Report Run Date: 21-Mar-2022

Data Lock Date: 09-Mar-2022 18:30:05

MedDRA Version: MedDRA 24.1

All suspected spontaneous reports from Scotland received up to and including 09/03/2022 for COVID-19 vaccines where the brand has not been specified.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	4	0
Thrombocytopenias		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	4	0
Ischaemic coronary artery disorders		
Myocardial infarction	2	0
Myocardial ischaemia	1	1
Myocardial disorders NEC		
Left ventricular dilatation	1	0
Noninfectious pericarditis		
Pericarditis	1	0
Rate and rhythm disorders NEC		
Tachycardia	1	0
Cardiac disorders SOC TOTAL	10	1

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	1	0
Eustachian tube disorders		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	1	0
Inner ear signs and symptoms		
Tinnitus	2	0
Vertigo	2	0
Ear disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Eye disorders		
Corneal infections, oedemas and inflammations		
Keratitis	1	0
Lacrimation disorders		
Dry eye	1	0
Ocular disorders NEC		
Eye swelling	2	0
Visual disorders NEC		
Diplopia	1	0
Eve disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	13	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Faecal abnormalities NEC		
Faeces discoloured	2	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	1	0
Abdominal pain upper	6	0
Gastrointestinal stenosis and obstruction NEC		
lleus	1	0
Gingival disorders, signs and symptoms NEC		
Gingival pain	1	0
Nausea and vomiting symptoms		
Nausea	17	0
Retching	1	0
Vomiting	5	0
Vomiting projectile	1	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	1	1
Haematemesis	1	0
Oral soft tissue signs and symptoms		
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	1	0
Stomatitis and ulceration		
Mouth ulceration	1	0
Gastrointestinal disorders SOC TOTAL	55	1

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Reaction Name	, Total	Fatal
General disorders		
Asthenic conditions		
Asthenia	5	C
Fatigue	21	C
Malaise	6	C
Death and sudden death		
Sudden death	1	1
Febrile disorders		
Pyrexia	23	
Feelings and sensations NEC		
Chills	12	
Feeling abnormal	3	(
Feeling cold	1 1	
Feeling of body temperature change	2	
General signs and symptoms NEC		
Condition aggravated	1	(
Illness	3	
Influenza like illness	4	
Peripheral swelling	5	
Swelling	3	
Inflammations		
Inflammation	1	
Injection site reactions	·	
Injection site erythema	2	
Injection site inflammation	2	
Injection site mass		
Injection site pain	2	
Injection site pruritus	1	
Injection site swelling	1	
Mass conditions NEC		
Cyst	1	
Pain and discomfort NEC		
Axillary pain	1	(
Chest pain	3	
Discomfort	1	
Pain	5	1
Vaccination site reactions		
Vaccination site bruising	1	(
Vaccination site erythema	1	
Vaccination site pain	1	
Vaccination site rash	1	
Vaccination site scab	1	[
Vaccination site swelling	2	
Vaccination site warmth	2	
General disorders SOC TOTAL	120	

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

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Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Appendicitis	1	0
Coronavirus infections		
COVID-19	3	0
Post-acute COVID-19 syndrome	1	0
Herpes viral infections		
Herpes zoster	1	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	2	1
Pneumonia	1	0
Urinary tract infections		
Urinary tract infection	1	0
Viral infections NEC		
Sweating fever	1	0
Infections SOC TOTAL	11	1

Reaction Name	Total	Fatal
Injuries		
Site specific injuries NEC		
Limb injury	1	0
Skin injuries NEC		
Contusion	1	0
Injuries SOC TOTAL	2	0

Reaction Name	Total	Fatal
Investigations		
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Heart rate and pulse investigations		
Heart rate increased	1	0
Physical examination procedures and organ system status		
Body temperature fluctuation	1	0
Body temperature increased	1	0
Weight decreased	1	0
Investigations SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	3	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	1	0
Disorders of purine metabolism		
Gout	2	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	2	0
Total fluid volume decreased		
Dehydration	1	0
Metabolic disorders SOC TOTAL	10	0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Bone related signs and symptoms		
Bone pain	1	0
Spinal pain	1	0
Joint related signs and symptoms		
Arthralgia	6	0
Joint swelling	1	0
Muscle pains		
Myalgia	14	0
Muscle related signs and symptoms NEC		
Muscle disorder	1	0
Muscle fatigue	1	0
Muscle twitching	1	0
Muscle weakness conditions		
Muscular weakness	4	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	2	0
Musculoskeletal and connective tissue pain and discomfort		
Limb discomfort	2	0
Musculoskeletal chest pain	1	0
Neck pain	1	0
Pain in extremity	16	0
Muscle & tissue disorders SOC TOTAL	52	0

Reaction Name	Total	Fatal
Nervous system disorders		
Central nervous system haemorrhages and cerebrovascular accidents		
Carotid artery occlusion	1	0
Coordination and balance disturbances		
Balance disorder	1	0
Disturbances in consciousness NEC		
Lethargy	4	0
Loss of consciousness	3	0
Syncope	2	0
Dyskinesias and movement disorders NEC		
Hypokinesia	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	1	0
Headaches NEC		
Headache	32	0
Tension headache	1	0
Memory loss (excl dementia)		
Amnesia	1	0
Memory impairment	2	0
Migraine headaches		
Migraine	5	0
Retinal migraine	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Dizziness	16	0
Dizziness postural	1	0
Neurological symptom	1	0
Paraesthesias and dysaesthesias		
Paraesthesia	5	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	0
Seizures and seizure disorders NEC		
Seizure	1	0
Tremor (excl congenital)		
Tremor	9	0
Nervous system disorders SOC TOTAL	91	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Nervousness	1	0
Stress	1	0
Confusion and disorientation		
Confusional state	2	0
Disorientation	2	0
Fluctuating mood symptoms		
Mood swings	1	0
Hallucinations (excl sleep-related)		
Hallucination	1	0
Increased physical activity levels		
Restlessness	1	0
Parasomnias		
Nightmare	1	0
Psychiatric disorders SOC TOTAL	10	0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Urinary abnormalities		
Urine odour abnormal	1	0
Renal & urinary disorders SOC	TOTAL 1	0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menopausal effects NEC		
Menopausal symptoms	1	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	3	0
Intermenstrual bleeding	3	0
Menstrual disorder	5	0
Menstruation irregular	3	0
Menstruation with decreased bleeding		
Hypomenorrhoea	1	0
Menstruation delayed	5	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	6	0
Polymenorrhoea	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	29	0

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	6	0
Bronchospasm and obstruction		
Wheezing	1	0
Coughing and associated symptoms		
Cough	4	0
Nasal disorders NEC		
Epistaxis	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	4	1
Pulmonary thrombosis	1	1
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	3	0
Respiratory disorders SOC TOTAL	20	2

Desetter News	Medbl (A Version: Medbl (A 24.1	T-4-1	Fatal
Reaction Name		<u>Total</u>	Fatal
Skin disorders			
Apocrine and eccrine gland disorders			_
Cold sweat		1	0
Hyperhidrosis		5	0
Night sweats		1	0
Bullous conditions			
Blister		1	0
Erythema multiforme		1	0
Dermal and epidermal conditions NEC			
Skin warm		1	0
Dermatitis and eczema			
Dermatitis allergic		1	0
Eczema		1	0
Erythemas			
Erythema		3	0
Pruritus NEC			
Pruritus		2	0
Purpura and related conditions			
, Petechiae		1	0
Rashes, eruptions and exanthems NE	c		
Rash		11	0
Rash macular		1	0
Rash pruritic		2	0
Skin haemorrhages			
Skin haemorrhage		1	0
Urticarias			
Urticaria		1	0
Skin disorders SOC TOTAL		34	Ő

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Reaction Name	Total	Fatal
Vascular disorders		
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	0
Thrombophlebitis	1	0
Peripheral vascular disorders NEC		
Hot flush	1	0
Site specific vascular disorders NEC		
Pallor	1	0
Vascular hypertensive disorders NEC		
Hypertension	3	0
Vascular disorders SOC TOTAL	7	0
TOTAL REACTIONS FOR DRUG	475	6
TOTAL REPORTS	161	
TOTAL FATAL OUTCOME REPORTS		6