

FOI 23/526 - Pfizer COVID-19 vaccine batch number FN 5254 - UK spontaneous 'suspected' Adverse Drug Reaction (ADR) reports
 Report run date: 07/08/2023

(Reaction) SOC	(Reaction) HLT	Number of reports	
Blood	Anaemias NEC	^	
	Lymphatic system disorders NEC	123	
	Thrombocytopenias	^	
Card	Thrombocytoses	^	
	Cardiac disorders NEC	^	
	Cardiac infections and inflammations NEC	^	
	Cardiac signs and symptoms NEC	67	
	Cardiomyopathies	^	
	Myocardial disorders NEC	^	
	Noninfectious myocarditis	^	
	Noninfectious pericarditis	6	
	Pericardial disorders NEC	^	
	Rate and rhythm disorders NEC	36	
	Supraventricular arrhythmias	^	
	Ventricular arrhythmias and cardiac arrest	^	
	Cong	Cardiac disorders congenital NEC	^
Neurological disorders congenital NEC		^	
Ear	Ear disorders NEC	9	
	Hearing losses	7	
Endo	Inner ear signs and symptoms	22	
	Anterior pituitary hypofunction	^	
Eye	Iris and uveal tract infections, irritations and inflammations	^	
	Lacrimation disorders	^	
	Lid, lash and lacrimal infections, irritations and inflammations	^	
	Ocular disorders NEC	19	
	Ocular infections, inflammations and associated manifestations	7	
	Ocular nerve and muscle disorders	^	
	Ocular sensation disorders	^	
	Retinal bleeding and vascular disorders (excl retinopathy)	^	
	Visual disorders NEC	10	
	Visual impairment and blindness (excl colour blindness)	^	
Gastr	Dental developmental disorders and anomalies	^	
	Diarrhoea (excl infective)	35	
	Dyspeptic signs and symptoms	^	
	Flatulence, bloating and distension	5	
	Gastrointestinal and abdominal pains (excl oral and throat)	27	
	Gastrointestinal signs and symptoms NEC	9	
	Gastrointestinal spastic and hypermotility disorders	^	
	Gingival disorders, signs and symptoms NEC	^	
	Gingival haemorrhages	^	
	Nausea and vomiting symptoms	99	
	Non-site specific gastrointestinal haemorrhages	^	
	Oral dryness and saliva altered	^	
	Oral soft tissue disorders NEC	^	
	Oral soft tissue haemorrhages	^	
	Oral soft tissue signs and symptoms	10	
	Oral soft tissue swelling and oedema	9	
	Stomatitis and ulceration	^	
	Tongue signs and symptoms	^	
	Genrl	Asthenic conditions	164
		Death and sudden death	^
Febrile disorders		98	
Feelings and sensations NEC		73	
General signs and symptoms NEC		100	
Inflammations		7	
Injection site reactions		21	
Interactions		^	
Oedema NEC		^	
Pain and discomfort NEC		190	
Therapeutic and nontherapeutic responses		13	
Vaccination site reactions		14	
Hepat		Hepatobiliary signs and symptoms	^
	Allergic conditions NEC	10	
Immun	Anaphylactic and anaphylactoid responses	6	
	Atopic disorders	^	
	Autoimmune disorders NEC	^	
	Immune and associated conditions NEC	^	
Infec	Bacterial infections NEC	^	
	Candida infections	^	
	Coronavirus infections	31	
	Ear infections	^	
	Epstein-Barr viral infections	^	
	Eye and eyelid infections	^	
	Herpes viral infections	12	
	Infections NEC	^	
	Influenza viral infections	^	
	Lower respiratory tract and lung infections	^	
	Sepsis, bacteraemia, viraemia and fungaemia NEC	^	
	Staphylococcal infections	^	
	Streptococcal infections	^	
	Upper respiratory tract infections	7	
	Vascular infections	^	
	Viral infections NEC	6	
	Inj&P	Exposures associated with pregnancy, delivery and lactation	20
Eye injuries NEC		1	
Medication errors, product use errors and issues NEC		^	
Non-site specific injuries NEC		5	
Off label uses		^	
Pathways and sources of exposure		^	

Sex	Number of reports
Female	605
Male	241
Unknown	55

Age	Number of reports
10-19	131
20-29	134
30-39	169
40-49	181
50-59	84
60-69	36
70-79	18
80-99	7
Unknown	141

	Poisoning and toxicity	^
	Product administration errors and issues	^
	Skin injuries NEC	5
Inv	Auditory and vestibular diagnostic procedures	^
	Cardiac function diagnostic procedures	^
	Endocrine analyses and imaging NEC	^
	Heart rate and pulse investigations	18
	Immunology analyses NEC	^
	Investigations NEC	^
	Physical examination procedures and organ system status	10
	Platelet analyses	^
	Respiratory and pulmonary function diagnostic procedures	^
	Urinalysis NEC	^
	Vascular tests NEC (incl blood pressure)	^
	Virus identification and serology	^
	Vitamin analyses	^
	Appetite disorders	14
Metab	General nutritional disorders NEC	^
	Hypoglycaemic conditions NEC	^
	Metabolic acidoses (excl diabetic acidoses)	^
	Total fluid volume decreased	5
Musc	Arthropathies NEC	^
	Bone related signs and symptoms	5
	Bursal disorders	^
	Cartilage disorders	^
	Connective tissue disorders NEC	^
	Joint related disorders NEC	^
	Joint related signs and symptoms	54
	Muscle pains	55
	Muscle related signs and symptoms NEC	14
	Muscle tone abnormalities	^
	Muscle weakness conditions	8
	Musculoskeletal and connective tissue conditions NEC	10
	Musculoskeletal and connective tissue infections and inflammations NEC	^
	Musculoskeletal and connective tissue pain and discomfort	112
Neopl	Soft tissue disorders NEC	7
	Ocular neoplasms malignancy unspecified	^
Nerv	Respiratory tract small cell carcinomas	^
	Acute polyneuropathies	^
	Central nervous system haemorrhages and cerebrovascular accidents	^
	Coordination and balance disturbances	^
	Cortical dysfunction NEC	^
	Disturbances in consciousness NEC	42
	Dyskinesias and movement disorders NEC	^
	Facial cranial nerve disorders	8
	Generalised tonic-clonic seizures	^
	Headaches NEC	169
	Increased intracranial pressure disorders	^
	Lumbar spinal cord and nerve root disorders	^
	Memory loss (excl dementia)	^
	Mental impairment (excl dementia and memory loss)	^
	Migraine headaches	17
	Narcolepsy and hypersomnia	^
	Neurologic visual problems NEC	^
	Neurological signs and symptoms NEC	62
	Olfactory nerve disorders	^
	Optic nerve disorders NEC	^
	Paraesthesias and dysaesthesias	36
	Paralysis and paresis (excl cranial nerve)	5
	Peripheral neuropathies NEC	^
	Seizures and seizure disorders NEC	6
	Sensory abnormalities NEC	7
	Speech and language abnormalities	^
	Spinal cord and nerve root disorders NEC	^
	Tremor (excl congenital)	11
	Trigeminal disorders	^
	Preg	Abortions spontaneous
Device malfunction events NEC		^
Prod	Product contamination and sterility issues	^
	Product physical issues	^
Psych	Anxiety symptoms	8
	Behaviour and socialisation disturbances	^
	Cognitive and attention disorders and disturbances NEC	^
	Confusion and disorientation	^
	Depressive disorders	5
	Disturbances in initiating and maintaining sleep	20
	Dyssomnias	^
	Emotional and mood disturbances NEC	5
	Fluctuating mood symptoms	^
	Hallucinations (excl sleep-related)	^
	Learning disorders	^
	Mental disorders NEC	^
	Mood alterations with depressive symptoms	^
	Panic attacks and disorders	^
	Parasomnias	^
	Psychotic disorder NEC	^
	Sexual dysfunction NEC	^
	Sleep disorders NEC	^
	Thinking disturbances	^
Tic disorders	^	
Renal	Bladder and urethral symptoms	^
	Renal disorders NEC	^
	Renal structural abnormalities and trauma	^

	Urinary tract signs and symptoms NEC	5
	Breast signs and symptoms	18
	Menopausal effects NEC	^
	Menstruation and uterine bleeding NEC	32
	Menstruation with decreased bleeding	29
	Menstruation with increased bleeding	21
	Pelvis and broad ligament disorders NEC	^
	Reproductive tract signs and symptoms NEC	^
	Sexual function and fertility disorders NEC	^
	Testicular and epididymal disorders NEC	^
	Uterine disorders NEC	^
	Uterine tone disorders	^
	Vulvovaginal disorders NEC	10
Repro	Breathing abnormalities	55
	Bronchospasm and obstruction	9
	Coughing and associated symptoms	15
	Laryngeal spasm, oedema and obstruction	^
	Lower respiratory tract signs and symptoms	^
	Nasal congestion and inflammations	^
	Nasal disorders NEC	7
	Paranasal sinus disorders (excl infections and neoplasms)	^
	Pharyngeal disorders (excl infections and neoplasms)	^
	Pneumothorax and pleural effusions NEC	^
	Pulmonary thrombotic and embolic conditions	5
	Respiratory failures (excl neonatal)	^
	Upper respiratory tract signs and symptoms	46
Resp	Acnes	^
	Alopecias	7
	Angioedemas	^
	Apocrine and eccrine gland disorders	28
	Bullous conditions	^
	Dermal and epidermal conditions NEC	19
	Dermatitis and eczema	5
	Erythemas	11
	Papulosquamous conditions	^
	Photosensitivity and photodermatitis conditions	^
	Pigmentation changes NEC	^
	Pruritus NEC	36
	Psoriatic conditions	^
	Purpura and related conditions	^
	Rashes, eruptions and exanthems NEC	58
	Skin and subcutaneous conditions NEC	^
	Skin and subcutaneous tissue ulcerations	^
	Urticarias	16
SocCi	Disability issues	^
	Tobacco use	^
	Immunisations	^
Surg	Respiratory tract therapeutic procedures NEC	^
	Tendon therapeutic procedures	^
	Therapeutic procedures NEC	^
	Circulatory collapse and shock	^
	Haemorrhages NEC	5
	Lymphoedemas	^
	Non-site specific embolism and thrombosis	^
	Peripheral embolism and thrombosis	^
	Peripheral vascular disorders NEC	11
	Peripheral vasoconstriction, necrosis and vascular insufficiency	^
	Site specific vascular disorders NEC	^
	Vascular hypertensive disorders NEC	^
	Vascular hypotensive disorders	^
Vasc		

^ Where there are less than 5 reports, numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters.