosis	21	1
Peripheral artery thrombosis	1	0
Superficial vein thrombosis	2	0
Thrombophlebitis	6	0



## Case Series Drug Analysis Print

**Name: FOI-23/022 all UK reports associated with SSRIs**

Report Run Date: 30-Jan-2023

Data Lock Date: 27-Jan-2023 14:00:04

Earliest Reaction Date: 01-Mar-1980

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	21	0
Erythromelalgia	1	0
Flushing	155	0
Hot flush	204	0
Peripheral vascular disorder	1	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Claudication of jaw muscles	1	0
Peripheral coldness	30	0
Peripheral ischaemia	6	0
Poor peripheral circulation	3	0
Raynaud's phenomenon	11	0
Vasoconstriction	2	0
<i><b>Phlebitis NEC</b></i>		
Phlebitis	2	0
Phlebitis superficial	1	0
<i><b>Site specific necrosis and vascular insufficiency NEC</b></i>		
Inferior vena caval occlusion	1	0
Superior vena cava occlusion	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	68	0
<i><b>Varicose veins NEC</b></i>		
Varicose vein	1	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	154	0
Systolic hypertension	1	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	199	0
Orthostatic hypotension	188	0
<i><b>Vasculitides NEC</b></i>		
Vasculitis	52	1
Vasculitis necrotising	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1424</b>	<b>5</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>104958</b>	<b>995</b>
<b>TOTAL REPORTS</b>	<b>40554</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>995</b>