

COVID-19 Moderna Vaccine Analysis Print

All UK spontaneous reports received up to and including 22/09/21 for COVID-19 Moderna vaccine.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 24-Sep-2021

Data Lock Date: 22-Sep-2021 18:30:09

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	4	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	133	0
Lymphadenitis	10	0
Lymphadenopathy	778	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	18	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	958	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	6	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	368	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	18	0
Myocardial infarction	13	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	2	0
Left ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	74	0
<i>Noninfectious pericarditis</i>		
Pericarditis	45	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	8	0
Bradycardia	8	0
Cardiac fibrillation	1	0
Cardiac flutter	34	0
Extrasystoles	14	0
Tachycardia	38	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
Atrial flutter	1	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	2	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	653	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	5	0
Ear discomfort	3	0
Ear disorder	1	0
Ear pain	113	0
Ear swelling	2	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>Hearing losses</i>		
Deafness	17	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	17	0
Sudden hearing loss	6	0
<i>Hyperacusia</i>		
Hyperacusis	5	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	12	0
Tinnitus	169	0
Vertigo	128	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	491	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	4	0
Ovulation delayed	8	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	25	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>		
Chorioretinopathy	1	0
Vitreous floaters	7	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	16	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	4	0
<i>Lacrimation disorders</i>		
Dry eye	14	0
Lacrimation increased	5	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	7	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	121	0
Eye swelling	37	0
Ocular discomfort	4	0
Periorbital oedema	2	0
Periorbital swelling	9	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	10	0
Eye pruritus	16	0
Ocular hyperaemia	17	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	8	0
Foreign body sensation in eyes	1	0
Hypoaesthesia eye	1	0
Photophobia	48	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
Papilloedema	1	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	1	0
<i>Pupil disorders</i>		
Mydriasis	3	0
<i>Refractive and accommodative disorders</i>		

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Eye disorders Eye disorders cont'd		
Accommodation disorder	1	0
Astigmatism	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	1	0
<i>Retinopathies NEC</i>		
Acute zonal occult outer retinopathy	1	0
Serous retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	4	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	14	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	6	0
Vision blurred	155	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	16	0
Blindness transient	3	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	25	0
Eye disorders SOC TOTAL	590	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	1	0
<i>Anal and rectal pains</i>		
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ulcerative	3	0
Crohn's disease	7	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	2	0
Hyperaesthesia teeth	4	0
Toothache	12	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	458	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	51	0
Epigastric discomfort	1	0
Eructation	6	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	5	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	34	0
Flatulence	16	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	138	0
Abdominal pain lower	12	0
Abdominal pain upper	316	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	12	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	20	0
Gastrooesophageal reflux disease	13	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Fistula of small intestine	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	57	0
Anal incontinence	3	0
Breath odour	4	0
Dysphagia	16	0
Odynophagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	4	0
Irritable bowel syndrome	7	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	6	0
Gingival swelling	4	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	5	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	8	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	1870	0
Retching	12	0
Vomiting	644	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	4	0
Melaena	1	0
Upper gastrointestinal haemorrhage	2	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dry mouth	51	0
Lip dry	4	0
Saliva altered	2	0
Salivary hypersecretion	6	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	2	0
Oral blood blister	2	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Coating in mouth	2	0
Hypoaesthesia oral	40	0
Lip discolouration	1	0
Lip pain	3	0
Lip pruritus	1	0
Oral discomfort	3	0
Oral mucosal roughening	1	0
Oral pain	9	0
Oral pruritus	1	0
Paraesthesia oral	65	0
Oral soft tissue swelling and oedema		
Lip swelling	74	0
Mouth swelling	9	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	2	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	1	0
Salivary gland enlargements		
Submaxillary gland enlargement	1	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	3	0
Mouth ulceration	42	0
Stomatitis	3	0
Tongue disorders		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
Tongue signs and symptoms		
Glossodynia	15	0
Swollen tongue	40	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	2	0
Tongue discomfort	2	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	4228	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Puncture site bruise	5	0
Puncture site pain	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	6	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	9	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	4	0
Application site warmth	1	0
Instillation site erythema	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	217	0
Chronic fatigue syndrome	3	0
Fatigue	2473	0
Malaise	418	0
<i>Death and sudden death</i>		
Death	8	8
<i>Febrile disorders</i>		
Pyrexia	2789	1
<i>Feelings and sensations NEC</i>		
Chills	1503	0
Feeling abnormal	219	0
Feeling cold	101	0
Feeling drunk	11	0
Feeling hot	175	0
Feeling jittery	8	0
Feeling of body temperature change	50	0
Hangover	12	0
Hunger	13	0
Sensation of blood flow	1	0
Sensation of foreign body	4	0
Temperature intolerance	16	0
Thirst	47	0
<i>Gait disturbances</i>		
Gait disturbance	16	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	11	0
Crying	21	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Foaming at mouth	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Illness	233	0
Induration	7	0
Influenza like illness	274	0
Irritability postvaccinal	1	0
Local reaction	12	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1162	0
Screaming	3	0
Secretion discharge	2	0
Swelling	612	0
Swelling face	70	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Inflammation	79	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	1	0
Infusion site mass	1	0
Infusion site pain	4	0
Infusion site pruritus	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	4	0
Injection site bruising	9	0
Injection site discolouration	1	0
Injection site erythema	108	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	5	0
Injection site indentation	2	0
Injection site inflammation	9	0
Injection site irritation	1	0
Injection site joint erythema	4	0
Injection site mass	112	0
Injection site oedema	2	0
Injection site pain	360	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	82	0
Injection site rash	149	0
Injection site reaction	13	0
Injection site swelling	50	0
Injection site urticaria	43	0
Injection site vesicles	1	0
Injection site warmth	54	0
Interactions		
Alcohol interaction	1	0
Drug interaction	1	0

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General disorders General disorders cont'd		
Mass conditions NEC		
Cyst	4	0
Mass	18	0
Nodule	3	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	2	0
Localised oedema	1	0
Oedema	4	0
Oedema peripheral	6	0
Pain and discomfort NEC		
Axillary pain	392	0
Chest discomfort	162	0
Chest pain	442	0
Discomfort	72	0
Facial pain	13	0
Inflammatory pain	1	0
Non-cardiac chest pain	2	0
Pain	1237	0
Tenderness	105	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	14	0
Drug ineffective	10	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	2	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	11	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	212	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	15	0
Vaccination site inflammation	8	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	2	0
Vaccination site mass	50	0
Vaccination site movement impairment	7	0

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General disorders General disorders cont'd		
Vaccination site oedema	1	0
Vaccination site pain	190	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	55	0
Vaccination site rash	113	0
Vaccination site reaction	3	0
Vaccination site scar	1	0
Vaccination site swelling	133	0
Vaccination site urticaria	9	0
Vaccination site vesicles	1	0
Vaccination site warmth	96	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	4	0
General disorders SOC TOTAL	15105	10

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	4	0
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
Jaundice cholestatic	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatic steatosis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	13	0

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	182	0
Infusion related hypersensitivity reaction	10	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Allergy to vaccine	7	0
Drug hypersensitivity	5	0
Milk allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	34	0
Anaphylactic shock	4	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	14	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	29	0
Immune-mediated adverse reaction	1	0
Sensitisation	3	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	319	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	4	0
Diverticulitis	2	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	48	0
Folliculitis	1	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	3	0
<i>Candida infections</i>		
Candida infection	4	0
Oral candidiasis	1	0
Vulvovaginal candidiasis	7	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	2	0
Myelitis	1	0
<i>Coronavirus infections</i>		
COVID-19	64	0
COVID-19 pneumonia	3	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		
Ear infection	3	0
Labyrinthitis	2	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	9	0
Eye infection	2	0
Eyelid boil	1	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<i>Fungal infections NEC</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Fungal infection	2	0
Fungal skin infection	2	0
Overgrowth fungal	1	1
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Herpes viral infections</i>		
Genital herpes	6	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	40	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	37	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	53	0
Injection site infection	1	0
Localised infection	13	0
Respiratory tract infection	1	0
Vaccination site infection	3	0
Vestibulitis	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	2	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	214	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	3	0
Lower respiratory tract infection	15	0
Pneumonia	8	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Impetigo	2	0
Pustule	8	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	8	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Staphylococcal infections</i>		
Furuncle	4	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	145	0
Peritonsillar abscess	1	0
Pharyngitis	2	0
Rhinitis	2	0
Sinusitis	7	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	5	0
Kidney infection	2	0
Urinary tract infection	17	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Gastroenteritis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	4	0
Sweating fever	24	0
Viral infection	1	0
Viral labyrinthitis	1	0
Viral pharyngitis	2	0
Viral rash	4	0
Infections SOC TOTAL	868	2

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cardiovascular injuries</i>		
Heart injury	1	0
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	6	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	8	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	3	0
Foetal exposure during pregnancy	4	0
Maternal exposure during breast feeding	338	0
Maternal exposure during pregnancy	164	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	2	0
Heat stroke	6	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	4	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	4	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	2	0
Muscle injury	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	8	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	3	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	3	0
Bite	1	0
Electric shock	4	0
Fall	15	0
Injury	2	0
Wound complication	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Wound haemorrhage	1	0
Non-site specific procedural complications		
Injection related reaction	3	0
Procedural pain	1	0
Off label uses		
Off label use	1	0
Overdoses NEC		
Overdose	7	0
Peripheral nerve injuries		
Sciatic nerve injury	1	0
Poisoning and toxicity		
Toxicity to various agents	1	0
Product administration errors and issues		
Expired product administered	6	0
Inappropriate schedule of product administration	7	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Poor quality product administered	1	0
Product administered at inappropriate site	1	0
Product dose omission issue	3	0
Wrong product administered	1	0
Product dispensing errors and issues		
Product dispensing error	1	0
Radiation injuries		
Sunburn	9	0
Site specific injuries NEC		
Head injury	5	0
Limb injury	15	0
Skin injuries NEC		
Contusion	165	0
Scar	9	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
Stoma complications		
Stoma site oedema	1	0
Thermal burns		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	6	0
Thermal burns of eye	1	0
Vaccination related complications		
Vaccination complication	3	0
Injuries SOC TOTAL	852	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen consumption decreased	1	0
Oxygen saturation decreased	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	1	0
Blood glucose increased	2	0
<i>Cardiac auscultatory investigations</i>		
Heart sounds	3	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Cholesterol analyses</i>		
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram P wave abnormal	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	4	0
<i>Fertility analyses</i>		
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate increased	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
X-ray with contrast upper gastrointestinal tract	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	76	0
Heart rate abnormal	6	0
Heart rate decreased	5	0
Heart rate increased	126	0
Heart rate irregular	21	0
Heart rate variability decreased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	3	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	2	0
Blood bilirubin increased	1	0
Liver function test abnormal	6	0
Liver function test increased	1	0
<i>Mineral and electrolyte analyses</i>		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	1	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	36	0
Body temperature abnormal	2	0
Body temperature decreased	3	0
Body temperature fluctuation	11	0
Body temperature increased	37	0
Grip strength	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	6	0
Skin temperature	8	0
Temperature difference of extremities	1	0
Weight decreased	11	0
Weight increased	6	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count decreased	7	0
Protein analyses NEC		
C-reactive protein increased	4	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Troponin T increased	1	0
Troponin increased	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	3	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased	1	0
Urinalysis NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood urine present	6	0
Protein urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	3	0
Urine output decreased	1	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	8	0
Blood pressure measurement	3	0
<i>Virus identification and serology</i>		
Coronavirus test	4	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	2	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	500	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	150	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	6	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Diabetes mellitus inadequate control	1	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	8	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	5	0
Feeding disorder	18	0
Food aversion	3	0
Neonatal insufficient breast milk syndrome	4	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	5	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	42	0
<i>Total fluid volume increased</i>		
Fluid retention	8	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	275	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	11	0
Arthritis enteropathic	1	0
Arthropathy	4	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	31	0
Bone swelling	1	0
Pain in jaw	35	0
Spinal pain	7	0
<i>Bursal disorders</i>		
Bursitis	7	0
<i>Cartilage disorders</i>		
Costochondritis	8	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
Reynold's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Joint lock	3	0
Periarthritis	16	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	856	0
Joint noise	3	0
Joint stiffness	31	0
Joint swelling	29	0
Joint vibration	1	0
Joint warmth	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
<i>Muscle infections and inflammations</i>		
Myositis	5	0
<i>Muscle pains</i>		
Fibromyalgia	6	0
Myalgia	1342	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle fatigue	42	0
Muscle haemorrhage	1	0
Muscle spasms	240	0
Muscle swelling	7	0
Muscle tightness	17	0
Muscle twitching	47	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle rigidity	2	0
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	83	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mastication disorder	1	0
Mobility decreased	5	0
Muscle contracture	1	0
Musculoskeletal stiffness	210	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dupuytren's contracture	1	0
Fasciitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	312	0
Flank pain	6	0
Limb discomfort	196	0
Musculoskeletal chest pain	17	0
Musculoskeletal discomfort	8	0
Musculoskeletal pain	2	0
Neck pain	156	0
Pain in extremity	1854	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	4	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	23	0
Groin pain	10	0
Neck mass	4	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	2	0
Arthritis reactive	3	0
Axial spondyloarthritis	1	0
<i>Synovial disorders</i>		
Synovial cyst	3	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Trigger finger	2	0
Muscle & tissue disorders SOC TOTAL	5688	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	4	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
Haemangioma of skin	3	0
Skin papilloma	3	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	2	1
Cerebral infarction	2	0
Cerebrovascular accident	8	1
Haemorrhage intracranial	1	0
Intracranial haematoma	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	2	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	24	0
Coordination abnormal	1	0
Dysstasia	4	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	7	0
Lethargy	197	0
Loss of consciousness	114	0
Somnolence	123	0
Stupor	1	0
Syncope	569	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	2	0
Dyskinesia	5	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	5	0
Movement disorder	5	0
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Facial cranial nerve disorders		
Bell's palsy	33	0
Facial paralysis	24	0
Facial paresis	2	0
Facial spasm	4	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	1	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cluster headache	28	0
Cold-stimulus headache	3	0
Drug withdrawal headache	1	0
Headache	3059	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Sinus headache	34	0
Tension headache	60	0
Thunderclap headache	1	0
Vascular headache	2	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	2	0
Lumbar spinal cord and nerve root disorders		
Sciatica	2	0
Memory loss (excl dementia)		
Amnesia	17	0
Memory impairment	17	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	9	0
Disturbance in attention	44	0
Mental impairment	4	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	337	0
Migraine with aura	27	0
Migraine without aura	2	0
Retinal migraine	2	0
Typical aura without headache	1	0
Vestibular migraine	2	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Muscle tone abnormal		
Hypotonia	3	0
Stiff leg syndrome	2	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	10	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Narcolepsy	2	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	2	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	5	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Dizziness	1569	0
Dizziness exertional	2	0
Dizziness postural	67	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	30	0
Inability to crawl	1	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	1	0
Presyncope	132	0
Unresponsive to stimuli	9	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	2	0
Muscle spasticity	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	16	0
Parosmia	11	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	3	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	1	0
Burning sensation	51	0
Formication	2	0
Hemianaesthesia	1	0
Hyperaesthesia	28	0
Hypoaesthesia	314	0
Paraesthesia	449	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	5	0
Hemiplegia	4	0
Monoparesis	9	0
Monoplegia	12	0
Paralysis	11	0
Paresis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Neuritis	1	0
Neuropathy peripheral	6	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	8	0
Febrile convulsion	3	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	99	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	32	0
Allodynia	1	0
Complex regional pain syndrome	1	0
Dysgeusia	103	0
Electric shock sensation	2	0
Hypogeusia	1	0
Neuralgia	42	0
Post herpetic neuralgia	2	0
Restless legs syndrome	23	0
Sensory disturbance	8	0
Sensory loss	10	0
Taste disorder	16	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	18	0
Incoherent	5	0
Slow speech	3	0
Speech disorder	8	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	6	0
<i>Tremor (excl congenital)</i>		
Tremor	195	0
<i>Trigeminal disorders</i>		
Facial neuralgia	1	0
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	8225	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	34	2
<i>Foetal complications NEC</i>		
Foetal hypokinesia	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	3	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
Pregnancy conditions SOC TOTAL	56	3

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Device malfunction events NEC</i>		
Thrombosis in device	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
<i>Product physical issues</i>		
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
null SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Flat affect	3	0
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	10	0
Anxiety	147	0
Nervousness	23	0
Stress	13	0
Tension	6	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	0
<i>Behaviour and socialisation disturbances</i>		
Disinhibition	1	0
Paranoia	4	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	28	0
<i>Confusion and disorientation</i>		
Confusional state	75	0
Disorientation	32	0
<i>Deliria</i>		
Delirium	14	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	45	0
Depression suicidal	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	8	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	165	0
Middle insomnia	9	0
Terminal insomnia	9	0
<i>Dyssomnias</i>		
Poor quality sleep	36	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	7	0
Emotional disorder	14	0
Emotional distress	7	0
Euphoric mood	7	0
Irritability	31	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Mood altered	8	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
Fear of death	2	0
Fear of injection	6	0
Phobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	10	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	48	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	30	0
<i>Mental disorders NEC</i>		
Mental disorder	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	47	0
Feeling of despair	2	0
Tearfulness	2	0
<i>Mood alterations with manic symptoms</i>		
Mania	3	0
<i>Mood disorders NEC</i>		
Apathy	5	0
Listless	2	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
<i>Orgasmic disorders and disturbances</i>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	35	0
Panic reaction	7	0
<i>Parasomnias</i>		
Abnormal dreams	20	0
Nightmare	22	0
Sleep talking	1	0
Sleep terror	1	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	7	0
<i>Psychiatric symptoms NEC</i>		
Psychiatric symptom	1	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sexual desire disorders</i>		
Libido decreased	3	0
Libido increased	1	0
Loss of libido	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	20	0
<i>Somatic symptom disorders</i>		
Conversion disorder	2	0
Habit cough	4	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	3	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
Head banging	1	0
<i>Stress disorders</i>		
Post-traumatic stress disorder	1	0
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	5	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	1055	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	4	0
Dysuria	6	0
Incontinence	2	0
Micturition urgency	4	0
Pollakiuria	15	0
Urethral pain	1	0
Urinary incontinence	6	0
Urinary retention	1	0
Urinary straining	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	4	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	8	0
Haematuria	2	0
Urine abnormality	4	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	5	0
Renal pain	41	0
Renal & urinary disorders SOC TOTAL	114	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	3	0
<i>Breast disorders NEC</i>		
Breast enlargement	3	0
Breast mass	8	0
Fibrocystic breast disease	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	61	0
Breast swelling	6	0
Breast tenderness	7	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	6	0
Nocturnal emission	1	0
Organic erectile dysfunction	6	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
Lactation puerperal increased	2	0
Suppressed lactation	4	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	6	0
Premature menopause	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	8	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	263	0
Intermenstrual bleeding	129	0
Menstrual discomfort	1	0
Menstrual disorder	232	0
Menstruation irregular	375	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	10	0
Premenstrual syndrome	11	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	57	0
Hypomenorrhoea	75	0
Menstruation delayed	492	0
Oligomenorrhoea	17	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	630	0
Menometrorrhagia	5	0
Polymenorrhoea	93	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Ovarian cyst	4	0
Polycystic ovaries	3	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	14	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	9	0
Pelvic haemorrhage	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	3	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	2	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	13	0
Pruritus genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	2	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	0
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	8	0
Testicular swelling	3	0
<i>Uterine disorders NEC</i>		
Endometriosis	9	0
Uterine haemorrhage	5	0
Uterine pain	2	0
<i>Uterine tone disorders</i>		
Uterine spasm	11	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	171	0
Vaginal ulceration	1	0
Vulval haemorrhage	5	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	11	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal pain	2	0
Reproductive & breast disorders SOC TOTAL	2830	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	401	0
Dyspnoea exertional	3	0
Hyperventilation	4	0
Hypopnoea	9	0
Hypoventilation	1	0
Irregular breathing	1	0
Respiration abnormal	8	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	25	0
Asthma late onset	1	0
Wheezing	37	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	199	0
Productive cough	16	0
Sputum discoloured	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	2	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	13	0
Pulmonary haemorrhage	1	0
Pulmonary pain	9	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	26	0
<i>Nasal disorders NEC</i>		
Epistaxis	82	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	5	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	36	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Tonsillar erythema	1	0
Tonsillar hypertrophy	8	0
<i>Pleural infections and inflammations</i>		
Pleurisy	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	2	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	18	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	6	0
Catarrh	1	0
Choking	2	0
Dry throat	15	0
Dysphonia	6	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	3	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	242	0
Paranasal sinus discomfort	5	0
Rhinalgia	2	0
Rhinorrhoea	63	0
Sinus pain	27	0
Sneezing	16	0
Throat irritation	20	0
Throat tightness	33	0
Upper-airway cough syndrome	1	0
Yawning	4	0
Respiratory disorders SOC TOTAL	1396	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	22	0
<i>Alopecias</i>		
Alopecia	24	0
Alopecia areata	4	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	21	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	146	0
Hidradenitis	1	0
Hyperhidrosis	441	0
Miliaria	46	0
Night sweats	92	0
<i>Bullous conditions</i>		
Blister	38	0
Blister rupture	1	0
Blood blister	1	0
Dermatitis bullous	1	0
Erythema multiforme	10	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	54	0
Pain of skin	50	0
Papule	19	0
Scab	4	0
Scar pain	2	0
Sensitive skin	73	0
Skin burning sensation	32	0
Skin discolouration	18	0
Skin induration	6	0
Skin lesion	20	0
Skin reaction	76	0
Skin sensitisation	9	0
Skin swelling	12	0
Skin tightness	4	0
Skin warm	146	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	18	0
Dermatitis allergic	72	0
Dermatitis atopic	9	0
Dermatitis contact	5	0
Dyshidrotic eczema	9	0
Eczema	33	0
Eczema nummular	2	0
Neurodermatitis	1	0
Skin irritation	17	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	717	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	9	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	5	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	13	0
<i>Pilar disorders NEC</i>		
Piloerection	8	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	1543	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	15	0
<i>Purpura and related conditions</i>		
Petechiae	14	0
Purpura	7	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	1802	0
Rash erythematous	711	0
Rash macular	117	0
Rash maculo-papular	1	0
Rash morbilliform	4	0
Rash papular	128	0
Rash pruritic	408	0
Rash vesicular	4	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin mass	4	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin ulcer	2	0
Skin cysts and polyps		
Dermal cyst	6	0
Skin dystrophies		
Keloid scar	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin injuries and mechanical dermatoses		
Needle track marks	1	0
Skin vasculitides		
Cutaneous vasculitis	2	0
Skin vasomotor conditions		
Livedo reticularis	3	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	254	0
Urticaria cholinergic	1	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	7362	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 24-Sep-2021

Data Lock Date: 22-Sep-2021 18:30:09

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	1	0
Menopause	4	0
<i>Disability issues</i>		
Bedridden	3	0
Immobile	2	0
Impaired driving ability	1	0
Sight disability	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	5	0
Social circumstances SOC TOTAL	20	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Immunisations</i>		
COVID-19 immunisation	12	0
Immunisation	18	0
<i>Joint therapeutic procedures</i>		
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	3	0
<i>Therapeutic procedures NEC</i>		
Bed rest	2	0
Botulinum toxin injection	1	0
Hospitalisation	1	0
Injection	15	0
Interchange of vaccine products	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	60	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
Neurogenic shock	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	4	0
Haemorrhage	139	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	6	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	2	0
Embolism venous	1	0
Thrombosis	31	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	6	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	2	0
Deep vein thrombosis	10	0
Thrombophlebitis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	5	0
Flushing	27	0
Hot flush	164	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	32	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	57	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	46	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Hypotension	57	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	621	0
TOTAL REACTIONS FOR DRUG	52344	19
TOTAL REPORTS	16361	
TOTAL FATAL OUTCOME REPORTS		19