Report Run Date: 15-Aug-2022

FOI 22/875 - All UK Spontaneously received Adverse Drug

AstraZeneca Vaccine - Reaction (ADR) reports received upto 04/08/2022 associated Guernsey: with the AstraZeneca COVID-19 Vaccine reported from within

Guernsey

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.

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
Coagulopathies		
Disseminated intravascular coagulation	1	0
Eosinophilic disorders		
Eosinophilia	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	4	0
Thrombocytopenias		
Thrombocytopenia	1	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	8	0

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	8	0
Cardiomyopathies		
Cardiomyopathy	1	0
Stress cardiomyopathy	1	0
Ischaemic coronary artery disorders		
Acute coronary syndrome	1	0
Acute myocardial infarction	3	0
Myocardial infarction	6	1
Left ventricular failures		
Left ventricular failure	1	0
Mitral valvular disorders		
Ischaemic mitral regurgitation	1	0
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Ventricular hypokinesia	1	0
Noninfectious myocarditis		
Myocarditis	1	0
Rate and rhythm disorders NEC		
Bradycardia	1	0
Tachycardia	3	0
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Sinus tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	33	1

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Ear disorders		
Inner ear signs and symptoms		
Tinnitus	5	0
Vertigo	3	0
Ear disorders SOC TOTAL	8	0

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders		
Ocular bleeding and vascular disorders NEC		
Eye haemorrhage	1	0
Ocular disorders NEC		
Eye pain	5	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Ocular hyperaemia	1	0
Ocular sensation disorders		
Eye paraesthesia	1	0
Photophobia	1	0
Visual disorders NEC		
Vision blurred	3	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	2	0
Eye disorders SOC TOTAL	15	0

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	5	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	4	0
Abdominal pain upper	2	0
Gastrointestinal disorders NEC		
Appendix disorder	1	0
Gingival disorders, signs and symptoms NEC		
Gingival pain	1	0
Nausea and vomiting symptoms		
Nausea	17	0
Vomiting	7	0
Vomiting projectile	1	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue swelling and oedema		
Mouth swelling	1	0
Tongue signs and symptoms		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	43	0

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders	Total	ı ataı
Asthenic conditions		
Asthenia	2	0
Chronic fatigue syndrome	2 2	0
Fatigue	35	0
Malaise	7	0
Death and sudden death	· ·	Ŭ
Sudden death	1	1
Febrile disorders		•
Pyrexia	34	0
Feelings and sensations NEC	•	ŭ
Chills	25	0
Feeling abnormal	4	0
Feeling cold	3	0
Feeling drunk	1	0
Feeling of body temperature change		0
Thirst	2 2	0
General signs and symptoms NEC		_
Illness	2	0
Influenza like illness	7	0
Local reaction	2	0
Peripheral swelling	2 5	0
Swelling	4	0
Inflammations		
Inflammation	2	0
Injection site reactions		
Injection site mass	1	0
Injection site pain	3	0
Oedema NEC		
Oedema	2	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	8	0
Discomfort	2 2	0
Facial pain		0
Pain	10	0
Vaccination site reactions		
Vaccination site erythema	1	0
Withdrawal and rebound effects		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	171	1

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Autoimmune disorders NEC		
Autoimmune disorder	1	0
Immune system disorders SOC TOTAL	2	0

Report Run Date: 15-Aug-2022

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Cellulitis	1	0
Vaccination site cellulitis	1	0
Cardiac infections		
Acute endocarditis	1	0
Endocarditis	1	0
Coronavirus infections		
COVID-19	2	2 0
Fungal infections NEC		
Fungal infection	1	0
Herpes viral infections		
Herpes simplex	1	0
Herpes zoster	3	0
Infections NEC		
Infection	1	0
Influenza viral infections		
Influenza	3	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	0
Upper respiratory tract infections		
Laryngitis	1	0
Nasopharyngitis	1	0
Viral infections NEC		
Gastroenteritis viral	1	0
Infections SOC TOTAL	19	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Injuries		
Chest and respiratory tract injuries NEC		
Chest crushing	1	0
Non-site specific injuries NEC		
Fall	1	0
Skin injuries NEC		
Contusion	2	0
Injuries SOC TOTAL	4	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Investigations		
ECG investigations		
Electrocardiogram T wave inversion	1	0
Physical examination procedures and organ system status		
Respiratory rate increased	1	0
Platelet analyses		
Platelet count decreased	2	0
Plateletcrit	1	0
Red blood cell analyses		
Haemoglobin	1	0
Renal function analyses		
Glomerular filtration rate decreased	1	0
Investigations SOC TOTAL	7	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	2	0
Metabolic disorders SOC TOTAL	2	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	0
Autoimmune arthritis	1	0
Bone related signs and symptoms		
Pain in jaw	1	0
Bursal disorders		
Bursitis	1	0
Joint related disorders NEC		
Periarthritis	1	0
Joint related signs and symptoms		
Arthralgia	15	0
Joint swelling	1	0
Muscle pains		
Myalgia	20	0
Muscle related signs and symptoms NEC		
Muscle fatigue	3	0
Muscle spasms	7	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	4	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	4	0
Neck pain	1	0
Pain in extremity	13	0
Muscle & tissue disorders SOC TOTAL	73	0

Report Run Date: 15-Aug-2022

Central nervous system haemorrhages and cerebrovascular accidents Cerebral haemorrhage	MedDRA Version: MedDRA 25	5.0	
Acute polyneuropathies Guillain-Barre syndrome Central nervous system haemorrhages and cerebrovascular accidents Cerebral haemorrhage 1	Reaction Name	Total	Fatal
Guillain-Barre syndrome 1	Nervous system disorders		
Central nervous system haemorrhages and cerebrovascular accidents 1 0 Cerebrol haemorrhage 1 0 Cerebrovascular accident 2 0 Ischaemic stroke 1 0 Thrombotic stroke 1 0 Central nervous system inflammation 1 0 Disturbances in consciousness NEC 1 0 Lethargy 4 0 0 Loss of consciousness 1 0 Somnolence 2 2 0 Dyskinesias and movement disorders NEC 1 0 Clumsiness 1 0 Hyperkinesia 1 0 Facial cranial nerve disorders 1 0 Bell's palsy 1 0 Headaches NEC 1 0 Cold-stimulus headache 1 0 Drug withdrawal headache 1 0 Headache 1 0 Sinus headache 1 0 Tension headache 1	Acute polyneuropathies		
Cerebrol haemorrhage	Guillain-Barre syndrome	1	0
Cerebrovascular accident 2 1 1 1 1 1 1 1 1 1	Central nervous system haemorrhages and cerebrovascular accidents	3	
Ischaemic stroke		1	0
Ischaemic stroke	Cerebrovascular accident	2	0
Central nervous system inflammation 1 Central nervous system inflammation 1 Disturbances in consciousness NEC 1 Lethargy 4 0 Loss of consciousness 1 0 Somnolence 2 0 Dyskinesias and movement disorders NEC 1 0 Clumsiness 1 0 Hyperkinesia 1 0 Facial cranial nerve disorders 1 0 Bell's palsy 1 0 Headaches NEC 1 0 Cold-stimulus headache 1 0 Drug withdrawal headache 4 0 Headache 49 0 Sinus headache 1 0 Lumbar spinal cord and nerve root disorders 1 0 Sciatica 1 0 Mernal impairment (excl dementia) 1 0 Amnesia 1 0 Mertal impairment (excl dementia and memory loss) 1 0 Disturbance in attention <	Ischaemic stroke	1	0
Central nervous system inflammation Disturbances in consciousness NEC Lethargy	Thrombotic stroke	1	0
Disturbances in consciousness NEC	Central nervous system inflammatory disorders NEC		
Lethargy	Central nervous system inflammation	1	0
Loss of consciousness 1	Disturbances in consciousness NEC		
Somnolence Dyskinesias and movement disorders NEC Clumsiness 1	Lethargy	4	0
Dyskinesias and movement disorders NEC Clumsineses	Loss of consciousness	1	0
Clumsiness	Somnolence	2	0
Hyperkinesia	Dyskinesias and movement disorders NEC		
Facial cranial nerve disorders Bell's palsy 1	Clumsiness	1	0
Bell's palsy Headaches NEC		1	0
Headaches NEC	Facial cranial nerve disorders		
Cold-stimulus headache	Bell's palsy	1	0
Drug withdrawal headache	Headaches NEC		
Headache 49 00	Cold-stimulus headache	1	0
Sinus headache	Drug withdrawal headache	1	0
Tension headache Lumbar spinal cord and nerve root disorders Sciatica 1 0 0	Headache	49	0
Lumbar spinal cord and nerve root disorders 1 0 Sciatica 1 0 Memory loss (excl dementia) 1 0 Amnesia 1 0 Mental impairment (excl dementia and memory loss) 1 0 Disturbance in attention 1 0 Migraine headaches 8 0 Migraine with aura 2 0 Meurological signs and symptoms NEC 18 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 8 0 Peripheral neuropathies NEC 0 Neuritis 1 0 Seizures and seiz	Sinus headache	1	0
Sciatica	Tension headache	1	0
Memory loss (excl dementia) 1 0 Mental impairment (excl dementia and memory loss) 1 0 Disturbance in attention 1 0 Migraine headaches 4 0 Migraine with aura 2 0 Meurological signs and symptoms NEC 2 Dizziness 18 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure status epilepticus 1 0 <td>Lumbar spinal cord and nerve root disorders</td> <td></td> <td></td>	Lumbar spinal cord and nerve root disorders		
Amnesia 1 0 Mental impairment (excl dementia and memory loss) 1 Disturbance in attention 1 0 Migraine headaches 4 0 Migraine with aura 2 0 Neurological signs and symptoms NEC 18 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizures and seizure disorders NEC 1 0 Seizures and seizure disorders NEC 1 0 <td>Sciatica</td> <td>1</td> <td>0</td>	Sciatica	1	0
Mental impairment (excl dementia and memory loss) 1 0 Disturbance in attention 1 0 Migraine headaches 4 0 Migraine with aura 2 0 Meurological signs and symptoms NEC 18 0 Dizziness postural 3 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 0 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure site priceptual disorders NEC 1 <td< td=""><td>Memory loss (excl dementia)</td><td></td><td></td></td<>	Memory loss (excl dementia)		
Disturbance in attention 1	Amnesia	1	0
Disturbance in attention 1	Mental impairment (excl dementia and memory loss)		
Migraine 4 0 Migraine with aura 2 0 Neurological signs and symptoms NEC 18 0 Dizziness 18 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 8 0 Neuritis 1 0 Seizures and seizure disorders NEC 0 0 Seizure 1 0 Status epilepticus 1 0		1	0
Migraine with aura 2 0 Neurological signs and symptoms NEC 18 0 Dizziness 18 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 8 0 Neuritis 1 0 Seizures and seizure disorders NEC 0 0 Seizure 1 0 Status epilepticus 1 0	Migraine headaches		
Neurological signs and symptoms NEC 18 0 Dizziness 18 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 8 0 Neuritis 1 0 Seizures and seizure disorders NEC 5 1 0 Status epilepticus 1 0	Migraine	4	0
Dizziness 18 0 Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 1 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Migraine with aura	2	0
Dizziness postural 3 0 Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Neurological signs and symptoms NEC		
Neurological symptom 1 0 Persistent postural-perceptual dizziness 1 0 Unresponsive to stimuli 1 0 Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Dizziness	18	0
Persistent postural-perceptual dizziness	Dizziness postural	3	0
Unresponsive to stimuli 1 0 Neuromuscular disorders NEC Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Neurological symptom	1	0
Neuromuscular disorders NEC 1 0 Muscle spasticity 1 0 Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 1 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Persistent postural-perceptual dizziness	1	0
Muscle spasticity 1 0 Olfactory nerve disorders Anosmia 2 0 Paraesthesias and dysaesthesias 2 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 3 0 Neuritis 1 0 Seizures and seizure disorders NEC 3 0 Seizure 1 0 Status epilepticus 1 0		1	0
Olfactory nerve disorders 2 0 Anosmia 2 0 Paraesthesias and dysaesthesias 1 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Neuromuscular disorders NEC		
Anosmia 2 0 Paraesthesias and dysaesthesias 1 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Muscle spasticity	1	0
Paraesthesias and dysaesthesias 1 0 Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC 1 0 Neuritis 1 0 Seizures and seizure disorders NEC 1 0 Seizure 1 0 Status epilepticus 1 0	Olfactory nerve disorders		
Formication 1 0 Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC	Anosmia	2	0
Hypoaesthesia 4 0 Paraesthesia 8 0 Peripheral neuropathies NEC	Paraesthesias and dysaesthesias		
Paraesthesia 8 0 Peripheral neuropathies NEC Neuritis 1 0 Seizures and seizure disorders NEC Seizure 1 0 Status epilepticus 1 0	Formication	1	0
Peripheral neuropathies NECNeuritis10Seizures and seizure disorders NECSeizure10Status epilepticus10	Hypoaesthesia	4	0
Neuritis 1 0 Seizures and seizure disorders NEC Seizure 1 0 Status epilepticus 1 0	Paraesthesia	8	0
Neuritis 1 0 Seizures and seizure disorders NEC Seizure 1 0 Status epilepticus 1 0	Peripheral neuropathies NEC		
Seizures and seizure disorders NECSeizure10Status epilepticus10		1	0
Seizure 1 0 Status epilepticus 1 0	Seizures and seizure disorders NEC		
Status epilepticus 1 0		1	0
	Status epilepticus	1	0
Sensory abnormalities NEC			

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Ageusia	1	0
Dysgeusia	2	0
Neuralgia	1	0
Sensory disturbance	1	0
Transient cerebrovascular events		
Transient ischaemic attack	2	0
Tremor (excl congenital)		
Action tremor	1	0
Tremor	5	0
Nervous system disorders SOC TOTAL	135	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Anxiety	2	0
Stress	1	0
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	2	0
Confusion and disorientation		
Disorientation	2	0
Depressive disorders		
Depression	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Irritability	1	0
Hallucinations (excl sleep-related)		
Hallucination	1	0
Mood disorders NEC		
Listless	1	0
Panic attacks and disorders		
Panic attack	1	0
Parasomnias		
Nightmare	1	0
Stereotypies and automatisms		
Head banging	1	0
Psychiatric disorders SOC TOTAL	15	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal failure and impairment		
Renal impairment	1	0
Urinary tract signs and symptoms NEC		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	2	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	1	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	3	0
Intermenstrual bleeding	1	0
Menstrual disorder	3	0
Menstruation irregular	3	0
Menstruation with decreased bleeding		
Hypomenorrhoea	1	0
Menstruation delayed	1	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	6	0
Polymenorrhoea	3	0
Reproductive tract signs and symptoms NEC		
Pelvic pain	1	0
Uterine tone disorders		
Uterine spasm	1	0
Reproductive & breast disorders SOC TOTAL	24	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	6	0
Conditions associated with abnormal gas exchange		
Нурохіа	1	0
Coughing and associated symptoms		
Cough	1	0
Nasal disorders NEC		
Epistaxis	2	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	3	0
Upper respiratory tract signs and symptoms		
Aphonia	1	0
Oropharyngeal pain	3	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	1	0
Respiratory disorders SOC TOTAL	19	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Skin disorders	1 0 10.1	
Alopecias		
Diffuse alopecia	1	0
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	5	0
Night sweats	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin warm	1	0
Erythemas		
Erythema	4	0
Pilar disorders NEC		
Piloerection	1	0
Pruritus NEC		
Pruritus	5	0
Rashes, eruptions and exanthems NEC		
Rash	5	
Rash papular	1	0
Rash pruritic	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin ulcer	1	0
Skin vasculitides		
Nodular vasculitis	1	0
Urticarias		
Urticaria	2	0
Skin disorders SOC TOTAL	36	0

Report Run Date: 15-Aug-2022

Reaction Name	Total	Fatal
Vascular disorders		
Blood pressure disorders NEC		
Labile blood pressure	1	0
Circulatory collapse and shock		
Circulatory collapse	1	0
Haemorrhages NEC		
Haemorrhage	1	0
Non-site specific embolism and thrombosis		
Embolism	2	0
Thrombosis	3	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	0
Peripheral vascular disorders NEC		
Hot flush	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Raynaud's phenomenon	1	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular disorders SOC TOTAL	12	0
TOTAL REACTIONS FOR DRUG	628	2
TOTAL REPORTS	182	
TOTAL FATAL OUTCOME REPORTS		2