

Case Series Drug Analysis Print

Name: FOI 22/1093

Report Run Date: 02-Dec-2022

Data Lock Date: 30-Nov-2022 18:30:05

Earliest Reaction Date: 20-Jan-2004

MedDRA Version: MedDRA 25.1

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

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Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	3	0
Bleeding tendencies		
Increased tendency to bruise	2	0
Coagulation factor deficiencies		
Acquired haemophilia	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Myelosuppression	2	0
Pancytopenia	1	0
Neutropenias		
Neutropenia	12	0
Thrombocytopenias		
Thrombocytopenia	3	0
Thrombocytoses		
Thrombocytosis	1	0
Blood disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrial conduction time prolongation	1	0
Atrioventricular block	2	0
Atrioventricular block complete	1	0
Atrioventricular block first degree	1	0
Atrioventricular block second degree	1	0
Long QT syndrome	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	4	1
Cardiovascular disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	22	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Coronary artery stenosis	1	1
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	12	0
Cardiac failure congestive	10	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	4	2
Angina pectoris	4	0
Myocardial infarction	11	3
Myocardial ischaemia	2	0
<i>Left ventricular failures</i>		
Left ventricular failure	1	1
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	3	0
Left atrial dilatation	2	0
Left ventricular hypertrophy	2	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Bradycardia	11	0
Extrasystoles	2	0
Tachyarrhythmia	1	0
Tachycardia	9	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	1	0
Atrial fibrillation	6	0
Atrial tachycardia	1	0
Sinus node dysfunction	1	0
Sinus tachycardia	2	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Cardio-respiratory arrest	1	0
Ventricular arrhythmia	2	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Ventricular extrasystoles	1	0
Ventricular tachycardia	2	0
Cardiac disorders SOC TOTAL	140	8

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear disorder	2	0
Ear pain	3	0
<i>Hearing losses</i>		
Deafness	4	0
Deafness bilateral	1	0
Deafness neurosensory	1	0
Deafness permanent	1	0
Hypoacusis	3	0
<i>Hyperacusia</i>		
Hyperacusis	4	0
<i>Inner ear disorders NEC</i>		
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	16	0
Vertigo	18	0
Ear disorders SOC TOTAL	55	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Anterior pituitary hyperfunction</i>		
Hyperprolactinaemia	1	0
Pituitary-dependent Cushing's syndrome	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	1	0
Secondary hypogonadism	1	0
<i>Posterior pituitary disorders</i>		
Inappropriate antidiuretic hormone secretion	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Eye disorders		
<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
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
Open angle glaucoma	1	0
<i>Lacrimation disorders</i>		
Dry eye	10	0
Lacrimation increased	6	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	1	0
Swelling of eyelid	2	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye disorder	6	0
Eye pain	16	0
Eye swelling	1	0
Periorbital oedema	1	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye irritation	2	0
Eye pruritus	3	0
Ocular hyperaemia	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
Oculogyric crisis	2	0
Ophthalmoplegia	1	0
Strabismus	3	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	1	0
<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>Refractive and accommodative disorders</i>		
Myopia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Epiretinal membrane	2	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal degeneration	1	0
Retinal, choroid and vitreous infections and inflammations		
Macular oedema	1	0
Retinal vasculitis	1	0
Retinopathies NEC		
Retinal exudates	1	0
Visual disorders NEC		
Diplopia	44	0
Glare	2	0
Metamorphopsia	1	0
Photopsia	2	0
Vision blurred	96	0
Visual brightness	4	0
Visual field disorders		
Visual field defect	4	0
Visual impairment and blindness (excl colour blindness)		
Blindness	11	0
Blindness transient	4	0
Sudden visual loss	1	0
Visual acuity reduced	5	0
Visual impairment	46	0
Eye disorders SOC TOTAL	311	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	3	0
Pancreatitis acute	1	0
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
<i>Dental disorders NEC</i>		
Tooth disorder	2	0
Tooth erosion	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	2	0
Toothache	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	50	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	37	0
Flatulence	9	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	12	0
Abdominal pain lower	1	0
Abdominal pain upper	14	0
Gastrointestinal pain	1	0
Infantile colic	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	38	0
Gastric dilatation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	6	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	2	0
Gastrointestinal disorder	6	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal fistulae</i>		
Anal fistula	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	10	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Anal incontinence	4	0
Breath odour	2	0
Dysphagia	36	0
Gastrointestinal spastic and hypermotility disorders		
Frequent bowel movements	1	0
Gastrointestinal stenosis and obstruction NEC		
Ileus	1	0
Intestinal obstruction	4	0
Gingival disorders, signs and symptoms NEC		
Gingival discomfort	1	0
Gingival disorder	2	0
Gingival recession	1	0
Gingival swelling	1	0
Gingival haemorrhages		
Gingival bleeding	1	0
Intestinal haemorrhages		
Rectal haemorrhage	4	0
Intestinal ulcers and perforation NEC		
Large intestine perforation	1	0
Nausea and vomiting symptoms		
Nausea	86	0
Regurgitation	1	0
Retching	1	0
Vomiting	48	0
Vomiting projectile	2	0
Non-mechanical ileus		
Ileus paralytic	3	0
Non-site specific gastrointestinal haemorrhages		
Haematemesis	3	0
Haematochezia	2	0
Upper gastrointestinal haemorrhage	1	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	1	0
Oesophageal ulcers and perforation		
Oesophageal ulcer	1	0
Oral dryness and saliva altered		
Dry mouth	42	0
Saliva altered	1	0
Salivary hypersecretion	5	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	7	0
Lip erythema	1	0
Lip exfoliation	1	0
Lip pain	1	0
Oral discomfort	4	0
Oral mucosal blistering	2	0
Oral pain	4	0
Paraesthesia oral	2	0
Oral soft tissue swelling and oedema		
Lip swelling	13	0
Mouth swelling	2	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Pancreatic disorders NEC</i>		
Pancreatic disorder	1	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	13	0
<i>Tongue disorders</i>		
Tongue disorder	2	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Swollen tongue	18	0
Tongue coated	1	0
Tongue discomfort	1	0
Tongue erythema	1	0
Tongue movement disturbance	2	0
Tongue spasm	1	0
<i>Tooth missing</i>		
Tooth loss	2	0
<i>Umbilical hernias</i>		
Umbilical hernia	1	0
Gastrointestinal disorders SOC TOTAL	561	1

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	28	0
Fatigue	79	0
Malaise	54	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	17	17
Sudden cardiac death	1	1
Sudden death	4	4
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	7	0
<i>Feelings and sensations NEC</i>		
Chills	17	0
Feeling abnormal	70	0
Feeling cold	9	0
Feeling drunk	36	0
Feeling hot	7	0
Feeling jittery	1	0
Feeling of body temperature change	1	0
Hunger	7	0
Temperature intolerance	2	0
Thirst	9	0
<i>Gait disturbances</i>		
Gait disturbance	44	0
Gait inability	10	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	26	0
Crepitations	1	0
Crying	11	0
Disease progression	1	0
Disease recurrence	2	0
Energy increased	1	0
General physical health deterioration	5	0
Illness	10	0
Influenza like illness	15	0
Multiple organ dysfunction syndrome	3	1
Performance status decreased	1	0
Peripheral swelling	31	0
Pre-existing condition improved	1	0
Screaming	1	0
Swelling	10	0
Swelling face	24	0
Terminal state	3	0
Unevaluable event	1	0
<i>Healing abnormal NEC</i>		
Impaired healing	2	0
<i>Inflammations</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Inflammation	2	0
Interactions		
Alcohol interaction	2	0
Drug interaction	41	0
Inhibitory drug interaction	1	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	5	0
Generalised oedema	3	0
Localised oedema	2	0
Oedema	27	0
Oedema peripheral	52	0
Pain and discomfort NEC		
Breakthrough pain	1	0
Chest discomfort	22	0
Chest pain	23	0
Discomfort	8	0
Facial pain	2	0
Pain	61	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
Drug ineffective	65	0
Drug ineffective for unapproved indication	2	0
Drug intolerance	3	0
Drug resistance	1	0
Drug tolerance	1	0
Therapeutic product effect incomplete	4	0
Therapeutic response delayed	1	0
Therapeutic response unexpected	7	0
Ulcers NEC		
Ulcer	2	0
Ulcer haemorrhage	2	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	17	0
Withdrawal syndrome	73	0
General disorders SOC TOTAL	991	23

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	3	0
Jaundice cholestatic	1	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
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Hepatic steatosis	1	0
Hepatitis	2	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	5	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	4	0
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	3	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>		
Immunosuppression	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Infections		
<i>Candida infections</i>		
Candida infection	1	0
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Meningitis	1	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Eye and eyelid infections</i>		
Eye infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Infections NEC</i>		
Infection	1	0
Localised infection	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	6	0
Pneumonia	7	1
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Septic shock	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
Rhinitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	5	0
Infections SOC TOTAL	31	1

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Reaction Name	Total	Fatal
Injuries		
<i>Anaesthetic and allied procedural complications</i>		
Sedation complication	1	0
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure during pregnancy	2	0
<i>Eye injuries NEC</i>		
Eye contusion	2	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Intentional product misuses</i>		
Intentional product misuse	7	0
<i>Intentional product use issues</i>		
Intentional product use issue	4	0
<i>Limb fractures and dislocations</i>		
Femoral neck fracture	1	0
Hip fracture	1	0
Lower 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	1	0
Intercepted medication error	1	0
Medication error	7	0
Prescription drug used without a prescription	4	0
Product use in unapproved indication	11	0
Product use issue	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle rupture	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	5	0
<i>Neurological and psychiatric procedural complications</i>		
Mental status changes postoperative	1	0
<i>Non-site specific injuries NEC</i>		
Accident	1	0
Fall	54	0
Injury	3	0
Road traffic accident	4	0
<i>Off label uses</i>		
Off label use	11	0
<i>Overdoses NEC</i>		
Intentional overdose	10	0
Overdose	23	3
<i>Poisoning and toxicity</i>		
Toxicity to various agents	7	3
<i>Product administration errors and issues</i>		
Accidental overdose	8	1
Contraindicated product administered	1	0
Counterfeit product administered	1	0
Expired product administered	1	0
Inappropriate schedule of product administration	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Incorrect dose administered	7	0
Product administration error	3	0
Product dose omission issue	4	0
Wrong product administered	1	0
Product dispensing errors and issues		
Product dispensing error	7	0
Product prescribing errors and issues		
Product prescribing error	2	0
Product prescribing issue	1	0
Radiation injuries		
Sunburn	1	0
Site specific injuries NEC		
Face injury	1	0
Head injury	3	0
Limb injury	1	0
Skin injuries NEC		
Contusion	5	0
Scar	1	0
Skin abrasion	1	0
Skin laceration	1	0
Stoma complications		
Stoma site haemorrhage	1	0
Underdoses NEC		
Prescribed underdose	1	0
Underdose	1	0
Injuries SOC TOTAL	226	7

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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 saturation decreased	1	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	1	0
Blood glucose increased	8	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	1	0
Coagulation and bleeding analyses		
Coagulation time abnormal	1	0
Coagulation time prolonged	2	0
International normalised ratio decreased	3	0
International normalised ratio increased	2	0
ECG investigations		
Electrocardiogram T wave inversion	1	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	1	0
Heart rate decreased	3	0
Heart rate increased	7	0
Heart rate irregular	3	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 increased	1	0
Liver function test abnormal	16	0
Liver function test increased	3	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
Metabolism tests NEC		
Brain natriuretic peptide increased	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Mineral and electrolyte analyses		
Blood potassium increased	3	0
Neurologic diagnostic procedures		
Coma scale abnormal	1	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	2	0
Physical examination procedures and organ system status		
Apgar score low	1	0
Body temperature increased	2	0
Grip strength decreased	2	0
Respiratory rate decreased	2	0
Weight decreased	15	0
Weight increased	103	0
Pituitary analyses anterior		
Blood luteinising hormone decreased	1	0
Platelet analyses		
Platelet count decreased	3	0
Protein analyses NEC		
C-reactive protein increased	1	0
Red blood cell analyses		
Haemoglobin decreased	4	0
Renal function analyses		
Blood creatinine increased	2	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 increased	6	0
Therapeutic drug monitoring analyses		
Anticonvulsant drug level increased	1	0
Drug level changed	2	0
Drug level increased	3	0
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
Urine analysis abnormal	1	0
Urinary tract function analyses NEC		
Urine output decreased	3	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	3	0
Blood pressure increased	13	0
Blood pressure systolic decreased	1	0
White blood cell analyses		
Neutrophil count decreased	2	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	282	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	17	0
Eating disorder symptom	1	0
Food craving	3	0
Food refusal	1	0
Increased appetite	21	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	3	0
Diabetes mellitus inadequate control	4	0
Increased insulin requirement	1	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	1
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Gluten sensitivity	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Abnormal weight gain	10	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	5	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	2	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
<i>Total fluid volume increased</i>		
Fluid retention	16	0
Metabolic disorders SOC TOTAL	109	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	3	0
Arthropathy	1	0
Seronegative arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw disorder	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pain in jaw	2	0
Spinal pain	2	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	30	0
Joint effusion	1	0
Joint stiffness	7	0
Joint swelling	26	0
<i>Metabolic bone disorders</i>		
Osteomalacia	2	0
Osteopenia	1	0
<i>Muscle pains</i>		
Fibromyalgia	2	0
Myalgia	36	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle disorder	6	0
Muscle spasms	42	0
Muscle swelling	1	0
Muscle tightness	3	0
Muscle twitching	36	0
<i>Muscle tone abnormalities</i>		
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	28	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	4	0
Mobility decreased	5	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	13	0
Posture abnormal	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	19	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	3	0
Neck pain	5	0
Pain in extremity	27	0
Sacral pain	1	0
<i>Myopathies</i>		
Myopathy	1	0
Rhabdomyolysis	5	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Tendon disorders</i>		
Tendon disorder	1	0
Tendon pain	1	0
Tendonitis	1	0
<i>Trunk deformities</i>		
Pelvic deformity	1	0
Muscle & tissue disorders SOC TOTAL	337	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>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
Neoplasm malignant	5	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	1	0
Throat cancer	1	0
Neoplasms SOC TOTAL	23	3

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Reflexes abnormal	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	3	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
Cerebrovascular accident	10	0
Lacunar infarction	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Arachnoiditis	2	0
<i>Central nervous system vascular disorders NEC</i>		
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	9	0
<i>Coordination and balance disturbances</i>		
Ataxia	37	0
Balance disorder	64	0
Cerebellar syndrome	1	0
Coordination abnormal	24	0
Dysdiadochokinesis	2	0
Dysstasia	11	0
Nystagmus	4	0
<i>Cortical dysfunction NEC</i>		
Aphasia	29	0
Dysgraphia	8	0
Dyspraxia	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	4	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
Osmotic demyelination syndrome	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	4	0
Depressed level of consciousness	8	0
Lethargy	20	0
Loss of consciousness	41	0
Postictal state	1	0
Sedation	20	0
Somnolence	138	0
Syncope	31	0
<i>Dyskinesias and movement disorders NEC</i>		
Ballismus	1	0
Clumsiness	12	0
Dyskinesia	32	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Extrapyramidal disorder	5	0
Fine motor skill dysfunction	1	0
Hypokinesia	2	0
Motor dysfunction	5	0
Movement disorder	9	0
Psychomotor hyperactivity	4	0
Dystonias		
Dystonia	8	0
Opisthotonus	1	0
Eye movement disorders		
IVth nerve paralysis	1	0
Facial cranial nerve disorders		
Bell's palsy	1	0
Facial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	2	0
Headaches NEC		
Drug withdrawal headache	2	0
Headache	90	0
Medication overuse headache	1	0
Sinus headache	1	0
Hydrocephalic conditions		
Normal pressure hydrocephalus	1	0
Increased intracranial pressure disorders		
Intracranial pressure increased	3	0
Memory loss (excl dementia)		
Amnesia	50	0
Memory impairment	62	0
Retrograde amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Borderline mental impairment	1	0
Cognitive disorder	16	0
Disturbance in attention	48	0
Mental impairment	20	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	8	0
Migraine with aura	2	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Nerve compression	1	0
Peroneal nerve palsy	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	3	0
Multiple sclerosis relapse	1	0
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	3	0
Serotonin syndrome	1	0
Narcolepsy and hypersomnia		
Hypersomnia	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Nervous system disorders NEC</i>		
Cerebral disorder	2	0
Nervous system disorder	3	1
<i>Neurologic visual problems NEC</i>		
Tunnel vision	3	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	205	0
Dizziness postural	3	0
Drooling	1	0
Grimacing	1	0
Head discomfort	5	0
Meningism	1	0
Myoclonus	15	0
Neurological symptom	1	0
Presyncope	1	0
Tongue biting	1	0
Unresponsive to stimuli	6	0
<i>Neuromuscular disorders NEC</i>		
Dropped head syndrome	1	0
Muscle contractions involuntary	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	1	0
Parosmia	3	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	18	0
Formication	3	0
Hyperaesthesia	4	0
Hypoaesthesia	35	0
Paraesthesia	41	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	3	0
Paralysis	6	0
<i>Parkinson's disease and parkinsonism</i>		
Parkinson's disease	3	0
Parkinsonism	2	0
<i>Partial complex seizures</i>		
Temporal lobe epilepsy	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	4	0
Epilepsy	15	0
Myoclonic epilepsy	1	0
Partial seizures	3	0
Seizure	42	0
<i>Sensory abnormalities NEC</i>		
Ageusia	2	0
Aura	2	0
Complex regional pain syndrome	1	0
Dysgeusia	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Electric shock sensation	3	0
Neuralgia	9	0
Phantom limb syndrome	1	0
Restless legs syndrome	8	0
Sensory disturbance	8	0
Sensory loss	6	0
Taste disorder	3	0
Sleep disturbances NEC		
Periodic limb movement disorder	1	0
Speech and language abnormalities		
Dysarthria	38	0
Incoherent	2	0
Language disorder	1	0
Speech disorder	50	0
Spinal cord and nerve root disorders NEC		
Spinal cord compression	1	0
Spinal cord disorder	1	0
Structural brain disorders NEC		
Brain injury	1	0
Hippocampal sclerosis	1	0
Transient cerebrovascular events		
Transient ischaemic attack	5	1
Tremor (excl congenital)		
Intention tremor	1	0
Tremor	86	0
Trigeminal disorders		
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	1571	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	1	0
Pregnancy conditions SOC TOTAL	6	0

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Reaction Name	Total	Fatal
<i>Counterfeit, falsified and substandard products</i>		
Suspected counterfeit 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	4	0
Product substitution issue	2	0
null SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	8	0
Behaviour disorder	2	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	33	0
Anxiety	74	0
Nervousness	14	0
Stress	4	0
Tension	4	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	35	0
Disinhibition	4	0
Disturbance in social behaviour	1	0
Homicidal ideation	2	0
Hostility	1	0
Impatience	1	0
Paranoia	11	0
Personality change	5	0
Social avoidant behaviour	5	0
Violence-related symptom	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	3	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	108	0
Disorientation	38	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	6	0
<i>Delusional disorders</i>		
Delusional disorder, unspecified type	1	0
<i>Delusional symptoms</i>		
Delusion	3	0
<i>Dementia NEC</i>		
Pseudodementia	1	0
<i>Depressive disorders</i>		
Agitated depression	2	0
Depression	75	0
Depression suicidal	3	0
Major depression	3	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Dissociation	9	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	65	0
Middle insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	4	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	14	0
Dysphoria	1	0
Emotional disorder	4	0
Emotional distress	6	0
Emotional poverty	1	0
Euphoric mood	15	0
Irritability	18	0
Mood altered	9	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	2	0
Fear	8	0
<i>Fluctuating mood symptoms</i>		
Mood swings	17	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	54	0
Hallucination, auditory	6	0
Hallucination, visual	15	0
Hallucinations, mixed	3	0
<i>Impulse control disorders</i>		
Impulsive behaviour	1	0
<i>Increased physical activity levels</i>		
Restlessness	4	0
<i>Learning disorders</i>		
Reading disorder	2	0
<i>Mental disorders NEC</i>		
Mental disorder	7	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	23	0
Depressive symptom	1	0
Feeling of despair	3	0
Negative thoughts	1	0
Tearfulness	6	0
<i>Mood alterations with manic symptoms</i>		
Mania	4	0
<i>Mood disorders NEC</i>		
Affective disorder	2	0
Apathy	4	0
Listless	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Body dysmorphic disorder	1	0
Dermatillomania	1	0
Obsessive thoughts	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Obsessive-compulsive disorder	3	0
Orgasmic disorders and disturbances		
Anorgasmia	3	0
Panic attacks and disorders		
Panic attack	20	0
Panic disorder	3	0
Panic reaction	4	0
Parasomnias		
Abnormal dreams	10	0
Nightmare	21	0
Sleep terror	1	0
Somnambulism	2	0
Perception disturbances NEC		
Deja vu	1	0
Delusional perception	1	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)		
Psychopathic personality	1	0
Psychiatric elimination disorders		
Enuresis	3	0
Psychiatric symptoms NEC		
Psychiatric symptom	2	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	14	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	5	0
Libido increased	2	0
Loss of libido	4	0
Sleep disorders NEC		
Sleep disorder	13	0
Somatic symptom disorders		
Conversion disorder	2	0
Illness anxiety disorder	1	0
Somatic symptom disorder	2	0
Speech and language usage disturbances		
Logorrhoea	1	0
Speech articulation and rhythm disturbances		
Dysphemia	6	0
Stereotypies and automatisms		
Bruxism	2	0
Head banging	1	0
Stress disorders		
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Dependence	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Drug abuse	50	1
Drug dependence	51	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	4	4
Intentional self-injury	8	0
Self-injurious ideation	5	0
Suicidal behaviour	1	0
Suicidal ideation	78	0
Suicide attempt	11	0
<i>Thinking disturbances</i>		
Bradyphrenia	3	0
Morbid thoughts	3	0
Thinking abnormal	14	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	1152	5

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	14	0
Incontinence	6	0
Micturition disorder	1	0
Micturition urgency	4	0
Pollakiuria	8	0
Post micturition dribble	1	0
Stress urinary incontinence	2	0
Urinary hesitation	1	0
Urinary incontinence	13	0
Urinary retention	18	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder disorder	2	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
Bladder sphincter atony	1	0
Hypertonic bladder	3	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	4	0
<i>Renal failure and impairment</i>		
Acute kidney injury	7	0
Chronic kidney disease	1	0
Renal failure	5	0
Renal impairment	10	0
<i>Renal vascular and ischaemic conditions</i>		
Renal tubular necrosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	2	0
Haematuria	3	0
Urine odour abnormal	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Nocturia	1	0
Polyuria	1	0
Renal & urinary disorders SOC TOTAL	114	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast disorder male	1	0
Breast enlargement	1	0
Breast mass	1	0
Gynaecomastia	7	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	7	0
Breast swelling	2	0
Breast tenderness	1	0
Nipple pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation disorder	1	0
Ejaculation failure	1	0
Erectile dysfunction	13	0
Retrograde ejaculation	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Intermenstrual bleeding	1	0
Menstrual disorder	2	0
Premenstrual syndrome	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	5	0
Menstruation delayed	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile oedema	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatism	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<i>Sexual function and fertility disorders NEC</i>		
Sexual dysfunction	4	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	3	0
Reproductive & breast disorders SOC TOTAL	64	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	1
Dyspnoea	66	0
Dyspnoea exertional	1	0
Dyspnoea paroxysmal nocturnal	1	0
Hypopnoea	1	0
Orthopnoea	1	0
Respiration abnormal	1	0
Respiratory depression	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Bronchospasm	1	0
Wheezing	6	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypercapnia	1	1
Hypoxia	3	0
<i>Coughing and associated symptoms</i>		
Cough	14	0
Haemoptysis	1	0
Productive cough	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
Pulmonary eosinophilia	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	6	0
Nasal dryness	2	0
Nasal pruritus	1	0
Nasal ulcer	1	0
<i>Parenchymal lung disorders NEC</i>		
Emphysema	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	8	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	2	0
<i>Pulmonary hypertension</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	1	0
Pulmonary oedema	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	5	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	3	0
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
Respiratory disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Catarrh	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Choking	1	0
Choking sensation	3	0
Dysphonia	3	0
Oropharyngeal pain	2	0
Rhinalgia	1	0
Rhinorrhoea	5	0
Sinus pain	1	0
Sneezing	1	0
Throat irritation	2	0
Throat tightness	5	0
Respiratory disorders SOC TOTAL	176	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Alopecias</i>		
Alopecia	16	0
<i>Angioedemas</i>		
Angioedema	8	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	57	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	9	0
Erythema multiforme	1	0
Stevens-Johnson syndrome	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dermatosis	1	0
Dry skin	6	0
Pain of skin	2	0
Skin burning sensation	5	0
Skin discolouration	5	0
Skin disorder	1	0
Skin fissures	1	0
Skin lesion	3	0
Skin odour abnormal	2	0
Skin sensitisation	1	0
Skin swelling	1	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	2	0
Eczema	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	1	0
<i>Dermatitis ascribed to specific agent</i>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	9	0
Palmar erythema	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	1	0
Skin exfoliation	6	0
<i>Hypertrichoses</i>		
Hypertrichosis	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail dystrophy	1	0
Nail growth abnormal	1	0
Onychoclasia	4	0
Onychomadesis	3	0
<i>Papulosquamous conditions</i>		
Lichen sclerosus	1	0
<i>Photosensitivity and photodermatitis conditions</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Photosensitivity reaction	6	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Pruritus NEC		
Pruritus	34	0
Psoriatic conditions		
Dermatitis psoriasiform	2	0
Erythrodermic psoriasis	1	0
Psoriasis	4	0
Purpura and related conditions		
Purpura	2	0
Rashes, eruptions and exanthems NEC		
Rash	38	0
Rash erythematous	8	0
Rash macular	3	0
Rash maculo-papular	5	0
Rash papular	2	0
Rash pruritic	5	0
Rash vesicular	2	0
Rosaceas		
Rosacea	1	0
Skin and subcutaneous tissue ulcerations		
Skin ulcer	8	0
Skin vascular conditions NEC		
Skin oedema	1	0
Skin vasculitides		
Hypersensitivity vasculitis	1	0
Vasculitic rash	1	0
Urticarias		
Urticaria	6	0
Skin disorders SOC TOTAL	299	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	3	0
Immobile	3	0
Impaired driving ability	7	0
Impaired work ability	3	0
Loss of personal independence in daily activities	5	0
<i>Social issues NEC</i>		
Substance use	1	0
Social circumstances SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Gastric therapeutic procedures</i>		
Gastric banding	1	0
Gastric bypass	2	0
Gastrostomy	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Gastrointestinal tube insertion	3	0
<i>Joint therapeutic procedures</i>		
Hip arthroplasty	1	0
<i>Spine and spinal cord therapeutic procedures</i>		
Spinal fusion surgery	1	0
<i>Therapeutic procedures NEC</i>		
Surgery	2	0
Surgical & medical procedures SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	1
Thrombosis	2	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Haemodynamic instability	1	0
Vascular pain	1	0
Vasodilatation	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	8	0
Hot flush	10	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	13	0
Raynaud's phenomenon	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Hypotension	12	0
Orthostatic hypotension	6	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
Vascular disorders SOC TOTAL	83	1
TOTAL REACTIONS FOR DRUG	6645	54
TOTAL REPORTS	2001	
TOTAL FATAL OUTCOME REPORTS		54