

Case Series Drug Analysis Print

Name: AstraZeneca COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022
Data Lock Date: 22-Feb-2022 18:30:04
Earliest Reaction Date: 25-Jan-2020
MedDRA Version: MedDRA 24.1

AstraZeneca COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield: All UK spontaneous, suspect reports associated with the AstraZeneca COVID-19 vaccine from Islington, Camden, Haringey, Barnet and Enfield Clinical Commissioning Groups up to and including 22/02/2022.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
<i>Anaemias NEC</i>		
Anaemia	4	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	2	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Spontaneous haematoma	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	1	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
<i>Leukocytoses NEC</i>		
Lymphocytosis	1	0
<i>Leukopenias NEC</i>		
Leukopenia	1	0
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	16	0
Lymphadenitis	1	0
Lymphadenopathy	80	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
Pancytopenia	2	0
<i>Neutropenias</i>		
Neutropenia	2	0
<i>Platelet disorders NEC</i>		
Platelet disorder	2	0
<i>Spleen disorders</i>		
Splenic haemorrhage	1	0
Splenic infarction	1	0
Splenic vein thrombosis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	19	0
Thrombotic thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	143	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	3	0
Cardiac ventricular thrombosis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	124	0
<i>Coronary artery disorders NEC</i>		
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	2	0
Acute myocardial infarction	2	0
Angina pectoris	5	0
Myocardial infarction	4	0
Prinzmetal angina	1	0
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
Myocardial injury	1	0
Right atrial dilatation	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	6	0
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
Pericardial rub	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	5	0
Cardiac flutter	7	0
Extrasystoles	2	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	33	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	12	1
Atrial flutter	1	0
Atrial tachycardia	1	0
Sinus tachycardia	1	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Cardiac disorders SOC TOTAL	228	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	1	0
<i>Male reproductive tract disorders congenital</i>		
Penoscrotal fusion	1	0
Congenital disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear disorder	1	0
Ear pain	31	0
Ear swelling	2	0
<i>Eustachian tube disorders</i>		
Eustachian tube dysfunction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	6	0
Deafness neurosensory	1	0
Hypoacusis	1	0
Sudden hearing loss	3	0
<i>Hyperacusia</i>		
Hyperacusis	5	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	5	0
Tinnitus	110	0
Vertigo	48	0
Vertigo positional	5	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	226	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	1	0
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	3	0
Endocrine disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	2	0
Vitreous floaters	6	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	3	0
Eyelid ptosis	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
Iritis	1	0
<i>Lacrimation disorders</i>		
Dry eye	13	0
Lacrimation increased	7	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid haematoma	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid rash	1	0
Swelling of eyelid	3	0
<i>Lid, lash and lacrimal structural disorders</i>		
Growth of eyelashes	2	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Eye pain	71	0
Eye swelling	10	0
Ocular discomfort	3	0
Periorbital pain	1	0
Periorbital swelling	4	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	2	0
Eye inflammation	2	0
Eye irritation	2	0
Eye pruritus	9	0
Ocular hyperaemia	6	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	15	0
Hypoaesthesia eye	1	0
Photophobia	27	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic nerve sheath haemorrhage	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular degeneration	1	0
Retinal degeneration	1	0
Retinal detachment	3	0
Retinal drusen	1	0
<i>Retinopathies NEC</i>		
Diabetic retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	1	0
Scleritis	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Endocrine ophthalmopathy	1	0
Exophthalmos	1	0
<i>Visual disorders NEC</i>		
Diplopia	8	0
Photopsia	8	0
Vision blurred	59	0
Visual brightness	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	6	0
Blindness transient	1	0
Blindness unilateral	1	0
Visual acuity reduced	4	0
Visual acuity reduced transiently	1	0
Visual impairment	11	0
Eye disorders SOC TOTAL	321	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
Pancreatitis acute	1	0
Pancreatitis necrotising	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal paraesthesia	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ischaemic	1	1
Colitis ulcerative	2	0
Crohn's disease	2	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	3	0
Toothache	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	156	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	13	0
Epigastric discomfort	1	0
Eructation	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	13	0
Flatulence	18	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	96	0
Abdominal pain lower	5	0
Abdominal pain upper	94	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	20	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	8	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Functional gastrointestinal disorder	1	0
Gastric disorder	1	0
Gastrointestinal disorder	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastrointestinal oedema	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Dyschezia	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	27	0
Anal incontinence	1	0
Breath odour	1	0
Dysphagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	3	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	3	0
Mesenteric vein thrombosis	1	0
Visceral venous thrombosis	2	1
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	4	0
Gingival swelling	3	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	4	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	4	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	668	0
Retching	3	0
Vomiting	219	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	3	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	17	0
Lip dry	3	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	2	0
Lip blister	1	0
Oral lichen planus	1	0
Palatal disorder	1	0
Uvulitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Oral blood blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	12	0
Lip exfoliation	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip pain	3	0
Oral discomfort	2	0
Oral mucosal blistering	1	0
Oral mucosal eruption	1	0
Oral pain	7	0
Paraesthesia oral	6	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	16	0
Mouth swelling	3	0
Palatal swelling	1	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	23	0
Stomatitis	5	0
<i>Tongue disorders</i>		
Tongue disorder	2	0
Tongue ulceration	1	0
Trichoglossia	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	4	0
Swollen tongue	16	0
Tongue discolouration	2	0
Tongue dry	1	0
Tongue pruritus	1	0
Tongue spasm	1	0
Gastrointestinal disorders SOC TOTAL	1563	2

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site erythema	1	0
Application site vesicles	1	0
<i>Asthenic conditions</i>		
Asthenia	117	0
Chronic fatigue syndrome	1	0
Fatigue	1052	0
Malaise	210	0
<i>Death and sudden death</i>		
Death	4	4
Sudden death	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	1359	0
<i>Feelings and sensations NEC</i>		
Chills	970	0
Early satiety	1	0
Feeling abnormal	58	0
Feeling cold	71	0
Feeling drunk	2	0
Feeling hot	30	0
Feeling of body temperature change	20	0
Hangover	2	0
Humidity intolerance	1	0
Hunger	1	0
Sensation of blood flow	1	0
Sensation of foreign body	1	0
Temperature intolerance	3	0
Thirst	17	0
<i>Gait disturbances</i>		
Gait disturbance	6	0
Gait inability	3	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crepitations	1	0
Crying	5	0
Energy increased	1	0
Exercise tolerance decreased	1	0
Illness	44	0
Influenza like illness	143	0
Local reaction	2	0
Peripheral swelling	92	0
Swelling	46	0
Swelling face	23	0
<i>Implant and catheter site reactions</i>		
Implant site discharge	1	0
<i>Inflamations</i>		
Inflammation	16	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site bruising	1	0
Injection site discomfort	1	0
Injection site erythema	6	0
Injection site extravasation	1	0
Injection site inflammation	2	0
Injection site mass	19	0
Injection site pain	80	0
Injection site papule	1	0
Injection site pruritus	7	0
Injection site rash	2	0
Injection site reaction	1	0
Injection site swelling	7	0
Injection site urticaria	1	0
Injection site warmth	5	0
<i>Interactions</i>		
Drug interaction	1	0
<i>Mass conditions NEC</i>		
Cyst	1	0
Mass	3	0
Nodule	2	0
<i>Mucosal findings abnormal</i>		
Mucosal inflammation	1	0
<i>Oedema NEC</i>		
Oedema	3	0
Oedema peripheral	6	0
<i>Pain and discomfort NEC</i>		
Axillary pain	16	0
Chest discomfort	32	0
Chest pain	110	0
Discomfort	17	0
Facial discomfort	1	0
Facial pain	13	0
Pain	331	0
Tenderness	32	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	4	0
Inadequate analgesia	1	0
Therapeutic response unexpected	4	0
Vaccination failure	1	0
<i>Trophic disorders</i>		
Atrophy	1	0
<i>Vaccination site reactions</i>		
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	3	0
Vaccination site discomfort	2	0
Vaccination site erythema	13	0
Vaccination site granuloma	1	0
Vaccination site hypersensitivity	1	0
Vaccination site induration	1	0
Vaccination site joint pain	2	0

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General disorders General disorders cont'd		
Vaccination site mass	12	0
Vaccination site pain	41	0
Vaccination site rash	4	0
Vaccination site reaction	1	0
Vaccination site swelling	10	0
Vaccination site warmth	6	0
General disorders SOC TOTAL	5131	5

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
Jaundice cholestatic	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	8	1
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	2	0
Hepatomegaly	1	0
Hepatic disorders SOC TOTAL	15	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	2	0
Hypersensitivity	46	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Oral allergy syndrome	1	0
Reaction to preservatives	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	10	0
Anaphylactic shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	4	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Haemophagocytic lymphohistiocytosis	1	0
Immune system disorder	1	0
Immune-mediated adverse reaction	1	0
<i>Transplant rejections</i>		
Transplant rejection	1	0
Immune system disorders SOC TOTAL	75	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	9	0
Periorbital cellulitis	1	0
Skin bacterial infection	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Breast infections</i>		
Mastitis	2	0
<i>Candida infections</i>		
Candida infection	2	0
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Cavernous sinus thrombosis	1	0
Encephalitis	1	0
<i>Coronavirus infections</i>		
COVID-19	28	0
COVID-19 pneumonia	1	0
Post-acute COVID-19 syndrome	1	0
Suspected COVID-19	4	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	2	0
Oral infection	1	0
Periodontitis	1	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	1	0
<i>Ectoparasitic infestations</i>		
Trombidiasis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
Eye infection	1	0
Hordeolum	3	0
<i>Herpes viral infections</i>		
Genital herpes	5	0
Genital herpes zoster	1	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	27	0
Herpes zoster oticus	1	0
Oral herpes	18	0
Varicella	1	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	3	0
Infection	8	0
Localised infection	1	0

Case Series Drug Analysis Print

Name: AstraZeneca COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield

Report Run Date: 23-Feb-2022
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Reaction Name	Total	Fatal
Infections Infections cont'd		
Lymph gland infection	1	0
<i>Influenza viral infections</i>		
Influenza	117	0
<i>Lower respiratory tract and lung infections</i>		
Infectious pleural effusion	1	0
Lower respiratory tract infection	5	0
Pneumonia	9	2
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Rash pustular	1	0
Skin infection	2	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
Toxic shock syndrome staphylococcal	1	0
<i>Treponema infections</i>		
Pinta	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Chronic sinusitis	1	0
Nasopharyngitis	32	0
Pharyngitis	1	0
Rhinitis	3	0
Sinusitis	8	0
Tonsillitis	2	0
<i>Urinary tract infections</i>		
Urinary tract infection	4	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infected varicose vein	1	0
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Post viral fatigue syndrome	2	0
Sweating fever	10	0
Viral infection	1	0
Viral labyrinthitis	1	0
Viral rash	1	0
Infections SOC TOTAL	353	2

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Lip injury	1	0
Tongue injury	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Ear injuries NEC</i>		
Deafness traumatic	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	3	0
Foetal exposure during pregnancy	2	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	35	0
Maternal exposure during pregnancy	10	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	2	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
Eye injury	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	1	0
Heat stroke	2	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
Muscle injury	1	0
Muscle strain	1	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	4	0
<i>Non-site specific injuries NEC</i>		
Electric shock	4	0
Fall	3	0
Soft tissue injury	1	0
Wound	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	4	0
Post procedural complication	2	0
Post procedural contusion	2	0
Procedural pain	1	0
Procedural site reaction	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Poisoning and toxicity</i>		
Metal poisoning	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Site specific injuries NEC</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Limb crushing injury	1	0
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	64	0
Skin wound	1	0
<i>Spinal cord injuries NEC</i>		
Prevertebral soft tissue swelling of cervical space	1	0
<i>Spinal fractures and dislocations</i>		
Spinal fracture	1	0
<i>Thermal burns</i>		
Burn of internal organs	1	0
Thermal burn	1	0
Thermal burns of eye	1	0
Injuries SOC TOTAL	169	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Cold agglutinins positive	1	0
<i>Blood counts NEC</i>		
Full blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Blood pH increased	2	0
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	2	0
Blood glucose abnormal	1	0
Blood glucose decreased	2	0
Blood glucose fluctuation	2	0
Blood glucose increased	3	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF test abnormal	1	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time prolonged	2	0
Fibrin D dimer increased	2	0
International normalised ratio decreased	2	0
<i>ECG investigations</i>		
Electrocardiogram	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram abnormal	2	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	22	0
Heart rate decreased	3	0
Heart rate increased	40	0
Heart rate irregular	7	0
Pulse abnormal	1	0
Pulse pressure increased	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	1	0
<i>Immunology analyses NEC</i>		
Immunology test	1	0
Mast cell degranulation present	1	0
<i>Investigations NEC</i>		
Blood test	1	0
Blood test abnormal	3	0
<i>Liver function analyses</i>		
Liver function test increased	2	0
Transaminases increased	1	0
<i>Metabolism tests NEC</i>		
Blood uric acid increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	1	0
Electromyogram abnormal	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Joint position sense decreased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Intraocular pressure test	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	13	0
Body temperature decreased	2	0
Body temperature fluctuation	3	0
Body temperature increased	19	0
Breath sounds	1	0
Breath sounds abnormal	1	0
Grip strength decreased	1	0
Male genital examination abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	1	0
Skin temperature	1	0
Weight decreased	4	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	6	0
<i>Protein analyses NEC</i>		
C-reactive protein abnormal	1	0
C-reactive protein increased	1	0
<i>Reproductive hormone analyses</i>		
Pregnancy test	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced vital capacity decreased	1	0
Total lung capacity decreased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	2	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	3	0
Blood pressure increased	9	0
Blood pressure measurement	6	0
<i>Virus identification and serology</i>		
Coronavirus test	3	0
SARS-CoV-2 antibody test	1	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test positive	2	0
<i>Vitamin analyses</i>		
Vitamin B12 abnormal	1	0
<i>White blood cell analyses</i>		
Eosinophil count	1	0
Neutrophil count decreased	1	0
Investigations SOC TOTAL	210	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	131	0
Food refusal	1	0
Hyperphagia	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	4	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	1	0
Gluten sensitivity	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	3	0
Feeding disorder	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	4	0
<i>Magnesium metabolism disorders</i>		
Hypomagnesaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Phosphorus metabolism disorders</i>		
Hypophosphataemia	1	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Sodium imbalance</i>		
Hypernatraemia	1	0
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	12	0
<i>Total fluid volume increased</i>		
Fluid retention	2	0
<i>Water soluble vitamin deficiencies</i>		
Vitamin B12 deficiency	1	0
Metabolic disorders SOC TOTAL	180	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	7	0
<i>Bone related signs and symptoms</i>		
Bone pain	25	0
Pain in jaw	8	0
Spinal pain	6	0
<i>Bursal disorders</i>		
Bursitis	4	0
<i>Cartilage disorders</i>		
Costochondritis	5	0
<i>Extremity deformities</i>		
Limb deformity	1	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
Periarthritis	10	0
Rotator cuff syndrome	2	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	402	0
Joint effusion	1	0
Joint noise	2	0
Joint stiffness	13	0
Joint swelling	15	0
Joint warmth	2	0
<i>Ligament disorders</i>		
Ligament pain	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Metabolic bone disorders</i>		
Dwarfism	1	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	3	0
Myalgia	655	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle fatigue	16	0
Muscle spasms	67	0
Muscle tightness	2	0
Muscle twitching	14	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	49	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	2	0
Musculoskeletal stiffness	46	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	120	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Flank pain	3	0
Limb discomfort	41	0
Musculoskeletal chest pain	11	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	2	0
Neck pain	52	0
Pain in extremity	422	0
Rheumatic disorder	1	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	2	0
Groin pain	5	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	1	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Tenosynovitis	1	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	2037	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Anal canal neoplasms malignant</i>		
Anal cancer	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Lip and oral cavity neoplasms benign</i>		
Papillary cystadenoma lymphomatosum	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma	1	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm progression	1	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<i>Plasma cell myelomas</i>		
Plasmacytoma	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
Neoplasms SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	2	0
Hyperreflexia	1	0
Hyporeflexia	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	4	0
<i>Central nervous system aneurysms and dissections</i>		
Intracranial aneurysm	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebellar stroke	1	0
Cerebral artery thrombosis	1	0
Cerebral haemorrhage	1	0
Cerebral infarction	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	17	1
Haemorrhagic stroke	1	0
Haemorrhagic transformation stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	3	0
Lacunar stroke	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	5	0
<i>Coordination and balance disturbances</i>		
Ataxia	4	0
Balance disorder	19	0
Cerebellar syndrome	1	0
Coordination abnormal	2	0
Dysstasia	4	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Agraphia	1	0
Aphasia	1	0
Visuospatial deficit	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	2	0
Demyelination	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	3	0
Lethargy	88	0
Loss of consciousness	19	0
Somnolence	43	0
Syncope	66	0
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	4	0
Extrapyramidal disorder	1	0
Hyperkinesia	1	0
Hypokinesia	1	0
<i>Encephalopathies NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Encephalopathy	1	0
Facial cranial nerve disorders		
Bell's palsy	16	0
Facial paralysis	2	0
Facial paresis	1	0
Facial spasm	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	3	0
Headaches NEC		
Cluster headache	14	0
Cold-stimulus headache	1	0
Exertional headache	2	0
Headache	1567	0
New daily persistent headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	10	0
Tension headache	38	0
Vascular headache	2	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Intellectual disabilities		
Intellectual disability	2	0
Lumbar spinal cord and nerve root disorders		
Lumbar radiculopathy	1	0
Sciatica	4	0
Memory loss (excl dementia)		
Amnesia	8	0
Memory impairment	6	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	9	0
Disturbance in attention	17	0
Mental impairment	6	0
Migraine headaches		
Migraine	140	0
Migraine with aura	2	0
Retinal migraine	1	0
Vestibular migraine	3	0
Mononeuropathies		
Nerve compression	2	0
Motor neurone diseases		
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	0
Multiple sclerosis relapse	1	0
Progressive multiple sclerosis	1	0
Muscle tone abnormal		
Hypotonia	2	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	3	0
Nervous system disorders NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Nervous system disorder	3	0
Neurological signs and symptoms NEC		
Dizziness	441	0
Dizziness postural	34	0
Exaggerated startle response	1	0
Head discomfort	18	0
Hyporesponsive to stimuli	1	0
Myoclonus	4	0
Neurological decompensation	1	0
Neurological symptom	2	0
Persistent postural-perceptual dizziness	2	0
Presyncope	10	0
Unresponsive to stimuli	2	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	12	0
Parosmia	8	0
Optic nerve disorders NEC		
Optic neuritis	4	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	1	0
Burning sensation	20	0
Burning sensation mucosal	1	0
Dysaesthesia	1	0
Formication	3	0
Hyperaesthesia	6	0
Hypoaesthesia	126	0
Paraesthesia	200	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	3	0
Hemiparesis	3	0
Monoparesis	1	0
Monoplegia	3	0
Paralysis	9	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	2	0
Parkinson's disease	2	0
Parkinsonism	1	0
Partial complex seizures		
Focal dyscognitive seizures	2	0
Partial simple seizures NEC		
Simple partial seizures	1	0
Peripheral neuropathies NEC		
Neuritis	1	0
Neuropathy peripheral	5	0
Seizures and seizure disorders NEC		
Epilepsy	10	0
Febrile convulsion	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Partial seizures	1	0
Psychogenic seizure	1	0
Seizure	28	0
Status epilepticus	1	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Ageusia	21	0
Complex regional pain syndrome	1	0
Dysgeusia	36	0
Electric shock sensation	1	0
Loss of proprioception	1	0
Neuralgia	30	0
Post herpetic neuralgia	1	0
Restless legs syndrome	6	0
Sensory disturbance	4	0
Sensory loss	5	0
Taste disorder	11	0
Speech and language abnormalities		
Dysarthria	7	0
Slow speech	1	0
Speech disorder	2	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Structural brain disorders NEC		
Brain injury	1	0
Cerebral mass effect	1	0
Intracranial mass	1	0
Transient cerebrovascular events		
Transient ischaemic attack	6	0
Tremor (excl congenital)		
Essential tremor	1	0
Tremor	133	0
Trigeminal disorders		
Trigeminal neuralgia	4	0
Nervous system disorders SOC TOTAL	3440	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
<i>Normal pregnancy, labour and delivery</i>		
Uterine contractions during pregnancy	1	0
Pregnancy conditions SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Flat affect	1	0
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	7	0
Anxiety	28	0
Nervousness	5	0
Stress	4	0
Tension	3	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Disinhibition	1	0
Paranoia	3	0
Personality change	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	11	0
<i>Confusion and disorientation</i>		
Confusional state	38	0
Disorientation	17	0
<i>Deliria</i>		
Delirium	5	0
<i>Delusional symptoms</i>		
Delusion of parasitosis	1	0
<i>Depressive disorders</i>		
Depression	21	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	81	0
Middle insomnia	1	0
Terminal insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	16	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Emotional disorder	2	0
Emotional distress	2	0
Euphoric mood	1	0
Irritability	7	0
Mood altered	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Phobia	1	0
Phonophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	6	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	15	0

Case Series Drug Analysis Print

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Report Run Date: 23-Feb-2022
Earliest Reaction Date: 25-Jan-2020

Data Lock Date: 22-Feb-2022 18:30:04
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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Hallucination, auditory	1	0
Increased physical activity levels		
Restlessness	10	0
Mood alterations with depressive symptoms		
Anhedonia	1	0
Decreased interest	2	0
Depressed mood	16	0
Tearfulness	2	0
Mood alterations with manic symptoms		
Mania	1	0
Mood disorders NEC		
Apathy	2	0
Listless	4	0
Orgasmic disorders and disturbances		
Anorgasmia	2	0
Panic attacks and disorders		
Panic attack	3	0
Panic reaction	1	0
Parasomnias		
Abnormal dreams	7	0
Nightmare	11	0
Sleep terror	2	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	1	0
Psychiatric elimination disorders		
Enuresis	1	0
Psychiatric symptoms NEC		
Decreased eye contact	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	2	0
Sexual arousal disorders		
Disturbance in sexual arousal	1	0
Sexual desire disorders		
Libido decreased	1	0
Loss of libido	5	0
Sleep disorders NEC		
Sleep disorder	8	0
Somatic symptom disorders		
Habit cough	2	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Stereotypies and automatisms		
Bruxism	2	0
Stress disorders		
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Alcohol abuse	1	0
Alcohol use disorder	2	0
Drug abuse	1	0
Substance abuse	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	5	0
<i>Thinking disturbances</i>		
Bradyphrenia	1	0
Tachyphrenia	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	398	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	3	0
Dysuria	2	0
Incontinence	2	0
Micturition urgency	1	0
Pollakiuria	10	0
Urinary incontinence	2	0
Urinary retention	3	0
Urine flow decreased	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urogenital haemorrhage	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Focal segmental glomerulosclerosis	1	0
Nephrotic syndrome	1	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	1	0
<i>Renal disorders NEC</i>		
Renal haemorrhage	1	0
<i>Renal failure and impairment</i>		
Renal failure	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal artery thrombosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Haematuria	1	0
Urine abnormality	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	16	0
Renal & urinary disorders SOC TOTAL	52	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	2	0
Gynaecomastia	2	0
<i>Breast signs and symptoms</i>		
Breast engorgement	1	0
Breast pain	10	0
Breast swelling	1	0
Breast tenderness	2	0
Nipple pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
Priapism	1	0
Retrograde ejaculation	1	0
<i>Lactation disorders</i>		
Lactation puerperal increased	1	0
Suppressed lactation	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	3	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	43	0
Intermenstrual bleeding	20	0
Menstrual disorder	44	0
Menstruation irregular	70	0
Premenstrual dysphoric disorder	2	0
Premenstrual pain	2	0
Premenstrual syndrome	2	0
Withdrawal bleed	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	22	0
Hypomenorrhoea	10	0
Menstruation delayed	96	0
Oligomenorrhoea	4	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	106	0
Polymenorrhoea	22	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst ruptured	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	2	0
Pelvic haemorrhage	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile discharge	1	0
Penis disorder	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	2	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	1	0
Infertility	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Sexual dysfunction	2	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	2	0
Uterine haemorrhage	1	0
Uterine pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	37	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	3	0
Vaginal odour	1	0
Vulvovaginal pain	1	0
Reproductive & breast disorders SOC TOTAL	535	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	153	0
Hyperventilation	4	0
Hypopnoea	7	0
Irregular breathing	1	0
Orthopnoea	1	0
Respiration abnormal	2	0
Respiratory arrest	1	0
Respiratory fatigue	1	0
Tachypnoea	1	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	13	0
Cough variant asthma	1	0
Wheezing	12	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	3	0
<i>Coughing and associated symptoms</i>		
Cough	78	0
Haemoptysis	2	0
Productive cough	4	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	4	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	10	0
<i>Nasal disorders NEC</i>		
Epistaxis	43	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Parenchymal lung disorders NEC</i>		
Idiopathic pulmonary fibrosis	1	0
Pulmonary cavitation	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	3	0
Pharyngeal oedema	1	0
Pharyngeal swelling	8	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	2	0
Pneumothorax	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	31	2

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pulmonary thrombosis	1	0
Respiratory failures (excl neonatal)		
Acute respiratory failure	1	0
Respiratory signs and symptoms NEC		
Diaphragmalgia	1	0
Respiratory tract disorders NEC		
Respiratory tract haemorrhage	1	0
Upper respiratory tract signs and symptoms		
Aphonia	2	0
Catarrh	1	0
Dry throat	6	0
Dysphonia	4	0
Increased viscosity of upper respiratory secretion	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	97	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	43	0
Sinus pain	8	0
Sneezing	7	0
Throat irritation	2	0
Throat tightness	2	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	578	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
Dermatitis acneiform	2	0
<i>Alopecias</i>		
Alopecia	11	0
Alopecia areata	1	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	8	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	21	0
Hyperhidrosis	150	0
Miliaria	3	0
Night sweats	45	0
<i>Bullous conditions</i>		
Blister	13	0
Blood blister	4	0
Erythema multiforme	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	14	0
Pain of skin	21	0
Papule	1	0
Sensitive skin	9	0
Skin burning sensation	15	0
Skin discolouration	3	0
Skin disorder	1	0
Skin fissures	1	0
Skin lesion	2	0
Skin odour abnormal	2	0
Skin reaction	3	0
Skin swelling	2	0
Skin warm	9	0
Sticky skin	1	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	6	0
Dermatitis allergic	5	0
Dermatitis atopic	3	0
Dermatitis contact	1	0
Dermatitis diaper	1	0
Dyshidrotic eczema	3	0
Eczema	7	0
Eczema asteatotic	3	0
Neurodermatitis	1	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	48	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
Exfoliative rash	1	0
Skin exfoliation	8	0
<i>Hyperpigmentation disorders</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Solar lentigo	1	0
Hypopigmentation disorders		
Skin depigmentation	1	0
Vitiligo	1	0
Nail and nail bed conditions (excl infections and infestations)		
Anonychia	1	0
Nail discolouration	1	0
Panniculitides		
Erythema nodosum	1	0
Papulosquamous conditions		
Pityriasis rosea	1	0
Photosensitivity and photodermatitis conditions		
Photosensitivity reaction	4	0
Pigmentation changes NEC		
Pigmentation disorder	1	0
Pilar disorders NEC		
Piloerection	4	0
Pruritus NEC		
Itching scar	1	0
Pruritus	138	0
Psoriatic conditions		
Guttate psoriasis	2	0
Psoriasis	4	0
Purpura and related conditions		
Ecchymosis	1	0
Petechiae	10	0
Purpura	2	0
Rashes, eruptions and exanthems NEC		
Rash	174	0
Rash erythematous	39	0
Rash macular	15	0
Rash maculo-papular	2	0
Rash morbilliform	2	0
Rash papular	11	0
Rash pruritic	40	0
Rash vesicular	1	0
Rosaceas		
Rosacea	3	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	1	0
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	2	0
Skin ulcer	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	2	0
Skin hypoplasias and atrophies		
Skin striae	1	0
Telangiectasia and related conditions		
Telangiectasia	1	0
Urticarias		
Urticaria	67	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria chronic	1	0
Skin disorders SOC TOTAL	978	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	2	0
Postmenopause	1	0
<i>Dependents</i>		
Sick relative	1	0
<i>Dietary and nutritional issues</i>		
Kosher diet	1	0
<i>Disability issues</i>		
Bedridden	3	0
Sight disability	1	0
Walking disability	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
<i>Sexuality issues</i>		
Homosexuality	1	0
Social circumstances SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	5	0
Immunisation	1	0
<i>Limb therapeutic procedures</i>		
Foot amputation	1	0
<i>Therapeutic procedures NEC</i>		
Hospitalisation	1	0
Surgical & medical procedures SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Tyramine reaction	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	4	0
<i>Circulatory collapse and shock</i>		
Shock	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	40	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	2	0
Embolism	6	0
Embolism venous	1	0
Post thrombotic syndrome	1	0
Thrombosis	32	1
Venous thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Infarction	1	0
Vasospasm	2	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary fragility	1	0
Vascular pain	5	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	4	0
Deep vein thrombosis	24	0
Peripheral artery thrombosis	1	0
Superficial vein thrombosis	2	0
Thrombophlebitis	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Erythromelalgia	1	0
Flushing	11	0
Hot flush	25	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Intermittent claudication	1	0
Peripheral coldness	25	0
Peripheral ischaemia	1	0
Poor peripheral circulation	3	0
Raynaud's phenomenon	3	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	4	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	12	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Systolic hypertension	1	0
Vascular hypotensive disorders		
Hypotension	15	0
Vasculitides NEC		
Vasculitis	4	1
Vena caval embolism and thrombosis		
Vena cava thrombosis	1	1
Vascular disorders SOC TOTAL	251	3
TOTAL REACTIONS FOR DRUG	16937	18
TOTAL REPORTS	4854	
TOTAL FATAL OUTCOME REPORTS		18