

COVID-19 Moderna vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 25/08/21 for Moderna vaccine analysis print.

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: 26-Aug-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 25-Aug-2021 18:30:56
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	3	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	122	0
Lymphadenitis	9	0
Lymphadenopathy	695	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	17	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	861	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	308	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	15	0
Myocardial infarction	11	1
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	43	0
<i>Noninfectious pericarditis</i>		
Pericarditis	32	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	7	0
Bradycardia	7	0
Cardiac flutter	31	0
Extrasystoles	12	0
Tachycardia	31	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	1	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	523	1

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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	4	0
Ear discomfort	2	0
Ear disorder	1	0
Ear pain	99	0
Ear swelling	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
<i>Hearing losses</i>		
Deafness	15	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	14	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	10	0
Tinnitus	156	0
Vertigo	116	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	441	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>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
Ovulation delayed	8	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	2	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	22	0

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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	6	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	13	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	3	0
<i>Lacrimation disorders</i>		
Dry eye	12	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	108	0
Eye swelling	36	0
Ocular discomfort	3	0
Periorbital oedema	2	0
Periorbital swelling	7	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	8	0
Eye pruritus	15	0
Ocular hyperaemia	15	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	6	0
Foreign body sensation in eyes	1	0
Hypoaesthesia eye	1	0
Photophobia	39	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	2	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
Metamorphopsia	1	0
Photopsia	4	0
Vision blurred	136	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	14	0
Blindness transient	2	0
Blindness unilateral	1	0
Visual acuity reduced	1	0
Visual impairment	21	0
Eye disorders SOC TOTAL	519	0

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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	2	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	2	0
Crohn's disease	5	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	4	0
Toothache	12	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	411	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	45	0
Epigastric discomfort	1	0
Eructation	4	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	5	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	29	0
Flatulence	13	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	124	0
Abdominal pain lower	10	0
Abdominal pain upper	278	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	8	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	17	0
Gastrooesophageal reflux disease	11	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Stomach mass	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<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	53	0
Anal incontinence	3	0
Breath odour	3	0
Dysphagia	15	0
Odynophagia	5	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	3	0
Irritable bowel syndrome	5	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	2	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	6	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	1620	0
Retching	11	0
Vomiting	538	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	4	0
Melaena	1	0
Upper gastrointestinal haemorrhage	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	45	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	6	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
Oral blood blister	2	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	1	0
Coating in mouth	2	0
Hypoaesthesia oral	37	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	62	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	64	0
Mouth swelling	9	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	2	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	1	0
<i>Salivary gland enlargements</i>		
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	3	0
Lip ulceration	2	0
Mouth ulceration	41	0
Stomatitis	2	0
<i>Tongue disorders</i>		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	3	0
<i>Tongue signs and symptoms</i>		
Glossodynia	14	0
Swollen tongue	32	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	2	0
Tongue discomfort	2	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
<i>Tooth missing</i>		
Tooth loss	1	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastrointestinal disorders SOC TOTAL	3684	0

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General disorders		
<i>Administration site reactions NEC</i>		
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	5	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	181	0
Chronic fatigue syndrome	2	0
Fatigue	2224	0
Malaise	368	0
<i>Death and sudden death</i>		
Death	7	7
<i>Febrile disorders</i>		
Pyrexia	2349	1
<i>Feelings and sensations NEC</i>		
Chills	1262	0
Feeling abnormal	188	0
Feeling cold	87	0
Feeling drunk	11	0
Feeling hot	156	0
Feeling jittery	7	0
Feeling of body temperature change	40	0
Hangover	11	0
Hunger	11	0
Sensation of blood flow	1	0
Sensation of foreign body	4	0
Temperature intolerance	15	0
Thirst	43	0
<i>Gait disturbances</i>		
Gait disturbance	14	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	7	0
Crying	20	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Foaming at mouth	2	0
Illness	191	0

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General disorders General disorders cont'd		
Induration	7	0
Influenza like illness	240	0
Irritability postvaccinal	1	0
Local reaction	12	0
Moaning	1	0
Perforation	1	0
Peripheral swelling	1063	0
Screaming	2	0
Secretion discharge	1	0
Swelling	565	0
Swelling face	62	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Inflammation	70	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	2	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	101	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	4	0
Injection site indentation	2	0
Injection site inflammation	8	0
Injection site irritation	1	0
Injection site joint erythema	4	0
Injection site mass	104	0
Injection site oedema	2	0
Injection site pain	334	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	80	0
Injection site rash	146	0
Injection site reaction	11	0
Injection site swelling	46	0
Injection site urticaria	43	0
Injection site vesicles	1	0
Injection site warmth	50	0
Interactions		
Alcohol interaction	1	0
Drug interaction	1	0
Mass conditions NEC		
Cyst	4	0

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General disorders General disorders cont'd		
Mass	16	0
Nodule	3	0
<i>Mucosal findings abnormal</i>		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
<i>Oedema NEC</i>		
Face oedema	1	0
Localised oedema	1	0
Oedema	4	0
Oedema peripheral	4	0
<i>Pain and discomfort NEC</i>		
Axillary pain	354	0
Chest discomfort	133	0
Chest pain	354	0
Discomfort	63	0
Facial pain	13	0
Inflammatory pain	1	0
Non-cardiac chest pain	2	0
Pain	1113	0
Tenderness	93	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	15	0
Adverse event	1	0
Drug ineffective	9	0
Drug intolerance	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	1	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
<i>Ulcers NEC</i>		
Ulcer	2	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	11	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	201	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	15	0
Vaccination site inflammation	7	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	47	0
Vaccination site movement impairment	6	0
Vaccination site oedema	1	0
Vaccination site pain	182	0
Vaccination site papule	2	0

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General disorders General disorders cont'd		
Vaccination site pruritus	52	0
Vaccination site rash	104	0
Vaccination site reaction	2	0
Vaccination site swelling	125	0
Vaccination site urticaria	7	0
Vaccination site vesicles	1	0
Vaccination site warmth	90	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	2	0
General disorders SOC TOTAL	13330	8

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	3	0
<i>Cholestasis and jaundice</i>		
Jaundice cholestatic	2	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	10	0

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	3	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	170	0
Infusion related hypersensitivity reaction	9	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	12	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	6	0
Drug hypersensitivity	3	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	28	0
Anaphylactic shock	4	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	13	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	25	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	288	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	3	0
Diverticulitis	2	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	47	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	2	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	52	0
COVID-19 pneumonia	1	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
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>		
Fungal infection	2	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
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 zoster	39	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	30	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	50	0
Injection site infection	1	0
Localised infection	10	0
Respiratory tract infection	1	0
Vaccination site infection	2	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	185	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	3	0
Lower respiratory tract infection	15	0
Pneumonia	7	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
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
<i>Staphylococcal infections</i>		
Furuncle	3	0
<i>Tinea infections</i>		

Case Series Drug Analysis Print

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Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Body tinea	2	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	135	0
Peritonsillar abscess	1	0
Pharyngitis	1	0
Rhinitis	1	0
Sinusitis	7	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	4	0
Kidney infection	1	0
Urinary tract infection	16	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Gastroenteritis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	3	0
Sweating fever	19	0
Viral infection	1	0
Viral pharyngitis	2	0
Viral rash	4	0
Infections SOC TOTAL	776	2

Case Series Drug Analysis Print

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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	7	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	4	0
Maternal exposure during breast feeding	296	0
Maternal exposure during pregnancy	138	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	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	7	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	6	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	14	0
Injury	1	0
Wound complication	2	0
Wound haemorrhage	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Non-site specific procedural complications</i>		
Injection related reaction	3	0
Procedural pain	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	5	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	5	0
Inappropriate schedule of product administration	6	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	1	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Radiation injuries</i>		
Sunburn	9	0
<i>Site specific injuries NEC</i>		
Head injury	5	0
Limb injury	12	0
<i>Skin injuries NEC</i>		
Contusion	148	0
Scar	8	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<i>Stoma complications</i>		
Stoma site oedema	1	0
<i>Thermal burns</i>		
Thermal burn	6	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Injuries SOC TOTAL	748	0

Case Series Drug Analysis Print

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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 decreased	1	0
Blood glucose increased	2	0
<i>Cardiac auscultatory investigations</i>		
Heart sounds	2	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	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-T segment abnormal	1	0
Electrocardiogram T wave inversion	2	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	3	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	66	0
Heart rate abnormal	5	0
Heart rate decreased	5	0
Heart rate increased	105	0
Heart rate irregular	19	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	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	5	0
Liver function test increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Visual tracking test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	35	0
Body temperature abnormal	1	0
Body temperature decreased	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Body temperature fluctuation	9	0
Body temperature increased	33	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	1	0
Respiratory rate decreased	2	0
Respiratory rate increased	6	0
Skin temperature	8	0
Temperature difference of extremities	1	0
Weight decreased	9	0
Weight increased	6	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	7	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Reproductive hormone analyses</i>		
Pregnancy test	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Troponin T increased	1	0
Troponin increased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	3	0
<i>Urinalysis NEC</i>		
Blood urine present	4	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	7	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	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
SARS-CoV-2 test positive	3	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	435	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	125	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	4	0
Hypophagia	1	0
Increased appetite	5	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	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	5	0
Feeding disorder	15	0
Food aversion	3	0
Neonatal insufficient breast milk syndrome	3	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	32	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	232	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	10	0
Arthritis enteropathic	1	0
Arthropathy	4	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	25	0
Bone swelling	1	0
Pain in jaw	32	0
Spinal pain	4	0
<i>Bursal disorders</i>		
Bursitis	5	0
<i>Cartilage disorders</i>		
Costochondritis	7	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	15	0
Rotator cuff syndrome	2	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	743	0
Joint noise	1	0
Joint stiffness	25	0
Joint swelling	25	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	4	0
<i>Muscle pains</i>		
Fibromyalgia	5	0
Myalgia	1193	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle fatigue	37	0
Muscle haemorrhage	1	0
Muscle spasms	203	0
Muscle swelling	6	0
Muscle tightness	14	0
Muscle twitching	42	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	73	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mastication disorder	1	0
Mobility decreased	3	0
Muscle contracture	1	0
Musculoskeletal stiffness	182	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	261	0
Flank pain	6	0
Limb discomfort	176	0
Musculoskeletal chest pain	14	0
Musculoskeletal discomfort	6	0
Musculoskeletal pain	1	0
Neck pain	128	0
Pain in extremity	1690	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	22	0
Groin pain	8	0
Neck mass	3	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	5028	0

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Reaction Name	Total	Fatal
Neoplasms		
<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	19	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	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	7	0
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	21	0
Coordination abnormal	1	0
Dysstasia	3	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	7	0
Lethargy	169	0
Loss of consciousness	102	0
Somnolence	110	0
Stupor	1	0
Syncope	516	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	2	0
Dyskinesia	5	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Hyperkinesia	1	0
Hypokinesia	5	0
Movement disorder	5	0
Psychomotor hyperactivity	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	32	0
Facial paralysis	22	0
Facial paresis	2	0
Facial spasm	4	0
<i>Glossopharyngeal nerve disorders</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cluster headache	24	0
Cold-stimulus headache	2	0
Drug withdrawal headache	1	0
Headache	2636	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Sinus headache	31	0
Tension headache	47	0
Thunderclap headache	1	0
Vascular headache	2	0
Increased intracranial pressure disorders		
Intracranial pressure increased	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	2	0
Memory loss (excl dementia)		
Amnesia	14	0
Memory impairment	14	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	7	0
Disturbance in attention	39	0
Mental impairment	3	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	270	0
Migraine with aura	26	0
Migraine without aura	2	0
Retinal migraine	2	0
Typical aura without headache	1	0
Vestibular migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	1	0
Muscle tone abnormal		
Hypotonia	2	0
Narcolepsy and hypersomnia		
Hypersomnia	9	0
Narcolepsy	2	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurologic visual problems NEC		
Tunnel vision	5	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	1404	0
Dizziness exertional	2	0
Dizziness postural	56	0
Drooling	2	0
Head discomfort	28	0
Neurological symptom	4	0
Persistent postural-perceptual dizziness	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Presyncope	113	0
Unresponsive to stimuli	8	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0
Olfactory nerve disorders		
Anosmia	11	0
Parosmia	9	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning sensation	44	0
Formication	2	0
Hemianaesthesia	1	0
Hyperaesthesia	26	0
Hypoaesthesia	277	0
Paraesthesia	395	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	5	0
Hemiplegia	3	0
Monoparesis	8	0
Monoplegia	11	0
Paralysis	10	0
Paresis	1	0
Parkinson's disease and parkinsonism		
Reduced facial expression	1	0
Peripheral neuropathies NEC		
Neuritis	1	0
Neuropathy peripheral	5	0
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Febrile convulsion	3	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	88	0
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	2	0
Sensory abnormalities NEC		
Ageusia	26	0
Allodynia	1	0
Dysgeusia	95	0
Electric shock sensation	2	0
Hypogeusia	1	0
Neuralgia	37	0
Post herpetic neuralgia	2	0
Restless legs syndrome	20	0
Sensory disturbance	7	0
Sensory loss	7	0
Taste disorder	14	0
Vibratory sense increased	1	0
Sleep disturbances NEC		

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Sleep deficit	1	0
Speech and language abnormalities		
Dysarthria	14	0
Incoherent	5	0
Slow speech	3	0
Speech disorder	7	0
Spinal cord and nerve root disorders NEC		
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	6	0
Tremor (excl congenital)		
Tremor	166	0
Trigeminal disorders		
Facial neuralgia	1	0
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	7173	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	27	0
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	2	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	7	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	49	1

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
null SOC TOTAL	12	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Flat affect	3	0
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	10	0
Anxiety	126	0
Nervousness	22	0
Stress	12	0
Tension	5	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	0
<i>Behaviour and socialisation disturbances</i>		
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	27	0
<i>Confusion and disorientation</i>		
Confusional state	67	0
Disorientation	31	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	42	0
Depression suicidal	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Dissociation	5	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	142	0
Middle insomnia	8	0
Terminal insomnia	9	0
<i>Dyssomnias</i>		
Poor quality sleep	31	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	7	0
Emotional disorder	11	0
Emotional distress	7	0
Euphoric mood	7	0
Irritability	27	0
Mood altered	7	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Fear	1	0
Fear of death	2	0
Fear of injection	7	0
Phobia	1	0
Fluctuating mood symptoms		
Mood swings	9	0
Hallucinations (excl sleep-related)		
Hallucination	43	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
Somatic hallucination	1	0
Increased physical activity levels		
Restlessness	27	0
Mental disorders NEC		
Mental disorder	3	0
Mood alterations with depressive symptoms		
Depressed mood	40	0
Feeling of despair	2	0
Tearfulness	2	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	5	0
Listless	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Orgasmic disorders and disturbances		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	29	0
Panic reaction	6	0
Parasomnias		
Abnormal dreams	17	0
Nightmare	20	0
Sleep talking	1	0
Sleep terror	1	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	3	0
Derealisation	1	0
Psychiatric elimination disorders		
Enuresis	6	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	1	0
Sexual desire disorders		
Libido decreased	3	0
Libido increased	1	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Loss of libido	2	0
Sleep disorders NEC		
Sleep disorder	15	0
Somatic symptom disorders		
Conversion disorder	2	0
Habit cough	4	0
Speech and language usage disturbances		
Disorganised speech	1	0
Speech articulation and rhythm disturbances		
Dysphemia	3	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	1	0
Head banging	1	0
Stress disorders		
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	5	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	936	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	3	0
Dysuria	6	0
Incontinence	2	0
Micturition urgency	3	0
Pollakiuria	13	0
Urethral pain	1	0
Urinary incontinence	6	0
Urinary retention	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	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	3	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	8	0
Haematuria	1	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	30	0
Renal & urinary disorders SOC TOTAL	95	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	2	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	54	0
Breast swelling	5	0
Breast tenderness	5	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	5	0
Nocturnal emission	1	0
Organic erectile dysfunction	3	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
Lactation disorder	1	0
Lactation puerperal increased	1	0
Suppressed lactation	2	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	6	0
Premature menopause	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	7	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	210	0
Intermenstrual bleeding	110	0
Menstrual discomfort	1	0
Menstrual disorder	196	0
Menstruation irregular	308	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	8	0
Premenstrual syndrome	9	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	49	0
Hypomenorrhoea	63	0
Menstruation delayed	403	0
Oligomenorrhoea	13	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	522	0
Menometrorrhagia	4	0
Polymenorrhoea	74	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
Polycystic ovaries	2	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	10	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	8	0
Pelvic haemorrhage	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	1	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	12	0
Pruritus genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	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	6	0
Testicular swelling	2	0
<i>Uterine disorders NEC</i>		
Endometriosis	8	0
Uterine haemorrhage	5	0
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	8	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	2	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	142	0
Vulval haemorrhage	5	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	7	0
Vulvovaginal burning sensation	1	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	2	0
Reproductive & breast disorders SOC TOTAL	2334	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	328	0
Dyspnoea exertional	3	0
Hyperventilation	4	0
Hypopnoea	7	0
Hypoventilation	1	0
Irregular breathing	1	0
Respiration abnormal	7	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	22	0
Wheezing	31	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	166	0
Haemoptysis	1	0
Productive cough	15	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	19	0
<i>Nasal disorders NEC</i>		
Epistaxis	70	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	34	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	7	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Pleural infections and inflammations</i>		
Pleurisy	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	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	17	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	5	0
Catarrh	1	0
Choking	1	0
Dry throat	12	0
Dysphonia	5	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	3	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	214	0
Paranasal sinus discomfort	5	0
Rhinalgia	1	0
Rhinorrhoea	58	0
Sinus pain	25	0
Sneezing	14	0
Throat irritation	19	0
Throat tightness	27	0
Upper-airway cough syndrome	1	0
Yawning	2	0
Respiratory disorders SOC TOTAL	1198	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	17	0
<i>Alopecias</i>		
Alopecia	21	0
Alopecia areata	4	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	17	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	128	0
Hidradenitis	1	0
Hyperhidrosis	371	0
Miliaria	43	0
Night sweats	80	0
<i>Bullous conditions</i>		
Blister	33	0
Blister rupture	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	50	0
Pain of skin	42	0
Papule	16	0
Scab	3	0
Scar pain	2	0
Sensitive skin	64	0
Skin burning sensation	32	0
Skin discolouration	16	0
Skin induration	6	0
Skin lesion	20	0
Skin reaction	71	0
Skin sensitisation	8	0
Skin swelling	11	0
Skin tightness	4	0
Skin warm	136	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	16	0
Dermatitis allergic	67	0
Dermatitis atopic	5	0
Dermatitis contact	4	0
Dyshidrotic eczema	8	0
Eczema	27	0
Eczema nummular	2	0
Neurodermatitis	1	0
Skin irritation	15	0
<i>Dermatitis ascribed to specific agent</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	670	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	1	0
Skin exfoliation	6	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	3	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	12	0
<i>Pilar disorders NEC</i>		
Piloerection	7	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	1480	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	14	0
<i>Purpura and related conditions</i>		
Petechiae	13	0
Purpura	7	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	1714	0
Rash erythematous	685	0
Rash macular	106	0
Rash maculo-papular	1	0
Rash morbilliform	4	0
Rash papular	119	0
Rash pruritic	393	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
Skin mass	4	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin cysts and polyps</i>		
Dermal cyst	4	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	2	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	3	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	233	0
Urticaria cholinergic	1	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	6879	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	3	0
<i>Disability issues</i>		
Bedridden	2	0
Immobile	1	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	4	0
Social circumstances SOC TOTAL	15	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

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	1	0
<i>Immunisations</i>		
COVID-19 immunisation	12	0
Immunisation	12	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	13	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	50	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	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	4	0
Haemorrhage	119	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	5	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	2	0
Embolism venous	1	0
Thrombosis	39	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	4	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	2	0
Deep vein thrombosis	11	0
Thrombophlebitis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	4	0
Flushing	23	0
Hot flush	143	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	31	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	49	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	44	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Hypotension	50	0
Orthostatic hypotension	4	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	561	0
TOTAL REACTIONS FOR DRUG	46224	15
TOTAL REPORTS	14641	
TOTAL FATAL OUTCOME REPORTS		15