

COVID-19 Moderna vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 21/07/21 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: 22-Jul-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 21-Jul-2021 18:30:10
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	1	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	96	0
Lymphadenitis	9	0
Lymphadenopathy	518	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Thrombocytopenia	10	0
Blood disorders SOC TOTAL	646	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	4	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	195	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	8	0
Myocardial infarction	9	0
<i>Mitral valvular disorders</i>		
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	19	0
<i>Noninfectious pericarditis</i>		
Pericarditis	20	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	4	0
Bradycardia	7	0
Cardiac flutter	14	0
Extrasystoles	5	0
Tachycardia	20	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Atrial tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	320	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	3	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	67	0
Ear swelling	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	2	0
<i>Hearing losses</i>		
Deafness	10	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	9	0
Sudden hearing loss	3	0
<i>Hyperacusia</i>		
Hyperacusis	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	7	0
Tinnitus	117	0
Vertigo	81	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	316	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	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
Ovulation delayed	4	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	1	0
Endocrine disorders SOC TOTAL	15	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>		
Vitreous floaters	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	10	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	6	0
Lacrimation increased	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	6	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye pain	70	0
Eye swelling	24	0
Periorbital oedema	2	0
Periorbital swelling	4	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	3	0
Eye pruritus	11	0
Ocular hyperaemia	11	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	4	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	3	0
Hypoaesthesia eye	1	0
Photophobia	17	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>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	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

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Eye disorders Eye disorders cont'd		
<i>Visual colour distortions</i>		
Cyanopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	9	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	101	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	9	0
Blindness transient	1	0
Visual acuity reduced	1	0
Visual impairment	13	0
Eye disorders SOC TOTAL	339	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	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	2	0
Crohn's disease	3	0
Inflammatory bowel disease	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	4	0
Toothache	9	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	282	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	29	0
Epigastric discomfort	1	0
Eructation	3	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	15	0
Flatulence	10	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	93	0
Abdominal pain lower	5	0
Abdominal pain upper	195	0
Abdominal rigidity	1	0
Abdominal tenderness	1	0
Gastrointestinal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	13	0
Gastrooesophageal reflux disease	6	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
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

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Gastrointestinal disorders		
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	38	0
Anal incontinence	2	0
Breath odour	3	0
Dysphagia	11	0
Odynophagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	3	0
Irritable bowel syndrome	4	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	2	0
Gingival swelling	4	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	5	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	1069	0
Retching	3	0
Vomiting	329	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	3	0
Melaena	1	0
Upper gastrointestinal haemorrhage	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	36	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	5	0
<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>		
Coating in mouth	2	0
Hypoaesthesia oral	31	0
Lip discolouration	1	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Lip pain	2	0
Lip pruritus	1	0
Oral discomfort	2	0
Oral mucosal roughening	1	0
Oral pain	7	0
Oral pruritus	1	0
Paraesthesia oral	52	0
Oral soft tissue swelling and oedema		
Lip swelling	49	0
Mouth swelling	9	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	1	0
Salivary gland enlargements		
Submaxillary gland enlargement	1	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	1	0
Mouth ulceration	30	0
Stomatitis	2	0
Tongue disorders		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	2	0
Tongue signs and symptoms		
Glossodynia	10	0
Swollen tongue	27	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	1	0
Tongue discomfort	2	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	2493	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site lymphadenopathy	1	0
Administration site pain	1	0
Puncture site bruise	4	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	4	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	8	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	3	0
Application site warmth	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	108	0
Fatigue	1506	0
Malaise	251	0
<i>Death and sudden death</i>		
Death	4	4
<i>Febrile disorders</i>		
Pyrexia	1292	1
<i>Feelings and sensations NEC</i>		
Chills	692	0
Feeling abnormal	116	0
Feeling cold	51	0
Feeling drunk	7	0
Feeling hot	116	0
Feeling jittery	4	0
Feeling of body temperature change	25	0
Hangover	6	0
Hunger	8	0
Sensation of blood flow	1	0
Sensation of foreign body	2	0
Temperature intolerance	8	0
Thirst	33	0
<i>Gait disturbances</i>		
Gait disturbance	10	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crying	17	0
Discharge	1	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Illness	109	0
Induration	5	0
Influenza like illness	137	0
Irritability postvaccinal	1	0
Local reaction	10	0

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General disorders General disorders cont'd		
Peripheral swelling	851	0
Screaming	2	0
Swelling	440	0
Swelling face	50	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Inflammation	52	0
Soft tissue inflammation	1	0
Infusion site reactions		
Infusion site mass	1	0
Infusion site pain	3	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	88	0
Injection site haemorrhage	2	0
Injection site hypersensitivity	5	0
Injection site hypoaesthesia	4	0
Injection site indentation	1	0
Injection site inflammation	5	0
Injection site irritation	1	0
Injection site joint erythema	3	0
Injection site mass	90	0
Injection site oedema	1	0
Injection site pain	228	0
Injection site paraesthesia	1	0
Injection site pruritus	70	0
Injection site rash	129	0
Injection site reaction	10	0
Injection site swelling	40	0
Injection site urticaria	42	0
Injection site vesicles	1	0
Injection site warmth	41	0
Interactions		
Alcohol interaction	1	0
Mass conditions NEC		
Cyst	4	0
Mass	13	0
Nodule	2	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	1	0
Localised oedema	1	0
Oedema	2	0
Oedema peripheral	2	0
Pain and discomfort NEC		

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General disorders General disorders cont'd		
Axillary pain	275	0
Chest discomfort	90	0
Chest pain	213	0
Discomfort	45	0
Facial pain	9	0
Pain	730	0
Tenderness	80	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	23	0
Drug ineffective	8	0
Drug intolerance	1	0
Inadequate analgesia	1	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	10	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	185	0
Vaccination site haemorrhage	1	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	14	0
Vaccination site inflammation	6	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	2	0
Vaccination site mass	42	0
Vaccination site movement impairment	5	0
Vaccination site oedema	1	0
Vaccination site pain	159	0
Vaccination site papule	2	0
Vaccination site pruritus	47	0
Vaccination site rash	89	0
Vaccination site reaction	2	0
Vaccination site swelling	110	0
Vaccination site urticaria	6	0
Vaccination site vesicles	1	0
Vaccination site warmth	87	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	1	0
General disorders SOC TOTAL	9040	5

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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
Hepatic disorders SOC TOTAL	6	0

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	3	0
Allergy to animal	1	0
Hypersensitivity	136	0
Infusion related hypersensitivity reaction	5	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	10	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	4	0
Drug hypersensitivity	3	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	22	0
Anaphylactic shock	3	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	10	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	18	0
Cytokine release syndrome	1	0
Immune-mediated adverse reaction	1	0
Sensitisation	2	0
Immune system disorders SOC TOTAL	224	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	2	0
Diverticulitis	1	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	43	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
<i>Candida infections</i>		
Candida infection	3	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
<i>Coronavirus infections</i>		
COVID-19	29	0
COVID-19 pneumonia	1	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Ear infections</i>		
Ear infection	2	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	8	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
Fungal skin infection	1	0
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Herpes viral infections</i>		
Genital herpes	5	0
Herpes zoster	27	0
Oral herpes	19	0
<i>Infections NEC</i>		

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Infections Infections cont'd		
Abscess limb	1	0
Abscess rupture	1	0
Infection	44	0
Injection site infection	1	0
Localised infection	8	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	97	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Lower respiratory tract infection	13	0
Pneumonia	5	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rubella viral infections</i>		
Rubella	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Impetigo	1	0
Pustule	6	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	8	0
<i>Staphylococcal infections</i>		
Furuncle	2	0
<i>Tinea infections</i>		
Body tinea	1	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	86	0
Peritonsillar abscess	1	0
Rhinitis	1	0
Sinusitis	3	0
Tonsillitis	8	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	2	0
Kidney infection	1	0
Urinary tract infection	10	0
<i>Vascular infections</i>		
Lymphangitis	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 22-Jul-2021

Data Lock Date: 21-Jul-2021 18:30:10

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Post viral fatigue syndrome	2	0
Sweating fever	10	0
Viral infection	1	0
Viral pharyngitis	2	0
Viral rash	3	0
Infections SOC TOTAL	518	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 22-Jul-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

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>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	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	6	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	3	0
Maternal exposure during breast feeding	199	0
Maternal exposure during pregnancy	91	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	3	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Muscle injury	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	4	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	3	0
Fall	9	0
Wound complication	2	0
Wound haemorrhage	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	4	0
Inappropriate schedule of product administration	4	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
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Radiation injuries</i>		
Sunburn	5	0
<i>Site specific injuries NEC</i>		
Head injury	5	0
Limb injury	10	0
<i>Skin injuries NEC</i>		
Contusion	104	0
Scar	5	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	3	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	512	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	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	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram T wave inversion	2	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	41	0
Heart rate abnormal	3	0
Heart rate decreased	3	0
Heart rate increased	67	0
Heart rate irregular	11	0
<i>Investigations NEC</i>		
Blood test abnormal	2	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	2	0
Aspartate aminotransferase	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	3	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	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	23	0
Body temperature abnormal	1	0
Body temperature decreased	3	0
Body temperature fluctuation	7	0
Body temperature increased	19	0
Grip strength	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Product residue present	1	0
Respiratory rate	1	0
Respiratory rate increased	6	0
Skin temperature	5	0
Temperature difference of extremities	1	0
Weight decreased	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Weight increased	5	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	5	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	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>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	1	0
<i>Urinalysis NEC</i>		
Blood urine present	2	0
Protein urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	5	0
Blood pressure measurement	2	0
<i>Virus identification and serology</i>		
Coronavirus test	3	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	1	0
SARS-CoV-2 test positive	2	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
White blood cell count decreased	1	0
Investigations SOC TOTAL	279	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	74	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	3	0
Hypophagia	1	0
Increased appetite	3	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	4	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	3	0
Feeding disorder	6	0
Neonatal insufficient breast milk syndrome	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	4	0
<i>Total fluid volume decreased</i>		
Dehydration	19	0
<i>Total fluid volume increased</i>		
Fluid retention	7	0
Metabolic disorders SOC TOTAL	138	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	7	0
Arthropathy	1	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	18	0
Pain in jaw	25	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	4	0
<i>Cartilage disorders</i>		
Costochondritis	5	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	1	0
<i>Joint related disorders NEC</i>		
Joint lock	2	0
Periarthritis	8	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	459	0
Joint noise	1	0
Joint stiffness	17	0
Joint swelling	23	0
Joint vibration	1	0
Joint warmth	1	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	3	0
Myalgia	745	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	22	0
Muscle haemorrhage	1	0
Muscle spasms	121	0
Muscle swelling	5	0
Muscle tightness	11	0
Muscle twitching	28	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	46	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle contracture	1	0
Musculoskeletal stiffness	138	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	157	0
Flank pain	2	0
Limb discomfort	136	0
Musculoskeletal chest pain	5	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	1	0
Neck pain	84	0
Pain in extremity	1303	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	16	0
Groin pain	4	0
Neck mass	1	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	3	0
Axial spondyloarthritis	1	0
<i>Synovial disorders</i>		
Synovial cyst	2	0
<i>Tendon disorders</i>		
Trigger finger	2	0
Muscle & tissue disorders SOC TOTAL	3444	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	2	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>		
Haemangioma of skin	1	0
Skin papilloma	2	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	11	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	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebral infarction	1	0
Cerebrovascular accident	7	0
Haemorrhage intracranial	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	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	15	0
Coordination abnormal	1	0
Dysstasia	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	5	0
Lethargy	120	0
Loss of consciousness	72	0
Somnolence	77	0
Stupor	1	0
Syncope	399	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Clumsiness	2	0
Dyskinesia	4	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Hyperkinesia	1	0
Hypokinesia	2	0
Movement disorder	2	0
Psychomotor hyperactivity	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	21	0
Facial paralysis	16	0
Facial paresis	2	0
Facial spasm	2	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	17	0
Cold-stimulus headache	1	0
Drug withdrawal headache	1	0
Headache	1646	0
New daily persistent headache	1	0
Sinus headache	18	0
Tension headache	29	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
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	1	0
Memory loss (excl dementia)		
Amnesia	12	0
Memory impairment	9	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	5	0
Disturbance in attention	27	0
Mental impairment	2	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	175	0
Migraine with aura	17	0
Migraine without aura	1	0
Retinal migraine	1	0
Vestibular migraine	1	0
Mononeuropathies		
Cubital tunnel syndrome	1	0
Mononeuritis	1	0
Muscle tone abnormal		
Hypotonia	2	0
Narcolepsy and hypersomnia		
Hypersomnia	5	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurologic visual problems NEC		
Tunnel vision	3	0
Neurological signs and symptoms NEC		
Dizziness	1032	0
Dizziness postural	35	0
Drooling	2	0
Head discomfort	19	0
Neurological symptom	2	0
Persistent postural-perceptual dizziness	1	0
Presyncope	89	0
Unresponsive to stimuli	6	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0
Olfactory nerve disorders		
Anosmia	5	0
Parosmia	7	0
Optic nerve disorders NEC		
Optic neuritis	2	0
Paraesthesias and dysaesthesias		
Burning sensation	36	0
Formication	1	0
Hemianaesthesia	1	0
Hyperaesthesia	17	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hypoaesthesia	200	0
Paraesthesia	294	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	3	0
Hemiplegia	2	0
Monoparesis	5	0
Monoplegia	7	0
Paralysis	7	0
Paresis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	5	0
<i>Seizures and seizure disorders NEC</i>		
Febrile convulsion	2	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	47	0
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	16	0
Dysgeusia	82	0
Electric shock sensation	2	0
Hypogeusia	1	0
Neuralgia	18	0
Post herpetic neuralgia	2	0
Restless legs syndrome	13	0
Sensory disturbance	4	0
Sensory loss	3	0
Taste disorder	12	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	12	0
Incoherent	2	0
Slow speech	1	0
Speech disorder	4	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	5	0
<i>Tremor (excl congenital)</i>		
Tremor	109	0
<i>Trigeminal disorders</i>		
Facial neuralgia	1	0
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	4904	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	16	0
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	1	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	6	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	32	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	7	0
<i>Product quality issues NEC</i>		
Product quality issue	1	0
null SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Flat affect	3	0
<i>Anxiety symptoms</i>		
Agitation	7	0
Anxiety	99	0
Nervousness	17	0
Stress	5	0
Tension	3	0
<i>Behaviour and socialisation disturbances</i>		
Paranoia	3	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	19	0
<i>Confusion and disorientation</i>		
Confusional state	47	0
Disorientation	22	0
<i>Deliria</i>		
Delirium	10	0
<i>Depressive disorders</i>		
Depression	24	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>		
Insomnia	77	0
Middle insomnia	3	0
Terminal insomnia	6	0
<i>Dyssomnias</i>		
Poor quality sleep	20	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	6	0
Emotional disorder	8	0
Emotional distress	6	0
Euphoric mood	6	0
Irritability	13	0
Mood altered	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Fear of death	1	0
Fear of injection	5	0
<i>Fluctuating mood symptoms</i>		
Mood swings	7	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	26	0
Hallucination, auditory	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Hallucination, visual	1	0
Increased physical activity levels		
Restlessness	18	0
Mental disorders NEC		
Mental disorder	1	0
Mood alterations with depressive symptoms		
Depressed mood	20	0
Feeling of despair	2	0
Tearfulness	2	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	4	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		
Panic attack	20	0
Panic reaction	3	0
Parasomnias		
Abnormal dreams	14	0
Nightmare	14	0
Sleep terror	1	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	2	0
Derealisation	1	0
Psychiatric elimination disorders		
Enuresis	2	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
Sleep disorders NEC		
Sleep disorder	11	0
Somatic symptom disorders		
Conversion disorder	1	0
Habit cough	2	0
Speech and language usage disturbances		
Disorganised speech	1	0
Speech articulation and rhythm disturbances		
Dysphemia	2	0
Lack of spontaneous speech	1	0
Stress disorders		
Post-traumatic stress disorder	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 22-Jul-2021

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Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal behaviour	2	0
Suicidal ideation	4	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	620	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	2	0
Dysuria	5	0
Incontinence	1	0
Micturition urgency	2	0
Pollakiuria	10	0
Urinary incontinence	2	0
Urinary retention	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Urinary bladder haemorrhage	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	2	0
Oliguria	1	0
Renal impairment	2	0
<i>Urinary abnormalities</i>		
Chromaturia	6	0
Haematuria	2	0
Urine abnormality	1	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	3	0
Renal pain	19	0
Renal & urinary disorders SOC TOTAL	64	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	2	0
Breast mass	4	0
Fibrocystic breast disease	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	32	0
Breast swelling	3	0
Breast tenderness	1	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation failure	2	0
Erectile dysfunction	2	0
Organic erectile dysfunction	1	0
Painful ejaculation	1	0
<i>Lactation disorders</i>		
Lactation disorder	1	0
Lactation puerperal increased	1	0
Suppressed lactation	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	4	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	147	0
Intermenstrual bleeding	81	0
Menstrual discomfort	1	0
Menstrual disorder	142	0
Menstruation irregular	238	0
Premenstrual headache	1	0
Premenstrual pain	3	0
Premenstrual syndrome	4	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	31	0
Hypomenorrhoea	49	0
Menstruation delayed	288	0
Oligomenorrhoea	11	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	398	0
Menometrorrhagia	2	0
Polymenorrhoea	50	0
<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	6	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<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
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	6	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	4	0
Testicular swelling	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	5	0
Uterine haemorrhage	5	0
<i>Uterine tone disorders</i>		
Uterine spasm	6	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	105	0
Vulval haemorrhage	5	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	6	0
Vulvovaginal discomfort	1	0
Vulvovaginal pain	2	0
Reproductive & breast disorders SOC TOTAL	1688	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	200	0
Dyspnoea exertional	3	0
Hyperventilation	2	0
Hypopnoea	4	0
Hypoventilation	1	0
Respiration abnormal	6	0
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	12	0
Wheezing	27	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	117	0
Haemoptysis	1	0
Productive cough	12	0
Sputum discoloured	1	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>		
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	12	0
Pulmonary haemorrhage	1	0
Pulmonary pain	5	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	15	0
<i>Nasal disorders NEC</i>		
Epistaxis	54	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	2	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	1	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	27	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	5	0
<i>Pleural infections and inflammations</i>		
Pleurisy	2	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	8	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	5	0
Catarrh	1	0
Dry throat	10	0
Dysphonia	2	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	2	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	161	0
Paranasal sinus discomfort	5	0
Rhinalgia	1	0
Rhinorrhoea	38	0
Sinus pain	16	0
Sneezing	8	0
Throat irritation	14	0
Throat tightness	16	0
Upper-airway cough syndrome	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	824	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	9	0
<i>Alopecias</i>		
Alopecia	13	0
Alopecia areata	1	0
<i>Angioedemas</i>		
Angioedema	14	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	79	0
Hyperhidrosis	220	0
Miliaria	40	0
Night sweats	40	0
<i>Bullous conditions</i>		
Blister	26	0
Blister rupture	1	0
Dermatitis bullous	1	0
Erythema multiforme	8	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	35	0
Pain of skin	21	0
Papule	10	0
Scab	1	0
Scar pain	1	0
Sensitive skin	34	0
Skin burning sensation	22	0
Skin discolouration	8	0
Skin induration	5	0
Skin lesion	18	0
Skin reaction	63	0
Skin sensitisation	5	0
Skin swelling	11	0
Skin tightness	3	0
Skin warm	108	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	14	0
Dermatitis allergic	58	0
Dermatitis atopic	4	0
Dermatitis contact	2	0
Dyshidrotic eczema	7	0
Eczema	19	0
Eczema nummular	1	0
Skin irritation	12	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	565	0
<i>Exfoliative conditions</i>		
Skin exfoliation	4	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
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	1	0
Pityriasis rosea	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	9	0
<i>Pilar disorders NEC</i>		
Piloerection	4	0
<i>Pruritus NEC</i>		
Itching scar	2	0
Pruritus	1263	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	8	0
<i>Purpura and related conditions</i>		
Petechiae	9	0
Purpura	5	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	1426	0
Rash erythematous	582	0
Rash macular	85	0
Rash maculo-papular	1	0
Rash morbilliform	4	0
Rash papular	105	0
Rash pruritic	336	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	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	2	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 vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Telangiectasia and related conditions</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	189	0
Urticaria cholinergic	1	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	5553	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	3	0
<i>Disability issues</i>		
Bedridden	1	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	14	0

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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>Immunisations</i>		
COVID-19 immunisation	8	0
Immunisation	8	0
<i>Joint therapeutic procedures</i>		
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	2	0
<i>Therapeutic procedures NEC</i>		
Botulinum toxin injection	1	0
Hospitalisation	1	0
Injection	4	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	29	0

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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>Circulatory collapse and shock</i>		
Neurogenic shock	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	3	0
Haemorrhage	83	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	4	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	37	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	3	0
Vasodilatation	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	2	0
Deep vein thrombosis	7	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	17	0
Hot flush	92	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	21	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	42	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	38	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	41	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	412	0
TOTAL REACTIONS FOR DRUG	32454	8
TOTAL REPORTS	10990	
TOTAL FATAL OUTCOME REPORTS		8