COVID-19 vaccine brand unspecified analysis print

Report Run Date:	22-Mar-2021
Data Lock Date:	14-Mar-2021 19:00:03

All UK spontaneous reports received up to and including 14/03/21 for COVID-19 vaccines where the brand has not been specified.

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021	Data Lock Date: 14-Mar-2021 19:00:03		
Earliest Reaction Date: 06-Feb-2020	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Blood disorders			
Lymphatic system disorders NEC			
Lymphadenopathy		3	0
Blood disorders SOC TOTAL		3	0

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

<u>Total</u>	<u>Fatal</u>
4	0
2	2
1	0
7	2
	Total 4 2 1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	1	0
Ear pain	2	0
Inner ear signs and symptoms		
Tinnitus	3	0
Vertigo	4	0
Ear disorders SOC TOTAL	10	0

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Earliest Reaction Date: 00-Feb-2020 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	1	0
Lacrimation disorders		
Lacrimation increased	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye pain	2	0
Eye swelling	1	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	2	0
Photopsia	1	0
Vision blurred	2	0
Visual impairment and blindness (excl colour blindness)		
Blindness transient	1	0
Visual impairment	1	0
Eve disorders SOC TOTAL	16	0

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
Gastrointestinal disorders		
Anal and rectal pains		
Proctalgia	1	0
Dental pain and sensation disorders		
Toothache	1	0
Diarrhoea (excl infective)		
Diarrhoea	12	0
Dyspeptic signs and symptoms		
Dyspepsia	1	0
Faecal abnormalities NEC		
Abnormal faeces	1	0
Faeces discoloured	1	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	6	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	5	0
Nausea and vomiting symptoms		
Nausea	45	0
Vomiting	25	0
Vomiting projectile	1	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1	0
Lip pain	1	0
Oral pain	1	0
Oral soft tissue swelling and oedema		
Lip swelling	2	0
Stomatitis and ulceration		
Mouth ulceration	2	0
Gastrointestinal disorders SOC TOTAL	111	0

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

	MedDRA Version: MedDRA 23.1	–
Reaction Name	Total	<u>Fatal</u>
General disorders		
Application and instillation site reactions		
Application site burn	1	1 0
Asthenic conditions		
Asthenia	11	
Fatigue	66	
Malaise	21	1 0
Death and sudden death		
Death	Z	4 4
Febrile disorders		
Pyrexia	59	9 0
Feelings and sensations NEC		
Chills	52	
Feeling abnormal	3	
Feeling cold	12	
Feeling hot	Ę	
Feeling of body temperature change	Z	
Thirst	1	1 0
Gait disturbances		
Gait disturbance	4	
Gait inability	1	1 O
General signs and symptoms NEC		
Condition aggravated		
Illness	5	
Influenza like illness	()	
Peripheral swelling		
Swelling	8	
Swelling face	6	6 0
Inflammations		
Systemic inflammatory response syndrome	1	1 0
Injection site reactions		
Injection site erythema	2	
Injection site inflammation	1	1 O
Injection site mass	2	2 0
Injection site pain	2	2 0
Injection site pruritus		1 0
Pain and discomfort NEC		
Axillary pain	1	1 0
Chest discomfort	5	5 0
Chest pain	Ę	
Discomfort	1	1 O
Facial discomfort	1	1 0
Facial pain	1	1 O
Pain	31	1 O
Therapeutic and nontherapeutic responses		
Adverse drug reaction	1	1 O
Vaccination site reactions		
Vaccination site bruising		
Vaccination site erythema	7	7 C
Vaccination site induration	1	1 0
Vaccination site inflammation	2	<u>2</u> C
Vaccination site mass		1 O
Vaccination site pain	3	
Vaccination site papule		1 0

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Earliest Reaction Date. 00-Feb-2020	MEUDRA VEISION. MEUDRA 23.1		
Reaction Name		Total	Fatal
General disorders General disorders cont'd			
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		371	4

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Earliest Reaction Date: 06-Feb-2020	MedDRA Version: MedDRA 23.1
Report Run Date: 22-Mar-2021	Data Lock Date: 14-Mar-2021 19:00:03

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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Earliest Reaction Date: 06-Feb-2020	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Immune system disorders			
Allergic conditions NEC			
Hypersensitivity		1	0
Allergies to foods, food additives, drugs and	d other chemicals		

Drug hypersensitivity Immune system disorders SOC TOTAL 0 0

1 2

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Reaction Name	Total	Fatal
Infections		
Coronavirus infections		
COVID-19	3	0
Herpes viral infections		
Herpes zoster	1	0
Oral herpes	1	0
Influenza viral infections		
Influenza	4	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	17	1

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

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

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

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	1	0
Heart rate increased	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
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	15	0

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Reaction Name 1	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	27	0
Hypophagia	2	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	1	0
Sodium imbalance		
Hyponatraemia	1	0
Metabolic disorders SOC TOTAL	31	0

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Earliest Reaction Date: 06-Feb-2020	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Fotal</u>	Fatal
Muscle & tissue disorders			
Bone related signs and symptoms			
Bone pain		1	0
Cartilage disorders			
Costochondritis		1	0
Joint related signs and symptoms			
Arthralgia		22	0
Joint stiffness		1	0
Joint swelling		1	0
Muscle pains			
Myalgia		26	0
Muscle related signs and symptoms NEC			
Muscle fatigue		1	0
Muscle spasms		2	0
Muscle tightness		2	0
Muscle twitching		1	0
Muscle weakness conditions			
Muscular weakness		5	0
Musculoskeletal and connective tissue con	nditions NEC		
Mobility decreased		1	0
Musculoskeletal stiffness		4	0
Musculoskeletal and connective tissue pa	in and discomfort		
Back pain		3	0
Musculoskeletal pain		1	0
Neck pain		2	0
Pain in extremity		28	0
Muscle & tissue disorders SOC TOTAL		102	0

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Earliest Reaction Date: 06-Feb-2020	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u> </u>
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome		2 (
Coordination and balance disturbances		
Balance disorder		3 (
Dysstasia		2 (
Disturbances in consciousness NEC		
Lethargy		9 (
Somnolence		8 (
Syncope		3 (
Dyskinesias and movement disorders NEC		
Bradykinesia		1 (
Hypokinesia		2 (
Eye movement disorders		
VIth nerve paralysis		1 (
Facial cranial nerve disorders		
Facial paresis		1 (
Headaches NEC		
Headache	9	6 (
Memory loss (excl dementia)		
Amnesia		2 (
Mental impairment (excl dementia and mem	orv loss)	
Disturbance in attention		2 (
Migraine headaches		
Migraine		8 (
Retinal migraine		1 0
Neurological signs and symptoms NEC		
Dizziness	2	9 (
Dizziness postural		4 0
Neurological symptom		1 0
Presyncope		1 0
Paraesthesias and dysaesthesias		
Burning sensation		3 (
Hypoaesthesia		3 (
Paraesthesia		8 0
Paralysis and paresis (excl cranial nerve)		
Paralysis		1 (
Seizures and seizure disorders NEC		
Convulsions local		1 (
Seizure		1
Sensory abnormalities NEC		
Dysgeusia		2 (
Sensory disturbance		1 (
Sleep disturbances NEC		
Poor quality sleep		1 (
Transient cerebrovascular events		1
Transient cerebrovascular events		1
		1 (
Tremor (excl congenital)		
Tremor	2	
Nervous system disorders SOC TOTAL	22	0

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Anxiety symptoms		
Anxiety	2	0
Nervousness	1	0
Stress	1	0
Confusion and disorientation		
Confusional state	7	0
Disorientation	4	0
Disturbances in initiating and maintaining sleep		
Insomnia	2	0
Emotional and mood disturbances NEC		
Emotional disorder	1	0
Irritability	1	0
Hallucinations (excl sleep-related)		
Hallucination	1	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	28	0

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

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

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Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020	Data Lock Date: 14-Mar-2021 19:0 MedDRA Version: MedDRA 23.1	0:03	
Reaction Name		Total	Fatal
Reproductive & breast disorders			
Menopausal effects on the genitourinary tra	ct		
Postmenopausal haemorrhage		1	0
Menstruation with increased bleeding			
Polymenorrhoea		1	0
Reproductive & breast disorders SOC TOTAL		2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dysphoea	12	1
Bronchospasm and obstruction		
Asthma	1	0
Chronic obstructive pulmonary disease	1	0
Coughing and associated symptoms		
Cough	5	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Nasal disorders NEC		
Epistaxis	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	1
Respiratory tract disorders NEC		
Lung disorder	1	0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	2	0
Rhinorrhoea	2	0
Respiratory disorders SOC TOTAL	27	2

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Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Cold sweat	2	0
Hyperhidrosis	11	0
Night sweats	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Skin burning sensation	1	0
Skin discolouration	1	0
Skin swelling	1	0
Erythemas		
Erythema	8	0
Exfoliative conditions		
Skin exfoliation	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	11	0
Rashes, eruptions and exanthems NEC		
Rash	12	0
Rash erythematous	2	0
Rash papular	1	0
Rash pruritic	4	0
Rash vesicular	1	0
Urticarias		
Urticaria	5	0
Skin disorders SOC TOTAL	65	0

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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	l o

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 22-Mar-2021 Earliest Reaction Date: 06-Feb-2020

Reaction Name	Total	Fatal
Vascular disorders		
Haemorrhages NEC		
Haematoma	1	0
Non-site specific vascular disorders NEC		
Vascular rupture	1	0
Peripheral vascular disorders NEC		
Flushing	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	1	0
Vascular hypertensive disorders NEC		
Hypertension	3	0
Vascular disorders SOC TOTAL	7	0
TOTAL REACTIONS FOR DRUG	1056	9
TOTAL REPORTS	325	
TOTAL FATAL OUTCOME REPORTS		9