

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

COVID-19 vaccine brand unspecified analysis print: All UK spontaneous reports received up to and including 14/02/21 for COVID-19 vaccines where the brand has not been specified.

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	3	0
Blood disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	1
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	2	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	2	0
Ear swelling	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	4	0
Ear disorders SOC TOTAL	9	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal toxicity	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness transient	1	0
Visual impairment	1	0
Eye disorders SOC TOTAL	11	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	9	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faeces discoloured	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	5	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
<i>Nausea and vomiting symptoms</i>		
Nausea	32	0
Vomiting	17	0
Vomiting projectile	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Lip pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
Gastrointestinal disorders SOC TOTAL	79	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site burn	1	0
<i>Asthenic conditions</i>		
Asthenia	9	0
Fatigue	42	0
Malaise	23	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	45	0
<i>Feelings and sensations NEC</i>		
Chills	42	0
Feeling abnormal	3	0
Feeling cold	12	0
Feeling hot	3	0
Feeling of body temperature change	4	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Illness	2	0
Influenza like illness	9	0
Peripheral swelling	5	0
Swelling	4	0
Swelling face	4	0
<i>Injection site reactions</i>		
Injection site inflammation	1	0
Injection site pain	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	4	0
Chest pain	4	0
Discomfort	1	0
Facial pain	1	0
Pain	29	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site erythema	6	0
Vaccination site induration	1	0
Vaccination site inflammation	2	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	1	0
Vaccination site pain	7	0
Vaccination site papule	1	0
Vaccination site pruritus	2	0
Vaccination site rash	1	0
Vaccination site swelling	4	0
Vaccination site warmth	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
General disorders SOC TOTAL	289	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	1	0
Immune system disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Coronavirus infections</i>		
COVID-19	1	0
<i>Herpes viral infections</i>		
Herpes simplex reactivation	1	0
Herpes zoster	1	0
Oral herpes	1	0
<i>Influenza viral infections</i>		
Influenza	4	0
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	1	1
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Infections SOC TOTAL	10	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Medication errors, product use errors and issues NEC</i>		
Wrong technique in product usage process	1	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	5	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
International normalised ratio increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature increased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Anticoagulation drug level below therapeutic	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	3	0
Investigations SOC TOTAL	11	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	24	0
Hypophagia	2	0
Metabolic disorders SOC TOTAL	26	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Spinal pain	1	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	15	0
Joint stiffness	2	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	21	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle tightness	1	0
Muscle twitching	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Neck pain	1	0
Pain in extremity	22	0
Muscle & tissue disorders SOC TOTAL	77	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	3	0
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	7	0
Somnolence	8	0
Syncope	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
<i>Eye movement disorders</i>		
Vlth nerve paralysis	1	0
<i>Headaches NEC</i>		
Headache	76	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	8	0
Retinal migraine	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	26	0
Dizziness postural	1	0
Neurological symptom	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hypoaesthesia	2	0
Paraesthesia	8	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Convulsions local	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	3	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	1	0
<i>Tremor (excl congenital)</i>		
Tremor	18	0
Nervous system disorders SOC TOTAL	177	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Anxiety	1	0
Nervousness	1	0
Stress	1	0
<i>Confusion and disorientation</i>		
Confusional state	7	0
Disorientation	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	1	0
Psychiatric disorders SOC TOTAL	22	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Urinary incontinence	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Urine odour abnormal	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	2	0
Renal & urinary disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation with increased bleeding</i>		
Polymenorrhoea	1	0
Reproductive & breast disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	8	1
<i>Coughing and associated symptoms</i>		
Cough	4	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Rhinorrhoea	2	0
Sinus pain	1	0
Respiratory disorders SOC TOTAL	18	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	7	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin burning sensation	1	0
<i>Erythemas</i>		
Erythema	4	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	6	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	7	0
Rash erythematous	1	0
Rash pruritic	3	0
<i>Urticarias</i>		
Urticaria	3	0
Skin disorders SOC TOTAL	38	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Social circumstances SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular rupture	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
Vascular disorders SOC TOTAL	7	0
TOTAL REACTIONS FOR DRUG	796	4
TOTAL REPORTS	228	
TOTAL FATAL OUTCOME REPORTS		4