

COVID-19 Moderna vaccine analysis print

Report Run Date: 06-May-2021
Data Lock Date: 05-May-2021 18:30:00

All UK spontaneous reports received between 9/12/20 and 05/05/21 for
Moderna vaccine analysis print

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	6	0
Lymphadenopathy	41	0
Blood disorders SOC TOTAL	47	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	11	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear pain	4	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness unilateral	1	0
Hypoacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	18	0
Vertigo	5	0
Ear disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Lacrimation disorders</i>		
Dry eye	2	0
Lacrimation increased	1	0
<i>Ocular disorders NEC</i>		
Eye pain	7	0
Eye swelling	3	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye irritation	1	0
Eye pruritus	1	0
Ocular hyperaemia	4	0
<i>Ocular sensation disorders</i>		
Photophobia	3	0
<i>Visual disorders NEC</i>		
Vision blurred	11	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	1	0
Eye disorders SOC TOTAL	38	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	2	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	37	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	4	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Gastric ulcers and perforation</i>		
Gastritis erosive	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	6	0
Abdominal pain upper	16	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
Dysphagia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	77	0
Vomiting	31	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	7	0
Lip dry	2	0
Saliva altered	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue haemorrhages</i>		
Oral blood blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Coating in mouth	1	0
Hypoaesthesia oral	3	0
Oral mucosal eruption	1	0
Paraesthesia oral	10	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	7	0
Mouth swelling	3	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	3	0
Stomatitis	1	0
<i>Tongue disorders</i>		

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Gastrointestinal disorders		
Glossitis	1	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	1	0
Swollen tongue	6	0
Gastrointestinal disorders SOC TOTAL	238	0

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Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site burn	1	0
Application site pruritus	1	0
<i>Asthenic conditions</i>		
Asthenia	6	0
Fatigue	147	0
Malaise	24	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	97	0
<i>Feelings and sensations NEC</i>		
Chills	72	0
Feeling abnormal	13	0
Feeling cold	12	0
Feeling drunk	2	0
Feeling hot	7	0
Feeling jittery	1	0
Feeling of body temperature change	3	0
Hunger	1	0
Thirst	5	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	2	0
Illness	11	0
Induration	2	0
Influenza like illness	10	0
Local reaction	1	0
Peripheral swelling	105	0
Screaming	1	0
Swelling	57	0
Swelling face	8	0
<i>Inflammations</i>		
Inflammation	7	0
Soft tissue inflammation	1	0
<i>Infusion site reactions</i>		
Infusion site pain	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site erythema	12	0
Injection site mass	8	0
Injection site pain	34	0
Injection site pruritus	7	0
Injection site rash	14	0
Injection site reaction	1	0
Injection site swelling	2	0
Injection site urticaria	7	0
Injection site warmth	8	0
<i>Mass conditions NEC</i>		

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General disorders General disorders cont'd		
Mass	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	18	0
Chest discomfort	2	0
Chest pain	8	0
Discomfort	8	0
Pain	59	0
Tenderness	10	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	7	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site erythema	25	0
Vaccination site induration	3	0
Vaccination site inflammation	1	0
Vaccination site mass	5	0
Vaccination site oedema	1	0
Vaccination site pain	16	0
Vaccination site pruritus	5	0
Vaccination site rash	7	0
Vaccination site swelling	11	0
Vaccination site warmth	6	0
General disorders SOC TOTAL	891	1

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

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	17	0
Infusion related hypersensitivity reaction	1	0
Type IV hypersensitivity reaction	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	5	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
Immune system disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	2	0
<i>Candida infections</i>		
Vulvovaginal candidiasis	2	0
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Coxiella infections</i>		
Q fever	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
<i>Fungal infections NEC</i>		
Fungal skin infection	1	0
<i>Herpes viral infections</i>		
Herpes zoster	5	0
Oral herpes	4	0
<i>Infections NEC</i>		
Infection	6	0
Localised infection	1	0
Respiratory tract infection	1	0
Vaccination site infection	1	0
Vestibulitis	1	0
<i>Infectious transmissions</i>		
Secondary transmission	1	0
<i>Influenza viral infections</i>		
Influenza	4	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
Pneumonia	2	0
<i>Skin structures and soft tissue infections</i>		
Pustule	3	0
Skin infection	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>		
Nasopharyngitis	6	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Sweating fever	2	0
Infections SOC TOTAL	54	0

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Reaction Name	Total	Fatal
Injuries		
<i>Conditions caused by cold</i>		
Chillblains	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	5	0
Maternal exposure during pregnancy	6	0
Paternal exposure during pregnancy	2	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	1	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	9	0
<i>Thermal burns</i>		
Thermal burn	2	0
Injuries SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	4	0
Heart rate increased	3	0
Heart rate irregular	1	0
<i>Liver function analyses</i>		
Liver function test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	3	0
Body temperature increased	2	0
Respiratory rate increased	1	0
Skin temperature	2	0
Weight decreased	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 increased	1	0
Blood pressure measurement	1	0
<i>Virus identification and serology</i>		
SARS-CoV-2 antibody test	1	0
Investigations SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	5	0
<i>Disorders of purine metabolism</i>		
Gout	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	2	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
Metabolic disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	3	0
Pain in jaw	3	0
Spinal pain	2	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	50	0
Joint stiffness	2	0
Joint swelling	3	0
<i>Muscle pains</i>		
Myalgia	54	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	2	0
Muscle haemorrhage	1	0
Muscle spasms	9	0
Muscle tightness	3	0
Muscle twitching	2	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	15	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dupuytren's contracture	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	9	0
Flank pain	1	0
Limb discomfort	16	0
Musculoskeletal discomfort	1	0
Neck pain	7	0
Pain in extremity	146	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Groin pain	1	0
Soft tissue swelling	1	0
<i>Tendon disorders</i>		
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	341	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebrovascular accident	2	0
Subarachnoid haemorrhage	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	17	0
Loss of consciousness	6	0
Somnolence	9	0
Syncope	19	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	2	0
<i>Headaches NEC</i>		
Cluster headache	3	0
Headache	155	0
Sinus headache	2	0
Tension headache	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	2	0
<i>Migraine headaches</i>		
Migraine	13	0
Migraine with aura	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	88	0
Dizziness postural	7	0
Head discomfort	1	0
Neurological symptom	2	0
Presyncope	4	0
Unresponsive to stimuli	1	0
<i>Olfactory nerve disorders</i>		
Parosmia	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	9	0
Hyperaesthesia	1	0
Hypoaesthesia	22	0
Paraesthesia	39	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiplegia	1	0
Monoparesis	1	0
Paralysis	2	0
<i>Seizures and seizure disorders NEC</i>		
Febrile convulsion	1	0
Seizure	3	0
Status epilepticus	4	0
<i>Sensory abnormalities NEC</i>		
Ageusia	2	0
Dysgeusia	21	0
Electric shock sensation	1	0
Neuralgia	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Post herpetic neuralgia	1	0
Restless legs syndrome	1	0
Sensory disturbance	1	0
Taste disorder	3	0
Sleep disturbances NEC		
Sleep deficit	1	0
Speech and language abnormalities		
Dysarthria	1	0
Incoherent	1	0
Slow speech	1	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	10	0
Nervous system disorders SOC TOTAL	476	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	1	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>Anxiety symptoms</i>		
Anxiety	4	0
Nervousness	3	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<i>Confusion and disorientation</i>		
Confusional state	3	0
Disorientation	1	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	5	0
Terminal insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	2	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional disorder	3	0
Emotional distress	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	3	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Abnormal dreams	4	0
Nightmare	3	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	2	0
Psychiatric disorders SOC TOTAL	50	0

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

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	2	0
Intermenstrual bleeding	2	0
Menstrual disorder	3	0
Menstruation irregular	4	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	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 signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	6	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
Reproductive & breast disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	14	0
<i>Bronchospasm and obstruction</i>		
Wheezing	3	0
<i>Coughing and associated symptoms</i>		
Cough	12	0
Haemoptysis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	10	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 paraesthesia	1	0
Pharyngeal swelling	4	0
<i>Upper respiratory tract signs and symptoms</i>		
Nasal discomfort	1	0
Oropharyngeal pain	13	0
Rhinorrhoea	6	0
Sinus pain	4	0
Throat irritation	4	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	79	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 06-May-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	8	0
Miliaria	2	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	3	0
Erythema multiforme	1	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	6	0
Pain of skin	1	0
Papule	2	0
Skin burning sensation	6	0
Skin induration	1	0
Skin lesion	1	0
Skin reaction	8	0
Skin sensitisation	1	0
Skin swelling	1	0
Skin warm	8	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	9	0
Dermatitis atopic	2	0
Eczema	3	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	68	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Pruritus NEC</i>		
Pruritus	188	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	127	0
Rash erythematous	71	0
Rash macular	6	0
Rash papular	10	0
Rash pruritic	42	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Urticarias</i>		
Urticaria	26	0
Skin disorders SOC TOTAL	616	0

Case Series Drug Analysis Print

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Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
Social circumstances SOC TOTAL	2	0

Case Series Drug Analysis Print

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Report Run Date: 06-May-2021

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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
Surgical & medical procedures SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 06-May-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haemorrhage	4	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	3	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Venous thrombosis limb	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	3	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	6	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	33	0
TOTAL REACTIONS FOR DRUG	3056	2
TOTAL REPORTS	1081	
TOTAL FATAL OUTCOME REPORTS		2