COVID-19 vaccine brand unspecified analysis print

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

All UK spontaneous reports received up to and including 28/03/21 for COVID-19 vaccines where the brand has not been specified.

Report Run Date: 01-Apr-2021, Page 1

Reaction Name	Total	Fatal
Blood disorders		
Coagulopathies		
Coagulopathy	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	6	0
Neutropenias		
Neutropenia	1	0
Thrombocytopenias		
Immune thrombocytopenia	3	3
Thrombocytopenia		0
Blood disorders SOC TOTAL	12	2 3

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	4	0
Ischaemic coronary artery disorders		
Myocardial infarction	2	2
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	7	2

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	1	0
Ear pain	3	0
Inner ear signs and symptoms		
Tinnitus	3	0
Vertigo	5	0
Ear disorders SOC TOTAL	12	0

Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	2	0
Lacrimation disorders		
Lacrimation increased	2	0
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye pain	2	0
Eye swelling	2	0
Ocular infections, inflammations and associated manifestations		
Eye pruritus	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal haemorrhage	1	0
Retinal structural change, deposit and degeneration		
Retinal toxicity	1	0
Visual disorders NEC		
Diplopia	3	0
Photopsia	1	0
Vision blurred	2	0
Visual impairment and blindness (excl colour blindness)		
Blindness transient	1	0
Visual impairment	1	0
Eye disorders SOC TOTAL	20	0

Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Gastrointestinal disorders		
Anal and rectal pains		
Proctalgia	1	0
Dental pain and sensation disorders		
Toothache	2	0
Diarrhoea (excl infective)		
Diarrhoea	14	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Faecal abnormalities NEC		
Abnormal faeces	2	0
Faecaloma	1	0
Faeces discoloured	2	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastritis (excl infective)		
Gastritis	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	1	0
Abdominal pain upper	7	0
Gastrointestinal pain	1	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	6	0
Nausea and vomiting symptoms		
Nausea	55	0
Vomiting	28	0
Vomiting projectile	1	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue disorders NEC		_
Oral papule	1	0
Oral soft tissue signs and symptoms		•
Hypoaesthesia oral	1	0
Lip pain	1	0
Oral pain	2	0
Oral soft tissue swelling and oedema		•
Lip swelling	2	0
Mouth swelling	1	0
Stomatitis and ulceration	4	^
Mouth ulceration	4	0
Tongue signs and symptoms	4	^
Swollen tongue	440	0
Gastrointestinal disorders SOC TOTAL	140	0

Name: COVID-19 vaccine brand unspecified analysis print

Run Date: 01-Apr-2021
Reaction Date: 06-Feb-2020
Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1 Report Run Date: 01-Apr-2021 Earliest Reaction Date: 06-Feb-2020

	DRA Version: MedDRA 23.1		
Reaction Name	To	<u>otal</u>	<u>Fatal</u>
General disorders			
Application and instillation site reactions			
Application site burn		1	0
Application site swelling		1	0
Asthenic conditions			
Asthenia		13	0
Fatigue		80	0
Malaise		31	0
Death and sudden death			
Death		4	4
Febrile disorders			
Pyrexia		76	0
Feelings and sensations NEC			
Chills		65	0
Feeling abnormal		4	0
Feeling cold		15	0
Feeling hot		7	0
Feeling of body temperature change		4	0
Thirst		2	0
Gait disturbances			
Gait disturbance		4	0
Gait inability		1	0
General signs and symptoms NEC		·	Ŭ
Condition aggravated		2	0
Illness		10	0
Influenza like illness		11	0
Peripheral swelling		12	0
Swelling		8	0
Swelling face		6	0
Inflammations		J	0
Systemic inflammatory response syndrome		1	0
Injection site reactions		•	0
Injection site erythema		2	0
Injection site inflammation		1	0
Injection site mass		2	0
Injection site pain		2	0
Injection site puritus		1	0
Pain and discomfort NEC		•	J
Axillary pain		1	0
Chest discomfort		5	0
Chest pain		6	0
Discomfort		1	0
Facial discomfort		1	0
Facial pain		1	0
Pain		40	0
Therapeutic and nontherapeutic responses		70	U
Adverse drug reaction		2	0
Vaccination site reactions			U
Vaccination site bruising		2	0
		8	
Vaccination site erythema Vaccination site induration		0	0
Vaccination site induration Vaccination site inflammation		ر ر	
Vaccination site inflammation Vaccination site mass		2 3	0 0
		3 11	
Vaccination site pain		11	0

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site papule	1	0
Vaccination site pruritus	2	0
Vaccination site rash	1	0
Vaccination site swelling	6	0
Vaccination site vesicles	1	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	463	4

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	1	0
Cholestasis and jaundice		
Jaundice	1	0
Hepatic disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Immune system disorders		
Acute and chronic sarcoidosis		
Sarcoidosis	1	0
Allergic conditions NEC		
Hypersensitivity	2	0
Allergies to foods, food additives, drugs and other chemicals		
Allergy to vaccine	1	0
Drug hypersensitivity	1	0
Immune system disorders SOC TOTAL	5	0

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Infections		
Central nervous system and spinal infections		
Encephalitis	1	0
Meningitis aseptic	1	0
Coronavirus infections		
COVID-19	4	0
Suspected COVID-19	1	0
Herpes viral infections		
Herpes zoster	2	0
Oral herpes	2	0
Infections NEC		
Infection	1	0
Influenza viral infections		
Influenza	5	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	0
Pneumonia	2	1
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	1	0
Upper respiratory tract infections		
Nasopharyngitis	1	0
Urinary tract infections		
Cystitis	1	0
Viral infections NEC		
Gastroenteritis viral	1	0
Sweating fever	1	0
Infections SOC TOTAL	25	1

Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during breast feeding	1	0
Eye injuries NEC		
Eye contusion	1	0
Eye injury	1	0
Medication errors, product use errors and issues NEC		
Wrong technique in product usage process	1	0
Non-site specific injuries NEC		
Fall	3	0
Non-site specific procedural complications		
Incision site pain	1	0
Injection related reaction	2	0
Skin injuries NEC		
Contusion	1	0
Injuries SOC TOTAL	11	0

Reaction Name	Total	Fatal
Investigations		
Coagulation and bleeding analyses		
Fibrin D dimer increased	1	0
International normalised ratio increased	1	0
Heart rate and pulse investigations		
Heart rate	2	0
Heart rate increased	1	0
Investigations NEC		
Blood test	1	0
Mineral and electrolyte analyses		
Blood potassium decreased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	1	0
Weight decreased	1	0
Respiratory and pulmonary function diagnostic procedures		
Peak expiratory flow rate decreased	1	0
Therapeutic drug monitoring analyses		
Anticoagulation drug level below therapeutic	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure increased	5	0
White blood cell analyses		
White blood cell count decreased	1	0
Investigations SOC TOTAL	21	0

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	30	0
Hypophagia		0
Hyperglycaemic conditions NEC		
Hyperglycaemia	1	0
Sodium imbalance		
Hyponatraemia		0 ا
Metabolic disorders SOC TOTAL	34	l o

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Bone related signs and symptoms		
Bone pain	1	0
Spinal pain	1	0
Cartilage disorders		
Costochondritis	1	0
Joint related signs and symptoms		
Arthralgia	33	
Joint stiffness	1	0
Joint swelling	1	0
Muscle pains		
Myalgia	32	0
Muscle related signs and symptoms NEC		
Muscle fatigue	1	0
Muscle spasms	3	0
Muscle tightness	2	0
Muscle twitching	1	0
Muscle tone abnormalities		
Muscle rigidity	2	0
Muscle weakness conditions		
Muscular weakness	7	0
Musculoskeletal and connective tissue conditions NEC		
Mobility decreased	1	0
Musculoskeletal stiffness	5	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	5	0
Limb discomfort	2	0
Musculoskeletal chest pain	1	0
Musculoskeletal pain	1	0
Neck pain	5	0
Pain in extremity	38	0
Muscle & tissue disorders SOC TOTAL	144	0

Name: COVID-19 vaccine brand unspecified analysis print
Run Date: 01-Apr-2021
Reaction Date: 06-Feb-2020
Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1 Report Run Date: 01-Apr-2021 Earliest Reaction Date: 06-Feb-2020

Earliest Reaction Date: 06-Feb-2020	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Nervous system disorders			
Acute polyneuropathies			
Guillain-Barre syndrome		2	0
Central nervous system haemorrhages and o	erebrovascular accidents		
Cerebrovascular accident		3	0
Coordination and balance disturbances			
Balance disorder		4	0
Dysstasia		2	0
Disturbances in consciousness NEC			
Lethargy		10	0
Loss of consciousness		3	0
Somnolence		10	0
Syncope		4	0
Dyskinesias and movement disorders NEC			
Bradykinesia		1	0
Eye movement disorders			
VIth nerve paralysis		1	0
Facial cranial nerve disorders			
Facial paralysis		2	0
Facial paresis		1	0
Headaches NEC			
Headache		124	0
Memory loss (excl dementia)			
Amnesia		2	0
Mental impairment (excl dementia and memo	ory loss)		
Disturbance in attention	,	2	0
Migraine headaches			
Migraine		10	0
Retinal migraine		1	0
Neurological signs and symptoms NEC			
Dizziness		35	0
Dizziness postural		4	0
Neurological symptom		1	0
Presyncope		1	0
Olfactory nerve disorders			
Anosmia		1	0
Parosmia		1	0
Paraesthesias and dysaesthesias			
Burning sensation		3	0
Hypoaesthesia		6	0
Paraesthesia		11	0
Paralysis and paresis (excl cranial nerve)			
Hemiparesis		1	0
Paralysis		1	0
Parkinson's disease and parkinsonism			
Freezing phenomenon		1	0
Seizures and seizure disorders NEC			
Convulsions local		1	0
Epilepsy		1	0
Seizure		2	0
Sensory abnormalities NEC			
Ageusia		2	0
Dysgeusia		2	0
Sensory disturbance		1	0

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Sleep disturbances NEC		
Poor quality sleep	1	I 0
Speech and language abnormalities		
Dysarthria	1	I 0
Transient cerebrovascular events		
Transient ischaemic attack	1	1 0
Tremor (excl congenital)		
Tremor	29	0
Nervous system disorders SOC TOTAL	290	o l

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Anxiety symptoms		
Anxiety	2	0
Nervousness	2	0
Stress	1	0
Confusion and disorientation		
Confusional state	7	0
Disorientation	5	0
Disturbances in initiating and maintaining sleep		
Insomnia	3	0
Emotional and mood disturbances NEC		
Emotional disorder	1	0
Irritability	1	0
Hallucinations (excl sleep-related)		
Hallucination	3	0
Increased physical activity levels		
Restlessness	1	0
Mood alterations with depressive symptoms		_
Depressed mood	1	0
Panic attacks and disorders		
Panic attack	1	0
Perception disturbances NEC		•
Autoscopy	1	0
Sleep disorders NEC		
Sleep disorder	2	0
Thinking disturbances		_
Bradyphrenia	1	0
Psychiatric disorders SOC TOTAL	33	0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	1	0
Urinary incontinence	2	2 0
Renal lithiasis		
Nephrolithiasis	1	0
Urinary abnormalities		
Haematuria	1	0
Urine odour abnormal	1	0
Urinary tract signs and symptoms NEC		
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	9	o o

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast signs and symptoms		
Breast pain	1	0
Menopausal effects NEC		
Premature menopause	1	0
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	1	0
Menstruation and uterine bleeding NEC		
Menstruation irregular	1	0
Menstruation with decreased bleeding		
Amenorrhoea	1	0
Menstruation with increased bleeding		
Polymenorrhoea	1	0
Reproductive & breast disorders SOC TOTAL	6	l o

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	15	5 1
Hypopnoea	1	0
Bronchospasm and obstruction		
Asthma	1	1 0
Chronic obstructive pulmonary disease	1	1 0
Wheezing	1	0
Coughing and associated symptoms		
Cough	(5 0
Productive cough	1	1 0
Nasal congestion and inflammations		
Nasal congestion	1	1 0
Nasal disorders NEC		
Epistaxis	1	1 0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	1
Respiratory tract disorders NEC		
Lung disorder	1	1 0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	4	۱ o
Rhinorrhoea	3	3 0
Respiratory disorders SOC TOTAL	37	7 2

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Skin disorders		
Alopecias		
Alopecia	1	0
Apocrine and eccrine gland disorders		
Cold sweat	2	0
Hyperhidrosis	14	0
Night sweats	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Scar pain	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin discolouration	1	0
Skin indentation	1	0
Skin swelling	1	0
Erythemas		
Erythema	9	0
Exfoliative conditions		
Skin exfoliation	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	13	0
Rashes, eruptions and exanthems NEC		
Rash	17	0
Rash erythematous	2	0
Rash macular	1	0
Rash papular	1	0
Rash pruritic	5	0
Rash vesicular	1	0
Urticarias		
Urticaria	5	0
Skin disorders SOC TOTAL	82	0

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 01-Apr-2021 Data Lock Date: 28-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
Disability issues		
Bedridden	1	0
Social circumstances SOC TOTAL	1	0

Report Run Date: 01-Apr-2021, Page 23

Name: COVID-19 vaccine brand unspecified analysis print

Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Shock	1	0
Haemorrhages NEC		
Haematoma	1	0
Non-site specific vascular disorders NEC		
Vascular rupture	1	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	3	0
Peripheral vascular disorders NEC		
Flushing	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	1	0
Phlebitis NEC		
Phlebitis	1	0
Vascular hypertensive disorders NEC		
Hypertension	4	0
Vascular disorders SOC TOTAL	13	0
TOTAL REACTIONS FOR DRUG	1367	12
TOTAL REPORTS	418	
TOTAL FATAL OUTCOME REPORTS		12