

Case Series Drug Analysis Print

Name: FOI 22/1093

Report Run Date: 02-Dec-2022

Data Lock Date: 30-Nov-2022 18:30:04

Earliest Reaction Date: 20-Jan-2004

MedDRA Version: MedDRA 25.1

FOI 22/1093: All spontaneous UK reports of Pregabalin up to and including 30.11.22

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	4	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	1	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	3	0
Hypereosinophilic syndrome	9	0
<i>Leukopenias NEC</i>		
Leukopenia	2	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	3	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	2	0
Pancytopenia	4	0
<i>Neutropenias</i>		
Agranulocytosis	1	0
Neutropenia	35	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	8	0
<i>Thrombocytoses</i>		
Thrombocytosis	3	0
Blood disorders SOC TOTAL	82	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrial conduction time prolongation	1	0
Atrioventricular block	6	0
Atrioventricular block complete	3	0
Atrioventricular block first degree	4	0
Atrioventricular block second degree	1	0
Long QT syndrome	2	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	5	1
Cardiovascular disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	52	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery stenosis	1	1
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	15	2
Cardiac failure acute	1	0
Cardiac failure chronic	1	1
Cardiac failure congestive	12	0
Cardiogenic shock	3	0
Cardiopulmonary failure	2	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	5	2
Angina pectoris	7	0
Angina unstable	1	0
Myocardial infarction	15	5
Myocardial ischaemia	3	0
<i>Left ventricular failures</i>		
Acute left ventricular failure	1	1
Left ventricular failure	1	1
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	4	0
Left atrial dilatation	2	0
Left ventricular hypertrophy	3	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	7	0
Bradycardia	15	0
Extrasystoles	6	0
Tachyarrhythmia	1	0
Tachycardia	23	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	1	0
Atrial fibrillation	11	0
Atrial tachycardia	1	0

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Cardiac disorders Cardiac disorders cont'd		
Sinus bradycardia	1	0
Sinus node dysfunction	1	0
Sinus tachycardia	4	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	35	5
Cardio-respiratory arrest	3	1
Pulseless electrical activity	2	0
Ventricular arrhythmia	2	0
Ventricular extrasystoles	1	0
Ventricular tachycardia	3	0
Cardiac disorders SOC TOTAL	283	21

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
Limb reduction defect	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Congenital scoliosis	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital musculoskeletal disorder	1	0
<i>Optic nerve and optic disc disorders congenital</i>		
Septo-optic dysplasia	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Pulmonary hypoplasia	1	1
<i>Vascular anomalies congenital NEC</i>		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	9	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear disorder	3	0
Ear pain	5	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	7	0
Deafness bilateral	1	0
Deafness neurosensory	1	0
Deafness permanent	1	0
Deafness transitory	1	0
Deafness unilateral	1	0
Hypacusis	6	0
<i>Hyperacusia</i>		
Hyperacusis	9	0
<i>Inner ear disorders NEC</i>		
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	28	0
Vertigo	31	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	99	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	5	0
<i>Anterior pituitary hyperfunction</i>		
Hyperprolactinaemia	9	0
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Growth hormone deficiency	1	0
Hypopituitarism	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	1	0
Secondary adrenocortical insufficiency	6	0
Secondary hypogonadism	1	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Pituitary neoplasms</i>		
Pituitary cyst	1	0
<i>Posterior pituitary disorders</i>		
Inappropriate antidiuretic hormone secretion	3	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	3	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	36	0

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Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	4	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal neovascularisation	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	2	0
Vitreous floaters	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	4	0
Eyelid ptosis	2	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
Open angle glaucoma	1	0
<i>Lacrimation disorders</i>		
Dry eye	20	0
Lacrimation increased	13	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Eyelid oedema	1	0
Swelling of eyelid	5	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	2	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye disorder	10	0
Eye pain	27	0
Eye swelling	11	0
Eyelid pain	1	0
Eyelids pruritus	1	0
Ocular discomfort	2	0
Periorbital oedema	1	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye irritation	7	0
Eye pruritus	6	0
Ocular hyperaemia	5	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Eye movement disorder	8	0
Gaze palsy	2	0
Oculogyric crisis	4	0
Ophthalmoplegia	1	0
Strabismus	3	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	4	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Optic disc abnormalities NEC</i>		
Papilloedema	2	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Orbital oedema	1	0
<i>Pupil disorders</i>		
Miosis	2	0
Mydriasis	2	0
Pupil fixed	2	0
<i>Refractive and accommodative disorders</i>		
Myopia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	3	0
Retinal vein occlusion	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Epiretinal membrane	2	0
Retinal degeneration	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Macular oedema	2	0
Retinal vasculitis	1	0
<i>Retinopathies NEC</i>		
Retinal exudates	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		
Chromatopsia	2	0
Cyanopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	66	0
Glare	2	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	4	0
Vision blurred	166	0
Visual brightness	4	0
<i>Visual field disorders</i>		
Visual field defect	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	18	0
Blindness transient	5	0
Night blindness	1	0
Sudden visual loss	1	0
Visual acuity reduced	9	0
Visual impairment	76	0
Eye disorders SOC TOTAL	545	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	6	0
Pancreatitis acute	2	1
Pancreatitis necrotising	1	1
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Colitis (excl infective)</i>		
Colitis ischaemic	2	0
Eosinophilic colitis	12	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Tooth disorder	4	0
Tooth erosion	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	2	0
Toothache	4	0
<i>Dental surface disorders</i>		
Tooth discolouration	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	105	0
Diarrhoea haemorrhagic	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	15	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	55	0
Flatulence	12	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	39	0
Abdominal pain lower	1	0
Abdominal pain upper	29	0
Abdominal tenderness	2	0
Gastrointestinal pain	2	0
Infantile colic	1	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	75	0
Gastric dilatation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	10	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastric disorder	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastrointestinal disorder	11	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	1	0
Change of bowel habit	2	0
Gastrointestinal motility disorder	2	0
Gastrointestinal fistulae		
Anal fistula	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	14	0
Anal incontinence	9	0
Breath odour	2	0
Dysphagia	49	0
Gastrointestinal spastic and hypermotility disorders		
Frequent bowel movements	3	0
Irritable bowel syndrome	2	0
Gastrointestinal stenosis and obstruction NEC		
Ileus	1	0
Intestinal obstruction	7	0
Subileus	1	0
Gingival disorders, signs and symptoms NEC		
Gingival discomfort	1	0
Gingival disorder	2	0
Gingival pain	1	0
Gingival recession	2	0
Gingival swelling	1	0
Gingival haemorrhages		
Gingival bleeding	2	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoids	1	0
Intestinal haemorrhages		
Rectal haemorrhage	5	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	1	0
Large intestine perforation	1	0
Nausea and vomiting symptoms		
Nausea	174	0
Regurgitation	1	0
Retching	2	0
Vomiting	107	0
Vomiting projectile	4	0
Non-mechanical ileus		
Ileus paralytic	4	0
Non-site specific gastrointestinal haemorrhages		
Haematemesis	5	0
Haematochezia	2	0
Intra-abdominal haematoma	1	0
Upper gastrointestinal haemorrhage	2	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	1	0
Oesophageal ulcers and perforation		
Oesophageal ulcer	1	0
Oral dryness and saliva altered		
Dry mouth	73	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip dry	1	0
Saliva altered	1	0
Salivary hypersecretion	6	0
Oral soft tissue disorders NEC		
Enlarged uvula	1	0
Lip blister	3	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	3	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	7	0
Lip discolouration	2	0
Lip erythema	2	0
Lip exfoliation	1	0
Lip pain	3	0
Oral discharge	1	0
Oral discomfort	7	0
Oral mucosal blistering	2	0
Oral pain	5	0
Paraesthesia oral	4	0
Oral soft tissue swelling and oedema		
Lip swelling	27	0
Mouth swelling	7	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Stomatitis and ulceration		
Mouth ulceration	19	0
Stomatitis	1	0
Tongue disorders		
Glossitis	1	0
Tongue disorder	3	0
Tongue signs and symptoms		
Glossodynia	4	0
Swollen tongue	35	0
Tongue blistering	1	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue discomfort	2	0
Tongue erythema	2	0
Tongue movement disturbance	2	0
Tongue spasm	1	0
Tooth missing		
Tooth loss	4	0
Umbilical hernias		
Umbilical hernia	1	0
Gastrointestinal disorders SOC TOTAL	1061	2

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
Application site rash	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	39	0
Fatigue	128	0
Malaise	117	0
Sluggishness	1	0
<i>Body temperature altered</i>		
Hypothermia	3	0
Temperature regulation disorder	2	0
<i>Death and sudden death</i>		
Accidental death	3	3
Brain death	2	1
Cardiac death	1	1
Death	57	52
Drowning	1	0
Sudden cardiac death	1	1
Sudden death	8	8
<i>Febrile disorders</i>		
Hyperpyrexia	2	0
Pyrexia	15	0
<i>Feelings and sensations NEC</i>		
Chills	29	0
Feeling abnormal	131	0
Feeling cold	15	0
Feeling drunk	53	0
Feeling hot	14	0
Feeling jittery	1	0
Feeling of body temperature change	6	0
Hangover	3	0
Hunger	7	0
Sensation of foreign body	1	0
Temperature intolerance	3	0
Thirst	11	0
<i>Gait disturbances</i>		
Gait disturbance	62	0
Gait inability	10	0
Loss of control of legs	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	49	0
Crepitations	2	0
Crying	21	0
Discharge	1	0
Disease progression	2	0
Disease recurrence	3	0
Energy increased	2	0
Exercise tolerance decreased	1	0
Foaming at mouth	5	0
General physical health deterioration	8	0
Illness	26	0
Influenza like illness	25	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Multiple organ dysfunction syndrome	5	1
Performance status decreased	1	0
Peripheral swelling	67	0
Pre-existing condition improved	1	0
Screaming	5	0
Swelling	19	0
Swelling face	41	0
Terminal state	4	0
Unevaluable event	2	0
Healing abnormal NEC		
Impaired healing	2	0
Inflammations		
Inflammation	4	0
Injection site reactions		
Injection site discomfort	1	0
Injection site pain	1	0
Interactions		
Alcohol interaction	20	0
Drug interaction	100	4
Inhibitory drug interaction	2	0
Potentiating drug interaction	4	0
Mucosal findings abnormal		
Mucosal disorder	2	0
Mucosal haemorrhage	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	7	0
Generalised oedema	3	0
Localised oedema	5	0
Oedema	36	0
Oedema peripheral	83	0
Pain and discomfort NEC		
Breakthrough pain	1	0
Chest discomfort	33	0
Chest pain	38	0
Discomfort	8	0
Facial pain	4	0
Inflammatory pain	1	0
Non-cardiac chest pain	1	0
Pain	119	0
Paradoxical pain	1	0
Suprapubic pain	1	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	14	0
Drug effective for unapproved indication	6	0
Drug ineffective	111	0
Drug ineffective for unapproved indication	5	0
Drug intolerance	10	0
Drug resistance	4	0
Drug tolerance	5	0
Drug tolerance increased	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Therapeutic product effect incomplete	10	0
Therapeutic response delayed	1	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	9	0
Therapy non-responder	4	0
Treatment failure	2	0
Treatment noncompliance	2	0
Ulcers NEC		
Ulcer	2	0
Ulcer haemorrhage	2	0
Vaccination site reactions		
Vaccination site swelling	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	43	0
Drug withdrawal syndrome neonatal	1	0
Rebound effect	8	0
Withdrawal syndrome	198	0
General disorders SOC TOTAL	1941	71

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	5	0
Jaundice cholestatic	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	4	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	2	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Hepatic failure	1	0
<i>Hepatic vascular disorders</i>		
Hepatic haemorrhage	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Fatty liver alcoholic	1	0
Hepatic steatosis	2	0
Hepatitis	5	0
Hepatitis fulminant	1	0
Hepatocellular injury	1	0
Liver injury	5	0
Hepatic disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	21	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	13	0
Food allergy	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	7	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immunosuppression	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
<i>Vasculitides</i>		
Eosinophilic granulomatosis with polyangiitis	2	0
Immune system disorders SOC TOTAL	54	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abscess intestinal	4	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
Bacterial vaginosis	1	0
Cellulitis	1	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Candida infections</i>		
Candida infection	1	0
Oral candidiasis	1	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Meningitis	1	0
<i>Dental and oral soft tissue infections</i>		
Gingival abscess	1	0
Tooth abscess	1	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Eye and eyelid infections</i>		
Eye infection	3	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Hepatitis virus infections</i>		
Hepatitis E	1	0
<i>Herpes viral infections</i>		
Herpes simplex	1	0
Herpes zoster	2	0
Oral herpes	1	0
<i>Infections NEC</i>		
Infection	3	0
Localised infection	1	0
Respiratory tract infection	1	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	11	0
Pneumonia	24	5
Pneumonia aspiration	13	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	1	0
Sepsis	5	0
Septic shock	1	0

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Report Run Date: 02-Dec-2022
Earliest Reaction Date: 20-Jan-2004

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Blister infected	1	0
Impetigo	1	0
Subcutaneous abscess	1	0
<i>Staphylococcal infections</i>		
Furuncle	2	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	4	0
Pharyngitis	1	0
Rhinitis	2	0
Tonsillitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	7	0
<i>Viral infections NEC</i>		
Viral infection	1	0
Infections SOC TOTAL	114	5

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Tooth injury	2	0
Traumatic liver injury	1	0
<i>Anaesthetic and allied procedural complications</i>		
Sedation complication	4	0
<i>Cerebral injuries NEC</i>		
Concussion	2	0
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	2	0
Exposure via breast milk	2	0
Foetal exposure during pregnancy	7	0
Maternal exposure during pregnancy	6	0
<i>Eye injuries NEC</i>		
Eye contusion	3	0
Eyelid contusion	1	0
<i>Fractures and dislocations NEC</i>		
Fracture	2	0
Joint dislocation	1	0
Multiple fractures	1	0
<i>Intentional product misuses</i>		
Intentional product misuse	66	4
<i>Intentional product use issues</i>		
Intentional product use issue	6	0
<i>Limb fractures and dislocations</i>		
Femoral neck fracture	1	0
Hip fracture	1	0
Lower limb fracture	1	0
Upper limb fracture	1	0
Wrist fracture	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	1	0
Drug titration error	2	0
Intercepted medication error	1	0
Medication error	28	0
Prescription drug used without a prescription	18	0
Product use in unapproved indication	31	0
Product use issue	2	0
Wrong dose	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
Muscle rupture	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	7	0
<i>Neurological and psychiatric procedural complications</i>		
Confusion postoperative	1	0
Mental status changes postoperative	2	0
<i>Non-site specific injuries NEC</i>		
Accident	1	0
Electric shock	1	0
Fall	83	1
Injury	7	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Road traffic accident	6	0
Stab wound	1	1
Wound	1	0
Wound haemorrhage	1	0
Off label uses		
Off label use	38	0
Overdoses NEC		
Intentional overdose	46	3
Overdose	115	21
Prescribed overdose	5	0
Poisoning and toxicity		
Alcohol poisoning	2	0
Metal poisoning	1	0
Poisoning	1	0
Toxicity to various agents	159	92
Product administration errors and issues		
Accidental overdose	25	5
Contraindicated product administered	2	0
Counterfeit product administered	3	0
Expired product administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	10	0
Incorrect route of product administration	1	0
Poor quality product administered	1	0
Product administration error	5	0
Product dose omission in error	2	0
Product dose omission issue	5	0
Wrong patient received product	1	0
Wrong product administered	5	0
Product dispensing errors and issues		
Drug dispensed to wrong patient	2	0
Product dispensing error	26	0
Product monitoring errors and issues		
Documented hypersensitivity to administered product	1	0
Labelled drug-drug interaction medication error	2	0
Product prescribing errors and issues		
Product prescribing error	7	0
Product prescribing issue	5	0
Radiation injuries		
Sunburn	1	0
Site specific injuries NEC		
Face injury	1	0
Head injury	6	0
Limb injury	3	0
Skin injuries NEC		
Contusion	13	0
Scar	2	0
Skin abrasion	1	0
Skin laceration	2	0
Skull fractures, facial bone fractures and dislocations		
Skull fracture	1	0
Spinal fractures and dislocations		
Cervical vertebral fracture	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Spinal compression fracture	1	0
Spinal fracture	2	0
Stoma complications		
Stoma site haemorrhage	1	0
Underdoses NEC		
Prescribed underdose	1	0
Underdose	1	0
Injuries SOC TOTAL	820	127

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Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol abnormal	1	0
Blood counts NEC		
Full blood count decreased	1	0
Blood gas and acid base analyses		
Oxygen consumption decreased	1	0
Oxygen saturation decreased	2	0
Bone marrow and immune tissue imaging procedures		
Scan bone marrow abnormal	1	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	1	0
Blood glucose increased	10	0
Glycosylated haemoglobin decreased	1	0
Glycosylated haemoglobin increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur functional	1	0
Cardiac function diagnostic procedures		
Cardiac output decreased	1	0
Ejection fraction decreased	2	0
Cholesterol analyses		
Blood cholesterol increased	2	0
Coagulation and bleeding analyses		
Coagulation time abnormal	1	0
Coagulation time prolonged	2	0
International normalised ratio decreased	5	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	2	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	14	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	2	0
Electrocardiogram change	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	1	0
Haematological analyses NEC		
Red blood cell sedimentation rate increased	1	0
Heart rate and pulse investigations		
Heart rate abnormal	2	0
Heart rate decreased	4	0
Heart rate increased	13	0
Heart rate irregular	4	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	8	0
Aspartate aminotransferase increased	5	0
Blood bilirubin abnormal	2	0
Blood bilirubin increased	3	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme abnormal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Hepatic enzyme increased	4	0
Liver function test abnormal	26	0
Liver function test increased	5	0
Transaminases increased	1	0
Imaging procedures NEC		
Magnetic resonance imaging abnormal	1	0
Immunoglobulin analyses		
Blood immunoglobulin M abnormal	1	0
Investigations NEC		
Quality of life decreased	2	0
Lipoprotein and lipid tests NEC		
Lipids abnormal	1	0
Metabolism tests NEC		
Blood homocysteine increased	1	0
Brain natriuretic peptide increased	4	0
Mineral and electrolyte analyses		
Blood potassium increased	3	0
Neurologic diagnostic procedures		
Coma scale abnormal	4	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	3	0
Physical examination procedures and organ system status		
Apgar score low	2	0
Body mass index decreased	1	0
Body temperature abnormal	2	0
Body temperature increased	5	0
Breath sounds abnormal	2	1
General physical condition abnormal	1	0
Grip strength decreased	2	0
Head circumference abnormal	1	0
Respiratory rate decreased	6	0
Weight decreased	18	0
Weight increased	138	0
Pituitary analyses anterior		
Blood luteinising hormone decreased	1	0
Blood prolactin increased	3	0
Platelet analyses		
Platelet count decreased	5	0
Protein analyses NEC		
C-reactive protein increased	3	0
Red blood cell analyses		
Haemoglobin decreased	6	0
Red blood cell count increased	1	0
Renal function analyses		
Blood creatinine increased	5	0
Creatinine renal clearance increased	1	0
Glomerular filtration rate decreased	3	0
Reproductive hormone analyses		
Blood testosterone abnormal	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase	1	0
Blood creatine phosphokinase increased	16	0
Therapeutic drug monitoring analyses		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Anticonvulsant drug level increased	1	0
Antipsychotic drug level increased	1	1
Drug level above therapeutic	3	0
Drug level changed	2	0
Drug level increased	15	1
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	2	0
Toxicology laboratory analyses		
Blood alcohol increased	1	0
Urinalysis NEC		
Blood urine present	1	0
Urea urine increased	1	0
Urine analysis abnormal	1	0
Urinary tract function analyses NEC		
Urine output decreased	4	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	7	0
Blood pressure increased	20	0
Blood pressure systolic decreased	1	0
White blood cell analyses		
Eosinophil count increased	2	0
Neutrophil count decreased	5	0
Neutrophil count increased	1	0
White blood cell count	1	0
White blood cell count abnormal	1	0
White blood cell count decreased	4	0
White blood cell count increased	1	0
Investigations SOC TOTAL	460	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	34	0
Eating disorder symptom	1	0
Food craving	4	0
Food refusal	1	0
Hyperphagia	4	0
Hypophagia	2	0
Increased appetite	28	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	6	0
Diabetes mellitus inadequate control	5	0
Increased insulin requirement	1	0
Type 2 diabetes mellitus	2	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	1
<i>Elevated triglycerides</i>		
Hypertriglyceridaemia	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Feeding intolerance	1	0
Gluten sensitivity	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	8	0
Abnormal weight gain	36	0
Feeding disorder	2	0
Obesity	1	0
Weight fluctuation	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	5	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	14	0
<i>Iron excess</i>		
Haemosiderosis	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Hyperlactacidaemia	3	0
Ketoacidosis	1	0
Metabolic acidosis	4	0
<i>Metabolic alkaloses</i>		
Metabolic alkalosis	1	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
Hypokalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	11	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Total fluid volume decreased</i>		
Dehydration	8	0
Hypovolaemia	1	0
<i>Total fluid volume increased</i>		
Fluid retention	24	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	1	0
Metabolic disorders SOC TOTAL	226	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	6	0
Arthropathy	2	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Jaw disorder	5	0
<i>Bone related signs and symptoms</i>		
Bone pain	3	0
Pain in jaw	4	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	2	0
Sjogren's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	1	0
<i>Joint related disorders NEC</i>		
Greater trochanteric pain syndrome	1	0
Joint lock	1	0
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	56	0
Joint effusion	2	0
Joint stiffness	12	0
Joint swelling	44	0
<i>Metabolic bone disorders</i>		
Osteomalacia	2	0
Osteopenia	1	0
<i>Muscle pains</i>		
Fibromyalgia	3	0
Myalgia	59	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	4	0
Muscle discomfort	1	0
Muscle disorder	6	0
Muscle fatigue	1	0
Muscle spasms	76	0
Muscle swelling	2	0
Muscle tightness	5	0
Muscle twitching	53	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
Trismus	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	34	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	4	0
Mobility decreased	12	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	19	0
Pelvic misalignment	1	0
Posture abnormal	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	36	0
Flank pain	1	0
Limb discomfort	2	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	3	0
Musculoskeletal pain	3	0
Neck pain	12	0
Pain in extremity	52	0
Sacral pain	1	0
<i>Myopathies</i>		
Compartment syndrome	1	0
Myopathy	1	0
Rhabdomyolysis	8	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	3	0
<i>Soft tissue disorders NEC</i>		
Groin pain	2	0
<i>Spine and neck deformities</i>		
Scoliosis	1	0
Spinal deformity	1	0
<i>Tendon disorders</i>		
Tendon disorder	1	0
Tendon pain	3	0
Tendonitis	2	0
<i>Trunk deformities</i>		
Pelvic deformity	1	0
Muscle & tissue disorders SOC TOTAL	576	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Bladder neoplasms malignant</i>		
Bladder cancer	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	6	0
<i>Leukaemias chronic NEC</i>		
Chronic leukaemia	1	0
<i>Lip and oral cavity neoplasms malignant</i>		
Tongue neoplasm malignant stage unspecified	1	0
<i>Lymphomas unspecified NEC</i>		
Central nervous system lymphoma	1	1
<i>Metastases to specified sites</i>		
Metastases to bone	1	0
Metastases to spine	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Malignant neoplasm progression	2	1
Metastatic neoplasm	1	0
Neoplasm malignant	6	1
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	0
<i>Ocular melanomas</i>		
Ocular melanoma	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Renal neoplasms malignant</i>		
Renal cancer	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	2	0
Throat cancer	1	0
Neoplasms SOC TOTAL	33	3

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Hyperreflexia	1	0
Hyporeflexia	1	0
Reflexes abnormal	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	6	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Intracranial aneurysm	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebellar haemorrhage	1	0
Cerebral haemorrhage	1	1
Cerebral infarction	2	0
Cerebrovascular accident	11	0
Lacunar infarction	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Arachnoiditis	2	0
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
Cerebral microangiopathy	1	0
<i>Choreiform movements</i>		
Athetosis	2	0
Chorea	1	0
Choreoathetosis	3	0
<i>Chronic polyneuropathies</i>		
Polyneuropathy in malignant disease	1	0
<i>Coma states</i>		
Coma	15	0
Hypoglycaemic coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	43	0
Balance disorder	109	0
Cerebellar ataxia	2	0
Cerebellar syndrome	1	0
Coordination abnormal	32	0
Dysdiadochokinesis	2	0
Dysstasia	13	0
Nystagmus	7	0
<i>Cortical dysfunction NEC</i>		
Aphasia	53	0
Dysgraphia	12	0
Dyspraxia	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	4	0
Senile dementia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
Osmotic demyelination syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	7	0
Consciousness fluctuating	2	0
Depressed level of consciousness	36	2
Lethargy	54	0
Loss of consciousness	92	0
Postictal state	1	0
Sedation	36	0
Somnolence	257	0
Stupor	3	0
Syncope	49	0
<i>Disturbances in sleep phase rhythm</i>		
Non-24-hour sleep-wake disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	4	0
Ballismus	2	0
Clumsiness	26	0
Dyskinesia	58	0
Extrapyramidal disorder	6	0
Fine motor skill dysfunction	2	0
Hypokinesia	4	0
Motor dysfunction	6	0
Movement disorder	10	0
Psychomotor hyperactivity	7	0
Tardive dyskinesia	2	0
<i>Dystonias</i>		
Dystonia	15	0
Dystonic tremor	1	0
Opisthotonus	1	0
Pleurothotonus	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
Hypoxic-ischaemic encephalopathy	1	0
<i>Encephalopathies toxic and metabolic</i>		
Hepatic encephalopathy	1	0
<i>Eye movement disorders</i>		
IVth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	3	0
Facial spasm	3	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	8	0
<i>Headaches NEC</i>		
Drug withdrawal headache	3	0
Headache	167	0
Medication overuse headache	1	0
Sinus headache	1	0
Tension headache	5	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
Normal pressure hydrocephalus	1	0
<i>Increased intracranial pressure disorders</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Brain oedema	2	1
Intracranial pressure increased	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	3	0
Memory loss (excl dementia)		
Amnesia	84	0
Memory impairment	108	0
Retrograde amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Borderline mental impairment	1	0
Cognitive disorder	41	0
Disturbance in attention	80	0
Judgement impaired	1	0
Mental impairment	30	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	18	0
Migraine with aura	3	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Mononeuropathy multiplex	1	0
Nerve compression	2	0
Peroneal nerve palsy	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	5	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	1	0
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	5	0
Neuroleptic malignant syndrome	2	0
Serotonin syndrome	5	0
Narcolepsy and hypersomnia		
Hypersomnia	20	0
Nervous system disorders NEC		
Cerebral disorder	2	0
Nerve degeneration	1	0
Nervous system disorder	5	1
Neurotoxicity	1	0
Neurologic visual problems NEC		
Tunnel vision	5	0
Neurological signs and symptoms NEC		
Clonus	1	0
Dizziness	340	0
Dizziness postural	5	0
Drooling	3	0
Grimacing	1	0
Head discomfort	8	0
Hyporesponsive to stimuli	1	0
Meningism	1	0
Myoclonus	38	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neurological symptom	2	0
Presyncope	2	0
Slow response to stimuli	3	0
Tongue biting	1	0
Unresponsive to stimuli	19	0
Neuromuscular disorders NEC		
Dropped head syndrome	4	0
Muscle contractions involuntary	2	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	1	0
Parosmia	7	0
Paraesthesias and dysaesthesias		
Burning sensation	25	0
Dysaesthesia	1	0
Formication	8	0
Hyperaesthesia	5	0
Hypoaesthesia	52	0
Paraesthesia	79	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	6	0
Hemiplegia	1	0
Paralysis	9	0
Paraplegia	1	0
Quadriparesis	1	0
Parkinson's disease and parkinsonism		
Parkinson's disease	3	0
Parkinsonism	5	0
Partial complex seizures		
Temporal lobe epilepsy	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	7	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	1	0
Seizures and seizure disorders NEC		
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	6	0
Epilepsy	21	0
Myoclonic epilepsy	2	0
Partial seizures	3	0
Psychogenic seizure	1	0
Seizure	78	0
Seizure like phenomena	1	0
Tonic clonic movements	1	0
Sensory abnormalities NEC		
Ageusia	3	0
Aura	2	0
Complex regional pain syndrome	2	0
Dysgeusia	5	0
Electric shock sensation	6	0
Neuralgia	17	0
Phantom limb syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Restless legs syndrome	15	0
Sensory disturbance	16	0
Sensory loss	9	0
Taste disorder	8	0
<i>Sleep disturbances NEC</i>		
Periodic limb movement disorder	1	0
Sudden onset of sleep	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	66	0
Incoherent	6	0
Language disorder	2	0
Slow speech	1	0
Speech disorder	75	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
Spinal cord compression	2	0
Spinal cord disorder	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	8	2
Hippocampal sclerosis	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	5	1
<i>Tremor (excl congenital)</i>		
Intention tremor	2	0
Tremor	152	0
<i>Trigeminal disorders</i>		
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	2	0
Nervous system disorders SOC TOTAL	2830	8

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	8	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Oligohydramnios	1	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	2	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	2	0
Premature baby	5	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	2	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
Premature rupture of membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Complication of pregnancy	1	0
Ectopic pregnancy	1	0
Morning sickness	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal vascular malperfusion	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	0
Pregnancy conditions SOC TOTAL	29	0

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Reaction Name	Total	Fatal
<i>Counterfeit, falsified and substandard products</i>		
Suspected counterfeit product	1	0
<i>Product label issues</i>		
Product label issue	1	0
Product label on wrong product	1	0
<i>Product packaging issues</i>		
Product packaging issue	1	0
<i>Product physical issues</i>		
Product physical issue	1	0
<i>Product quality issues NEC</i>		
Product quality issue	7	0
Product substitution issue	32	0
<i>Product supply and availability issues</i>		
Product supply issue	1	0
null SOC TOTAL	45	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	24	0
Behaviour disorder	12	0
<i>Affect alterations NEC</i>		
Affect lability	8	0
Flat affect	1	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	3	0
Generalised anxiety disorder	2	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	81	0
Anxiety	161	0
Nervousness	16	0
Stress	7	0
Tension	5	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	70	0
Antisocial behaviour	1	0
Asocial behaviour	1	0
Disinhibition	5	0
Disturbance in social behaviour	1	0
Homicidal ideation	2	0
Hostility	3	0
Impatience	2	0
Indifference	1	0
Negativism	1	0
Paranoia	23	0
Personality change	15	0
Social avoidant behaviour	8	0
Violence-related symptom	2	0
<i>Bipolar disorders</i>		
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	2	0
<i>Communications disorders</i>		
Communication disorder	1	0
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	204	0
Disorientation	57	0
<i>Decreased physical activity levels</i>		
Catatonia	2	0
<i>Deliria</i>		
Delirium	12	0
<i>Delusional disorders</i>		
Delusional disorder, unspecified type	1	0
<i>Delusional symptoms</i>		
Delusion	10	0
<i>Dementia NEC</i>		
Pseudodementia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Depressive disorders</i>		
Agitated depression	3	0
Depression	124	0
Depression suicidal	7	0
Major depression	10	0
Persistent depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	7	0
Dissociation	14	0
Dissociative disorder	1	0
Dissociative identity disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	146	0
Middle insomnia	3	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	6	0
<i>Eating disorders NEC</i>		
Eating disorder	4	0
<i>Emotional and mood disturbances NEC</i>		
Anger	50	0
Dysphoria	1	0
Emotional disorder	8	0
Emotional distress	11	0
Emotional poverty	1	0
Euphoric mood	29	0
Frustration tolerance decreased	3	0
Irritability	52	0
Mood altered	15	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	3	0
Fear	12	0
Nocturnal fear	1	0
Phobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	28	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	101	0
Hallucination, auditory	9	0
Hallucination, synaesthetic	1	0
Hallucination, visual	40	0
Hallucinations, mixed	11	0
<i>Impulse control disorders</i>		
Impulsive behaviour	2	0
<i>Increased physical activity levels</i>		
Restlessness	15	0
<i>Learning disorders</i>		
Reading disorder	2	0
<i>Mental disorders NEC</i>		
Mental disorder	11	0
Mental status changes	1	0
<i>Mood alterations with depressive symptoms</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Anhedonia	1	0
Decreased interest	1	0
Depressed mood	38	0
Depressive symptom	2	0
Feeling of despair	7	0
Negative thoughts	1	0
Tearfulness	9	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	8	0
Mood disorders NEC		
Affective disorder	5	0
Apathy	12	0
Listless	3	0
Obsessive-compulsive disorders and symptoms		
Body dysmorphic disorder	1	0
Compulsive shopping	1	0
Dermatillomania	1	0
Obsessive thoughts	1	0
Obsessive-compulsive disorder	4	0
Orgasmic disorders and disturbances		
Anorgasmia	10	0
Female orgasmic disorder	1	0
Orgasm abnormal	2	0
Panic attacks and disorders		
Panic attack	33	0
Panic disorder	5	0
Panic reaction	10	0
Parasomnias		
Abnormal dreams	20	0
Nightmare	37	0
Sleep terror	1	0
Somnambulism	6	0
Perception disturbances NEC		
Deja vu	1	0
Delusional perception	1	0
Derealisation	2	0
Time perception altered	1	0
Personality disorders NEC		
Personality disorder	2	0
Personality disorders with anxious behaviour (Cluster C)		
Dependent personality disorder	1	0
Obsessive-compulsive personality disorder	1	0
Personality disorders with dramatic behaviour (Cluster B)		
Borderline personality disorder	1	0
Psychopathic personality	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	1	0
Psychiatric elimination disorders		
Enuresis	5	0
Psychiatric symptoms NEC		
Psychiatric symptom	5	0
Trance	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
<i>Psychotic disorder NEC</i>		
Acute psychosis	3	0
Psychotic behaviour	1	0
Psychotic disorder	27	1
<i>Schizophrenia NEC</i>		
Schizophrenia	4	0
<i>Sexual and gender identity disorders NEC</i>		
Psychosexual disorder	1	0
<i>Sexual desire disorders</i>		
Compulsive sexual behaviour	1	0
Hypersexuality	1	0
Libido decreased	11	0
Libido increased	3	0
Loss of libido	9	0
<i>Sleep disorders NEC</i>		
Sleep disorder	25	0
<i>Somatic symptom disorders</i>		
Conversion disorder	4	0
Illness anxiety disorder	1	0
Somatic symptom disorder	2	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	2	0
Logorrhoea	2	0
Poverty of speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	7	0
Pressure of speech	2	0
<i>Stereotypies and automatisms</i>		
Bruxism	4	0
Head banging	3	0
Posturing	1	0
<i>Stress disorders</i>		
Post-traumatic stress disorder	4	0
<i>Substance related and addictive disorders</i>		
Alcohol abuse	1	0
Dependence	19	1
Drug abuse	155	8
Drug dependence	128	0
Substance abuse	3	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	16	14
Intentional self-injury	18	0
Self-injurious ideation	9	0
Suicidal behaviour	10	0
Suicidal ideation	155	0
Suicide attempt	33	1
Suspected suicide attempt	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	5	0
Intrusive thoughts	1	0
Morbid thoughts	3	0
Tachyphrenia	2	0
Thinking abnormal	22	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	2	0
Psychiatric disorders SOC TOTAL	2441	25

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	20	0
Incontinence	12	0
Micturition disorder	2	0
Micturition urgency	4	0
Pollakiuria	12	0
Post micturition dribble	1	0
Stress urinary incontinence	2	0
Urge incontinence	1	0
Urinary hesitation	4	0
Urinary incontinence	32	0
Urinary retention	30	0
Urine flow decreased	3	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
Bladder dysfunction	1	0
Bladder sphincter atony	1	0
Hypertonic bladder	3	0
Loss of bladder sensation	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	4	0
Single functional kidney	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	21	1
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	5	0
Renal impairment	12	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal tubular necrosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	5	0
Haematuria	4	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Nocturia	1	0
Polyuria	3	0
Renal pain	4	0
Renal & urinary disorders SOC TOTAL	201	1

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Anisomastia	1	0
Breast disorder male	1	0
Breast enlargement	5	0
Breast mass	2	0
Breast ulceration	1	0
Gynaecomastia	13	0
<i>Breast signs and symptoms</i>		
Breast discharge	1	0
Breast discomfort	1	0
Breast pain	10	0
Breast swelling	3	0
Breast tenderness	2	0
Nipple pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation disorder	2	0
Ejaculation failure	3	0
Erectile dysfunction	22	0
Erection increased	1	0
Priapism	2	0
Retrograde ejaculation	2	0
<i>Lactation disorders</i>		
Galactorrhoea	3	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	3	0
Intermenstrual bleeding	1	0
Menstrual disorder	4	0
Premenstrual syndrome	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	8	0
Menstruation delayed	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovarian mass	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile oedema	1	0
Penis disorder	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatism	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	2	0
<i>Sexual function and fertility disorders NEC</i>		
Sexual dysfunction	8	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	6	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Reproductive & breast disorders SOC TOTAL	119	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	3	1
Dyspnoea	123	0
Dyspnoea at rest	1	0
Dyspnoea exertional	1	0
Dyspnoea paroxysmal nocturnal	1	0
Hypopnoea	3	0
Hypoventilation	9	0
Orthopnoea	1	0
Respiration abnormal	1	0
Respiratory arrest	9	0
Respiratory depression	13	3
Respiratory distress	2	0
Sleep apnoea syndrome	3	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	9	0
Bronchospasm	1	0
Chronic obstructive pulmonary disease	2	0
Wheezing	10	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypercapnia	1	1
Hypoxia	7	2
<i>Coughing and associated symptoms</i>		
Cough	23	0
Haemoptysis	1	0
Productive cough	2	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Eosinophilic pneumonia	1	0
Hypersensitivity pneumonitis	1	0
Pneumonitis	9	0
Pulmonary eosinophilia	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Pulmonary haemorrhage	1	1
Pulmonary pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	7	0
<i>Nasal disorders NEC</i>		
Epistaxis	20	0
Nasal dryness	2	0
Nasal pruritus	1	0
Nasal ulcer	1	0
<i>Neonatal hypoxic conditions</i>		
Neonatal respiratory distress syndrome	1	0
<i>Parenchymal lung disorders NEC</i>		
Emphysema	1	0
Idiopathic pulmonary fibrosis	1	1
Interstitial lung disease	1	0
Organising pneumonia	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pulmonary fibrosis	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal swelling	10	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	3	0
Pulmonary hypertensions		
Pulmonary hypertension	3	0
Pulmonary oedemas		
Acute lung injury	1	0
Acute pulmonary oedema	2	1
Acute respiratory distress syndrome	14	1
Pulmonary oedema	6	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	8	0
Respiratory failures (excl neonatal)		
Acute respiratory failure	2	2
Respiratory failure	29	2
Respiratory signs and symptoms NEC		
Suffocation feeling	1	0
Respiratory tract disorders NEC		
Aspiration	2	0
Lung disorder	1	0
Respiratory disorder	4	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	1	0
Upper respiratory tract signs and symptoms		
Aphonia	2	0
Catarrh	1	0
Choking	3	0
Choking sensation	4	0
Dry throat	1	0
Dysphonia	6	0
Nasal discharge discolouration	1	0
Nasal discomfort	2	0
Oropharyngeal discolouration	1	0
Oropharyngeal pain	16	0
Rhinalgia	1	0
Rhinorrhoea	10	0
Sinus pain	1	0
Sneezing	2	0
Snoring	9	0
Throat clearing	1	0
Throat irritation	5	0
Throat tightness	5	0
Upper respiratory tract inflammation	1	0
Respiratory disorders SOC TOTAL	440	15

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	4	0
<i>Alopecias</i>		
Alopecia	41	0
Diffuse alopecia	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	15	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	9	0
Hyperhidrosis	91	0
Night sweats	5	0
<i>Bullous conditions</i>		
Blister	23	0
Dermatitis bullous	1	0
Erythema multiforme	2	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dermatosis	1	0
Dry skin	10	0
Pain of skin	3	0
Scab	1	0
Skin burning sensation	8	0
Skin discolouration	10	0
Skin disorder	5	0
Skin fissures	2	0
Skin lesion	3	0
Skin odour abnormal	2	0
Skin reaction	2	0
Skin sensitisation	1	0
Skin swelling	1	0
Skin texture abnormal	1	0
Skin tightness	1	0
Skin warm	2	0
Skin weeping	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	3	0
Dermatitis allergic	5	0
Dermatitis atopic	1	0
Eczema	6	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	4	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Drug reaction with eosinophilia and systemic symptoms	11	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	18	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Palmar erythema	2	0
Exfoliative conditions		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	1	0
Skin exfoliation	13	0
Hyperpigmentation disorders		
Chloasma	1	0
Hypertrichoses		
Hirsutism	1	0
Hypertrichosis	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail disorder	1	0
Nail dystrophy	1	0
Nail growth abnormal	2	0
Nail pigmentation	1	0
Onychoclasia	7	0
Onychomadesis	3	0
Papulosquamous conditions		
Lichen sclerosus	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	12	0
Pilar disorders NEC		
Hair disorder	1	0
Hair growth abnormal	5	0
Pruritus NEC		
Pruritus	72	0
Psoriatic conditions		
Dermatitis psoriasiform	2	0
Erythrodermic psoriasis	2	0
Psoriasis	7	0
Purpura and related conditions		
Petechiae	2	0
Purpura	3	0
Rashes, eruptions and exanthems NEC		
Rash	84	0
Rash erythematous	17	0
Rash macular	11	0
Rash maculo-papular	9	0
Rash papular	6	0
Rash pruritic	15	0
Rash vesicular	5	0
Rosaceas		
Rosacea	1	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Diabetic foot	1	0
Diabetic ulcer	1	0
Skin ulcer	8	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin vascular conditions NEC		
Skin oedema	1	0

Case Series Drug Analysis Print

Name: FOI 22/1093

Report Run Date: 02-Dec-2022
Earliest Reaction Date: 20-Jan-2004

Data Lock Date: 30-Nov-2022 18:30:04
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin vasculitides</i>		
Hypersensitivity vasculitis	1	0
Vasculitic rash	3	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	34	0
Skin disorders SOC TOTAL	652	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Social circumstances		
<i>Criminal activity</i>		
Drug diversion	1	0
Homicide	1	0
Physical assault	10	0
Theft	1	0
<i>Disability issues</i>		
Bedridden	4	0
Immobile	5	0
Impaired driving ability	8	0
Impaired work ability	3	0
Loss of personal independence in daily activities	6	0
Walking disability	1	0
Wheelchair user	1	0
<i>Family and partner issues</i>		
Sexual relationship change	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	1	0
<i>Sexuality issues</i>		
Homosexuality	1	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
Substance use	4	0
Social circumstances SOC TOTAL	49	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Gastric therapeutic procedures</i>		
Gastrectomy	1	0
Gastric banding	1	0
Gastric bypass	2	0
Gastrostomy	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Enterostomy	1	0
Gastrointestinal tube insertion	3	0
<i>Joint therapeutic procedures</i>		
Hip arthroplasty	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Neurosurgery	1	0
<i>Obstetric therapeutic procedures</i>		
Forceps delivery	1	0
<i>Spine and spinal cord therapeutic procedures</i>		
Spinal fusion surgery	1	0
<i>Therapeutic procedures NEC</i>		
Hospitalisation	1	0
Interchange of vaccine products	1	0
Multiple drug therapy	1	1
Surgery	2	0
Therapy cessation	3	0
Therapy interrupted	1	0
Surgical & medical procedures SOC TOTAL	22	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	14	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	1	0
Haemorrhage	4	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	1
Thrombosis	3	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	2	0
<i>Non-site specific vascular disorders NEC</i>		
Haemodynamic instability	1	0
Reperfusion injury	1	0
Vascular pain	1	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	11	0
Hot flush	23	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	18	0
Peripheral ischaemia	1	0
Raynaud's phenomenon	4	0
<i>Site specific vascular disorders NEC</i>		
Pallor	6	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	18	0
<i>Vascular hypotensive disorders</i>		
Hypotension	26	0
Orthostatic hypotension	8	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
Vascular disorders SOC TOTAL	158	1
TOTAL REACTIONS FOR DRUG	13358	285
TOTAL REPORTS	4100	
TOTAL FATAL OUTCOME REPORTS		285