COVID-19 vaccine brand unspecified analysis print

Report Run Date: 12-Apr-2021

Data Lock Date: 05-Apr-2021 19:00:03

All UK spontaneous reports received up to and including 05/04/21 for COVID-19 vaccines where the brand has not been specified.

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Reaction Name	Total	Fatal
Blood disorders		
Coagulopathies		
Coagulopathy	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	6	0
Neutropenias		
Neutropenia	1	0
Thrombocytopenias		
Heparin-induced thrombocytopenia	1	0
Immune thrombocytopenia	3	3
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	13	l 3l

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Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	6	6 0
Ischaemic coronary artery disorders		
Myocardial infarction	2	2 2
Supraventricular arrhythmias		
Atrial fibrillation	2	0
Cardiac disorders SOC TOTAL	10) 2

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	2	0
Ear pain	3	0
Hearing losses		
Hypoacusis	1	0
Inner ear signs and symptoms		
Tinnitus	3	0
Vertigo	5	0
Ear disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Eve 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	3	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	1	0
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	2	0
Eve disorders SOC TOTAL	23	0

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Earliest Reaction Date: 06-Feb-2020	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders		
Anal and rectal pains		
Proctalgia	1	0
Dental pain and sensation disorders		
Toothache	2	. 0
Diarrhoea (excl infective)		
Diarrhoea	16	0
Dyspeptic signs and symptoms		
Dyspepsia	1	0
Faecal abnormalities NEC		
Abnormal faeces	2	. 0
Faecaloma	1	
Faeces discoloured	2	.l o
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastritis (excl infective)		
Gastritis	1	0
Gastrointestinal and abdominal pains (ex	cl oral and throat)	
Abdominal pain	1	0
Abdominal pain upper	7	
Gastrointestinal pain	1	0
Gastrointestinal atonic and hypomotility d	isorders NEC	
Constipation	1	0
Gastrooesophageal reflux disease	1	0
Gastrointestinal signs and symptoms NE	c l	
Abdominal discomfort	7	0
Anal incontinence	1 1	0
Nausea and vomiting symptoms		
Nausea	59	0
Vomiting	28	1
Vomiting projectile	1	
Oral dryness and saliva altered		
Dry mouth	1 1	0
Oral soft tissue disorders NEC		
Oral papule	1 1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1 1	0
Lip pain	1	0
Oral pain	2	
Oral soft tissue swelling and oedema		
Lip swelling	2	. 0
Mouth swelling	1	Ö
Stomatitis and ulceration		
Mouth ulceration	4	. 0
Tongue signs and symptoms		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	148	

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Earliest Reaction Date: 06-Feb-2020 MedDRA Version: M	edDRA 23.1	
Reaction Name	Total	<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	87	
Malaise	31	
Death and sudden death		
Death	4	4
Febrile disorders		
Pyrexia	78	0
Feelings and sensations NEC		
Chills	66	0
Feeling abnormal	4	_
Feeling cold	15	
Feeling hot	8	
Feeling of body temperature change	4	
Thirst	2	
Gait disturbances		
Gait disturbance	4	0
Gait inability	1	_
General signs and symptoms NEC		, and the second
Condition aggravated	2	0
Illness	10	
Influenza like illness	11	
Peripheral swelling	13	
Swelling	10	
Swelling face	6	
Inflammations		
Systemic inflammatory response syndrome	1	0
Injection site reactions		
Injection site erythema	2	0
Injection site inflammation	1	
Injection site mass	2	
Injection site pain	l	۸ ا
Injection site pruritus	1	Ö
Pain and discomfort NEC		
Axillary pain	1	0
Chest discomfort	5	I
Chest pain	5 7	0
Discomfort	1	Ō
Facial discomfort	1	0
Facial pain	1	Ō
Pain	41	Ö
Therapeutic and nontherapeutic responses		
Adverse drug reaction	5	0
Vaccination site reactions		
Vaccination site bruising	2	0
Vaccination site erythema	9	
Vaccination site induration	1	Ö
Vaccination site indulation Vaccination site inflammation	2	
Vaccination site mass	2 3	0
Vaccination site mass Vaccination site pain	11	

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site papule	1	0
Vaccination site pruritus	2	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site swelling	6	0
Vaccination site vesicles	1	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	485	4

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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

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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
Transplant rejections		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Vaccination site cellulitis	1	0
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	7	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	28	1

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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		
Medication error	1	0
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
Product administration errors and issues		
Incorrect route of product administration	1	0
Skin injuries NEC		
Contusion	1	0
Vaccination related complications		
Vaccination complication	1	0
Injuries SOC TOTAL	14	0

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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
Investigations SOC TOTAL	20	l o

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	31	0
Hypophagia	2	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	1	0
Sodium imbalance		
Hyponatraemia	1	0
Metabolic disorders SOC TOTAL	35	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	0
Bone related signs and symptoms		
Bone pain	1	0
Spinal pain	1	0
Cartilage disorders		
Costochondritis	1	0
Joint related signs and symptoms		
Arthralgia	38	0
Joint stiffness	1	0
Joint swelling	1	0
Muscle pains		
Myalgia	35	0
Muscle related signs and symptoms NEC		
Muscle fatigue	2	0
Muscle spasms	4	0
Muscle tightness	2	0
Muscle twitching	1	0
Muscle tone abnormalities		
Muscle rigidity	2	0
Muscle weakness conditions		
Muscular weakness	9	0
Musculoskeletal and connective tissue conditions NEC		
Mobility decreased	1	0
Musculoskeletal stiffness	5	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	7	0
Limb discomfort	2	0
Musculoskeletal chest pain	1	0
Musculoskeletal pain	1	0
Neck pain	6	0
Pain in extremity	38	
Muscle & tissue disorders SOC TOTAL	160	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies	4	
Acute polyneuropathy	1	0
Guillain-Barre syndrome	2	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebrovascular accident	3	0
Haemorrhage intracranial	1	0
Coordination and balance disturbances	_	
Balance disorder	5	0
Dysstasia	2	0
Disturbances in consciousness NEC	4.0	
Lethargy	10	C
Loss of consciousness	3	C
Somnolence	10	C
Syncope	4	C
Dyskinesias and movement disorders NEC		
Bradykinesia	1	C
Eye movement disorders		
VIth nerve paralysis	1	C
Facial cranial nerve disorders		
Facial paralysis	2	C
Facial paresis	1	C
Headaches NEC		
Headache	134	C
Tension headache	1	C
Memory loss (excl dementia)		
Amnesia	2	C
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	2	C
Migraine headaches		
Migraine	10	C
Retinal migraine	1	C
Neurological signs and symptoms NEC		
Dizziness	38	C
Dizziness postural	4	C
Neurological symptom	1	C
Presyncope	1	C
Olfactory nerve disorders		
Anosmia	1	(
Parosmia	1	(
Paraesthesias and dysaesthesias		
Burning sensation	3	(
Hypoaesthesia	5	(
Paraesthesia	10	(
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	C
Paralysis	1	C
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	(
Seizures and seizure disorders NEC		
Convulsions local	1	C
Epilepsy	1	Č
Seizure	3	Č

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders us system disorders cont'd		
Ageusia	2	2 0
Dysgeusia	3	3 0
Sensory disturbance	1	I 0
Sleep disturbances NEC		
Poor quality sleep	1	I 0
Speech and language abnormalities		
Dysarthria	1	ı o
Transient cerebrovascular events		
Transient ischaemic attack	2	2 0
Tremor (excl congenital)		
Tremor	29	0
Nervous system disorders SOC TOTAL	307	7 0

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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	8	0
Disorientation	5	0
Disturbances in initiating and maintaining sleep		
Insomnia	4	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	35	l o

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	1	0
Urinary incontinence	2	2 0
Renal lithiasis		
Nephrolithiasis	1	0
Renal neoplasms		
Renal cyst	1	0
Urinary abnormalities		
Haematuria	2	2 0
Urine odour abnormal	1	0
Urinary tract signs and symptoms NEC		
Renal pain	2	0
Renal & urinary disorders SOC TOTAL	10	0

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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	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	16	5 1
Hypopnoea	1	0
Bronchospasm and obstruction		
Asthma	1	0
Chronic obstructive pulmonary disease	1	ı o
Wheezing	1	0 ا
Coughing and associated symptoms		
Cough		5 0
Nasal congestion and inflammations		
Nasal congestion	1	1 0
Nasal disorders NEC		
Epistaxis	1	ı 0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	ı 1
Respiratory tract disorders NEC		
Lung disorder	1	ı o
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	4	l o
Rhinorrhoea	3	3 0
Respiratory disorders SOC TOTAL	36	8 2

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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 reaction	1	0
Skin swelling	1	0
Erythemas		
Erythema	10	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	18	0
Rash erythematous	2	0
Rash macular	1	0
Rash papular	1	0
Rash pruritic	7	0
Rash vesicular	1	0
Urticarias		
Urticaria	6	0
Skin disorders SOC TOTAL	88	0

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

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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	1454	12
TOTAL REPORTS	457	
TOTAL FATAL OUTCOME REPORTS		12