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Report Run Date: 14-Jun-2021
Data Lock Date: 09-Jun-2021 19:00:03

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Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	34	0
Lymphadenitis	3	0
Lymphadenopathy	197	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	239	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	50	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	3	0
<i>Myocardial disorders NEC</i>		
Ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	1	0
Cardiac flutter	2	0
Extrasystoles	1	0
Tachycardia	10	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	0
Cardiac disorders SOC TOTAL	77	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Craniosynostosis	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear discomfort	2	0
Ear pain	31	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	4	0
Deafness transitory	1	0
Deafness unilateral	2	0
Hypoacusis	3	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	3	0
Tinnitus	65	0
Vertigo	32	0
Ear disorders SOC TOTAL	149	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	3	0
<i>Lacrimation disorders</i>		
Dry eye	3	0
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye pain	26	0
Eye swelling	10	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye irritation	2	0
Eye pruritus	4	0
Ocular hyperaemia	7	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Hypoaesthesia eye	1	0
Photophobia	5	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	3	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Metamorphopsia	1	0
Vision blurred	40	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	4	0
Eye disorders SOC TOTAL	124	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	2	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	2	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	2	0
Toothache	3	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	117	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	6	0
Epigastric discomfort	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	4	0
Flatulence	7	0
<i>Gastric ulcers and perforation</i>		
Gastritis erosive	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	27	0
Abdominal pain upper	59	0
Gastrointestinal pain	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	5	0
Gastrooesophageal reflux disease	4	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Breath odour	1	0
Dysphagia	1	0
Odynophagia	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	367	0
Vomiting	102	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	1	0
Melaena	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral dryness and saliva altered</i>		
Dry mouth	17	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	2	0
<i>Oral soft tissue disorders NEC</i>		
Lip blister	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	1	0
Hypoaesthesia oral	17	0
Lip pain	1	0
Oral discomfort	1	0
Oral pain	1	0
Oral pruritus	1	0
Paraesthesia oral	29	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	15	0
Mouth swelling	4	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	1	0
<i>Salivary gland enlargements</i>		
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	11	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Glossitis	1	0
Tongue disorder	2	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	5	0
Swollen tongue	13	0
Tongue blistering	1	0
Tongue dry	2	0
Gastrointestinal disorders SOC TOTAL	880	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
Puncture site bruise	1	0
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site burn	1	0
Application site erythema	2	0
Application site pain	1	0
Application site pruritus	5	0
Application site rash	1	0
Application site swelling	1	0
Application site vesicles	1	0
Application site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	31	0
Fatigue	573	0
Malaise	90	0
<i>Death and sudden death</i>		
Death	2	2
<i>Febrile disorders</i>		
Pyrexia	336	0
<i>Feelings and sensations NEC</i>		
Chills	221	0
Feeling abnormal	45	0
Feeling cold	21	0
Feeling drunk	5	0
Feeling hot	50	0
Feeling jittery	1	0
Feeling of body temperature change	12	0
Hangover	3	0
Hunger	1	0
Sensation of blood flow	1	0
Sensation of foreign body	1	0
Thirst	17	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	3	0
Crying	7	0
Exercise tolerance decreased	2	0
Illness	36	0
Induration	4	0
Influenza like illness	34	0
Local reaction	5	0
Peripheral swelling	386	0
Screaming	1	0
Swelling	178	0
Swelling face	19	0
<i>Inflammations</i>		
Inflammation	26	0
Soft tissue inflammation	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Infusion site reactions</i>		
Infusion site mass	1	0
Infusion site pain	3	0
Infusion site urticaria	2	0
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site bruising	5	0
Injection site discolouration	1	0
Injection site erythema	38	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	1	0
Injection site inflammation	2	0
Injection site joint erythema	1	0
Injection site mass	39	0
Injection site pain	90	0
Injection site pruritus	34	0
Injection site rash	63	0
Injection site reaction	5	0
Injection site swelling	13	0
Injection site urticaria	20	0
Injection site warmth	21	0
<i>Mass conditions NEC</i>		
Cyst	2	0
Mass	9	0
Nodule	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
Oedema	2	0
Oedema peripheral	2	0
<i>Pain and discomfort NEC</i>		
Axillary pain	94	0
Chest discomfort	25	0
Chest pain	43	0
Discomfort	19	0
Facial pain	2	0
Pain	250	0
Tenderness	36	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	11	0
Drug ineffective	2	0
Therapeutic response unexpected	1	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	5	0
Vaccination site discolouration	1	0
Vaccination site discomfort	5	0
Vaccination site erythema	94	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	10	0
Vaccination site inflammation	5	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	17	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site movement impairment	2	0
Vaccination site oedema	1	0
Vaccination site pain	75	0
Vaccination site papule	1	0
Vaccination site pruritus	28	0
Vaccination site rash	41	0
Vaccination site reaction	1	0
Vaccination site swelling	51	0
Vaccination site urticaria	2	0
Vaccination site warmth	40	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	1	0
General disorders SOC TOTAL	3357	2

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	56	0
Infusion related hypersensitivity reaction	4	0
Type IV hypersensitivity reaction	5	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	11	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	6	0
Sensitisation	1	0
Immune system disorders SOC TOTAL	91	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	1	0
Cellulitis	15	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
<i>Breast infections</i>		
Breast abscess	1	0
<i>Candida infections</i>		
Candida infection	1	0
Vulvovaginal candidiasis	5	0
<i>Central nervous system and spinal infections</i>		
Meningitis	1	0
<i>Coronavirus infections</i>		
COVID-19	6	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	2	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
<i>Fungal infections NEC</i>		
Fungal skin infection	1	0
<i>Herpes viral infections</i>		
Herpes zoster	17	0
Oral herpes	8	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	19	0
Localised infection	3	0
Respiratory tract infection	1	0
Vaccination site infection	2	0
Vestibulitis	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	1	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	24	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	5	0
Pneumonia	3	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Pustule	3	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Rash pustular	1	0
Skin infection	5	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>		
Nasopharyngitis	34	0
Peritonsillar abscess	1	0
Rhinitis	1	0
Sinusitis	2	0
Tonsillitis	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Sweating fever	3	0
Viral pharyngitis	2	0
Viral rash	3	0
Infections SOC TOTAL	198	1

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Reaction Name	Total	Fatal
Injuries		
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	3	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	68	0
Maternal exposure during pregnancy	31	0
Paternal exposure during pregnancy	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	1	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Wrong schedule	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	1	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	2	0
Fall	2	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0
<i>Product administration errors and issues</i>		
Incorrect dose administered	1	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Radiation injuries</i>		
Sunburn	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
Limb injury	3	0
<i>Skin injuries NEC</i>		
Contusion	43	0
Scar	1	0
Subcutaneous haematoma	1	0
<i>Stoma complications</i>		
Stoma site oedema	1	0
<i>Thermal burns</i>		
Thermal burn	3	0
Injuries SOC TOTAL	178	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
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	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	16	0
Heart rate abnormal	1	0
Heart rate decreased	1	0
Heart rate increased	18	0
Heart rate irregular	1	0
<i>Liver function analyses</i>		
Liver function test abnormal	2	0
<i>Ophthalmic function diagnostic procedures</i>		
Visual tracking test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	6	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	4	0
Lymph node palpable	1	0
Respiratory rate increased	2	0
Skin temperature	2	0
Weight decreased	3	0
Weight increased	3	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	3	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 diastolic increased	1	0
Blood pressure increased	2	0
Blood pressure measurement	2	0
<i>Virus identification and serology</i>		
Hepatitis B surface antibody positive	1	0
SARS-CoV-2 antibody test	1	0
SARS-CoV-2 test	1	0
SARS-CoV-2 test negative	1	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
Investigations SOC TOTAL	85	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	21	0
Increased appetite	1	0
<i>Disorders of purine metabolism</i>		
Gout	2	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	2	0
Feeding disorder	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	3	0
<i>Total fluid volume decreased</i>		
Dehydration	8	0
<i>Total fluid volume increased</i>		
Fluid retention	3	0
Metabolic disorders SOC TOTAL	42	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	6	0
Pain in jaw	10	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	3	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Reynold's syndrome	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	5	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	156	0
Joint noise	1	0
Joint stiffness	9	0
Joint swelling	7	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	240	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	8	0
Muscle haemorrhage	1	0
Muscle spasms	38	0
Muscle swelling	5	0
Muscle tightness	5	0
Muscle twitching	9	0
<i>Muscle tone abnormalities</i>		
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	20	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	54	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	45	0
Flank pain	1	0
Limb discomfort	64	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	2	0
Neck pain	30	0
Pain in extremity	577	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Psoriatic arthropathies</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	5	0
Groin pain	2	0
Neck mass	1	0
Soft tissue swelling	1	0
<i>Tendon disorders</i>		
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	1326	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms		
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebrovascular accident	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	3	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	42	0
Loss of consciousness	21	0
Somnolence	32	0
Syncope	102	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	1	0
Fine motor skill dysfunction	1	0
Hypokinesia	1	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	6	0
Facial paralysis	10	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Cluster headache	6	0
Cold-stimulus headache	1	0
Drug withdrawal headache	1	0
Headache	572	0
Sinus headache	6	0
Tension headache	10	0
Thunderclap headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	13	0
<i>Migraine headaches</i>		
Migraine	59	0
Migraine with aura	6	0
Retinal migraine	1	0
<i>Mononeuropathies</i>		
Cubital tunnel syndrome	1	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	2	0
<i>Neurological signs and symptoms NEC</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dizziness	373	0
Dizziness postural	13	0
Drooling	1	0
Head discomfort	9	0
Neurological symptom	1	0
Presyncope	22	0
Unresponsive to stimuli	2	0
Olfactory nerve disorders		
Anosmia	4	0
Parosmia	3	0
Paraesthesias and dysaesthesias		
Burning sensation	20	0
Hyperaesthesia	7	0
Hypoaesthesia	90	0
Paraesthesia	141	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	0
Hemiplegia	1	0
Monoparesis	4	0
Monoplegia	2	0
Paralysis	1	0
Paresis	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Febrile convulsion	2	0
Partial seizures	1	0
Seizure	10	0
Status epilepticus	16	0
Sensory abnormalities NEC		
Ageusia	8	0
Dysgeusia	46	0
Electric shock sensation	1	0
Neuralgia	7	0
Post herpetic neuralgia	2	0
Restless legs syndrome	7	0
Sensory disturbance	2	0
Taste disorder	7	0
Sleep disturbances NEC		
Sleep deficit	1	0
Speech and language abnormalities		
Dysarthria	5	0
Incoherent	2	0
Slow speech	1	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	34	0
Nervous system disorders SOC TOTAL	1769	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	1	0
Ectopic pregnancy with contraceptive device	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	10	0

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device leakage	1	0
null SOC TOTAL	1	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>		
Flat affect	1	0
<i>Anxiety symptoms</i>		
Agitation	3	0
Anxiety	26	0
Nervousness	9	0
Stress	1	0
Tension	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	6	0
<i>Confusion and disorientation</i>		
Confusional state	19	0
Disorientation	9	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	8	0
Depression suicidal	1	0
<i>Dissociative states</i>		
Dissociation	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	28	0
Middle insomnia	1	0
Terminal insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	5	0
<i>Emotional and mood disturbances NEC</i>		
Anger	4	0
Emotional disorder	5	0
Emotional distress	2	0
Euphoric mood	2	0
Irritability	5	0
Mood altered	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear of injection	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	8	0
<i>Increased physical activity levels</i>		
Restlessness	4	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	6	0
<i>Mood alterations with manic symptoms</i>		
Mania	1	0
<i>Mood disorders NEC</i>		
Apathy	2	0
Listless	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Panic attacks and disorders</i>		
Panic attack	4	0
Panic reaction	1	0
<i>Parasomnias</i>		
Abnormal dreams	6	0
Nightmare	7	0
Sleep terror	1	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	1	0
<i>Sexual desire disorders</i>		
Libido decreased	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	4	0
<i>Thinking disturbances</i>		
Bradyphrenia	2	0
Psychiatric disorders SOC TOTAL	205	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	2	0
Dysuria	1	0
Pollakiuria	2	0
Urinary retention	1	0
<i>Urinary abnormalities</i>		
Chromaturia	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Renal pain	7	0
Renal & urinary disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	1	0
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Breast mass	2	0
Fibrocystic breast disease	1	0
<i>Breast signs and symptoms</i>		
Breast pain	8	0
Nipple swelling	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	4	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	29	0
Intermenstrual bleeding	25	0
Menstrual disorder	35	0
Menstruation irregular	59	0
Premenstrual syndrome	3	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	10	0
Hypomenorrhoea	7	0
Menstruation delayed	38	0
Oligomenorrhoea	3	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	84	0
Menometrorrhagia	1	0
Polymenorrhoea	8	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Premature ovulation	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	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
<i>Uterine disorders NEC</i>		
Uterine haemorrhage	2	0
<i>Uterine tone disorders</i>		
Uterine spasm	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
<i>Vulvovaginal disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vaginal haemorrhage	37	0
Vulval haemorrhage	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Vulvovaginal discomfort	1	0
Reproductive & breast disorders SOC TOTAL	378	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	58	0
Hypopnoea	2	0
Hypoventilation	1	0
Respiration abnormal	2	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	5	0
Wheezing	8	0
<i>Coughing and associated symptoms</i>		
Cough	43	0
Haemoptysis	1	0
Productive cough	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	9	0
Pulmonary haemorrhage	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	8	0
<i>Nasal disorders NEC</i>		
Epistaxis	24	0
Nasal oedema	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	11	0
Tonsillar hypertrophy	3	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	3	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	2	0
Catarrh	1	0
Dry throat	6	0
Dysphonia	1	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	70	0
Paranasal sinus discomfort	1	0
Rhinalgia	1	0
Rhinorrhoea	13	0
Sinus pain	7	0
Sneezing	2	0
Throat irritation	6	0
Throat tightness	3	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	308	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Alopecias</i>		
Alopecia	4	0
Alopecia areata	1	0
<i>Angioedemas</i>		
Angioedema	7	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	26	0
Hyperhidrosis	49	0
Miliaria	14	0
Night sweats	10	0
<i>Bullous conditions</i>		
Blister	14	0
Erythema multiforme	3	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	11	0
Pain of skin	12	0
Papule	5	0
Sensitive skin	10	0
Skin burning sensation	13	0
Skin discolouration	2	0
Skin induration	3	0
Skin lesion	8	0
Skin reaction	28	0
Skin sensitisation	2	0
Skin swelling	6	0
Skin tightness	1	0
Skin warm	49	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	7	0
Dermatitis allergic	31	0
Dermatitis atopic	2	0
Dyshidrotic eczema	1	0
Eczema	10	0
Skin irritation	7	0
<i>Erythemas</i>		
Erythema	257	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	5	0
<i>Pruritus NEC</i>		
Itching scar	1	0
Pruritus	635	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Psoriatic conditions</i>		
Psoriasis	4	0
<i>Purpura and related conditions</i>		
Petechiae	3	0
Purpura	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	590	0
Rash erythematous	265	0
Rash macular	35	0
Rash morbilliform	2	0
Rash papular	49	0
Rash pruritic	151	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	2	0
<i>Skin cysts and polyps</i>		
Dermal cyst	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	1	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Urticaria	80	0
Skin disorders SOC TOTAL	2435	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	4	0
<i>Disability issues</i>		
Immobile	1	0
Sight disability	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	2	0
Social circumstances SOC TOTAL	9	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>Immunisations</i>		
COVID-19 immunisation	2	0
Immunisation	1	0
<i>Therapeutic procedures NEC</i>		
Injection	1	0
Surgical & medical procedures SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	1	0
Haemorrhage	20	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	2	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	6	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	9	0
Hot flush	40	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	7	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	14	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	20	0
<i>Vascular hypotensive disorders</i>		
Hypotension	16	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	151	0
TOTAL REACTIONS FOR DRUG	12042	4
TOTAL REPORTS	4267	
TOTAL FATAL OUTCOME REPORTS		4