

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Data Lock Date: 21-Apr-2021 19:00:03

All UK spontaneous reports received between 07/04/2021 and 21/04/21
for COVID-19 vaccine Moderna

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2021

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenopathy	7	0
Blood disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	4	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	1	0
Cardiac disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Hearing losses</i>		
Deafness	1	0
Hypoacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	5	0
Vertigo	2	0
Ear disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	3	0
Eye disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	10	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	18	0
Vomiting	4	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
Lip dry	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Paraesthesia oral	3	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	3	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	2	0
Gastrointestinal disorders SOC TOTAL	57	0

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General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Asthenia	4	0
Fatigue	40	0
Malaise	2	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	26	0
<i>Feelings and sensations NEC</i>		
Chills	26	0
Feeling abnormal	2	0
Feeling cold	2	0
Feeling drunk	1	0
Feeling hot	1	0
Feeling of body temperature change	1	0
Thirst	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	1	0
Illness	4	0
Influenza like illness	3	0
Peripheral swelling	17	0
Swelling	2	0
Swelling face	3	0
<i>Infusion site reactions</i>		
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site erythema	3	0
Injection site mass	1	0
Injection site pain	14	0
Injection site pruritus	1	0
Injection site warmth	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	4	0
Chest discomfort	1	0
Chest pain	3	0
Pain	11	0
Tenderness	3	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	1	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	3	0
Vaccination site induration	1	0
Vaccination site mass	1	0
Vaccination site pain	3	0
Vaccination site pruritus	1	0
Vaccination site rash	2	0
Vaccination site swelling	1	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	199	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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Immune system disorders		
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
Immune system disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Infections		
<i>Coronavirus infections</i>		
COVID-19	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Fungal infections NEC</i>		
Fungal skin infection	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
Oral herpes	1	0
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Tinea infections</i>		
Body tinea	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Sweating fever	1	0
Infections SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	1	0
Paternal exposure during pregnancy	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Post procedural complication	1	0
<i>Skin injuries NEC</i>		
Contusion	2	0
Injuries SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	2	0
Heart rate increased	1	0
Heart rate irregular	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	1	0
Skin temperature	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure measurement	1	0
Investigations SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Disorders of purine metabolism</i>		
Gout	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
Metabolic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	19	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	19	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle tightness	1	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	3	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Limb discomfort	3	0
Musculoskeletal discomfort	1	0
Neck pain	1	0
Pain in extremity	32	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
<i>Tendon disorders</i>		
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	90	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	1
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Loss of consciousness	3	0
Somnolence	1	0
Syncope	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
<i>Headaches NEC</i>		
Headache	44	0
Sinus headache	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	23	0
Dizziness postural	3	0
Presyncope	2	0
<i>Olfactory nerve disorders</i>		
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hypoaesthesia	11	0
Paraesthesia	7	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Febrile convulsion	1	0
Seizure	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	5	0
Sensory disturbance	1	0
Taste disorder	2	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	1	0
<i>Speech and language abnormalities</i>		
Incoherent	1	0
<i>Tremor (excl congenital)</i>		
Tremor	5	0
Nervous system disorders SOC TOTAL	128	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	1	0
Nervousness	1	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
Terminal insomnia	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	3	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
Nightmare	1	0
Psychiatric disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	2	0
Renal & urinary disorders SOC TOTAL	2	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>		
Menstrual disorder	1	0
Menstruation irregular	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	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
Reproductive & breast disorders SOC TOTAL	7	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	4	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	4	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	7	0
Sinus pain	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	22	0

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Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	4	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Papule	1	0
Skin burning sensation	2	0
Skin reaction	1	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
Dermatitis atopic	1	0
Eczema	1	0
<i>Erythemas</i>		
Erythema	3	0
<i>Pruritus NEC</i>		
Pruritus	18	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	13	0
Rash erythematous	7	0
Rash papular	4	0
Rash pruritic	3	0
<i>Urticarias</i>		
Urticaria	5	0
Skin disorders SOC TOTAL	68	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	6	0
TOTAL REACTIONS FOR DRUG	660	2
TOTAL REPORTS	228	
TOTAL FATAL OUTCOME REPORTS		2