

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Data Lock Date: 06-Mar-2024 18:30:04
Earliest Reaction Date: 17-Apr-2020
MedDRA Version: MedDRA 26.1

FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the COVID-19 Vaccine AstraZeneca (Batch PV46674)

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	3	0
Hypochromic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	7	0
Lymphadenopathy	53	0
Lymphadenopathy mediastinal	2	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Spleen disorders</i>		
Splenic haematoma	1	0
Splenic haemorrhage	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	5	0
<i>Thrombocytoses</i>		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	77	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	59	0
<i>Coronary artery disorders NEC</i>		
Coronary artery thrombosis	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	3	0
Myocardial infarction	3	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
Myopericarditis	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	9	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	3	0
Bradycardia	1	0
Cardiac flutter	2	0
Extrasystoles	2	0
Tachycardia	13	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
Sinus bradycardia	1	0
Cardiac disorders SOC TOTAL	106	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	26	0
Ear pruritus	1	0
Ear swelling	3	0
<i>Hearing losses</i>		
Deafness	6	0
Deafness bilateral	1	0
Hypoacusis	1	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	2	0
Tinnitus	56	0
Vertigo	17	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	119	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	2	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
<i>Thyroid disorders NEC</i>		
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	2	0
Vitreous floaters	2	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	5	0
<i>Eyelid movement disorders</i>		
Blepharospasm	2	0
Excessive eye blinking	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
Uveitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	2	0
Lacrimation increased	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Erythema of eyelid	1	0
Swelling of eyelid	3	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye pain	24	0
Eye swelling	8	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye irritation	2	0
Eye pruritus	6	0
Ocular hyperaemia	11	0
<i>Ocular sensation disorders</i>		
Asthenopia	3	0
Photophobia	9	0
<i>Pupil disorders</i>		
Anisocoria	1	0
Miosis	2	0
Mydriasis	1	0
<i>Refractive and accommodative disorders</i>		
Altered visual depth perception	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal vascular occlusion	1	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	3	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal detachment	1	0
<i>Retinopathies NEC</i>		
Retinal white dots syndrome	1	0
<i>Visual disorders NEC</i>		
Diplopia	4	0
Photopsia	6	0
Scintillating scotoma	1	0
Vision blurred	36	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024

Data Lock Date: 06-Mar-2024 18:30:04

Earliest Reaction Date: 17-Apr-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	4	0
Night blindness	1	0
Sudden visual loss	1	0
Visual impairment	17	0
Eye disorders SOC TOTAL	173	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	41	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	9	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faeces soft	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	16	0
Flatulence	4	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	54	0
Abdominal pain lower	1	0
Abdominal pain upper	41	0
Abdominal tenderness	1	0
Gastrointestinal pain	7	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	6	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	21	0
Anal incontinence	1	0
Dysphagia	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal vascular malformations</i>		
Splenic artery aneurysm	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	3	0
Gingival swelling	3	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	3	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	2	0
Haemorrhoids thrombosed	1	0
<i>Nausea and vomiting symptoms</i>		

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Nausea	239	0
Retching	5	0
Vomiting	72	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	2	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	14	0
Lip dry	2	0
Saliva altered	1	0
<i>Oral soft tissue disorders NEC</i>		
Lip blister	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	3	0
Oral blood blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	9	0
Lip pain	1	0
Oral discomfort	2	0
Oral pain	3	0
Paraesthesia oral	6	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	8	0
Mouth swelling	2	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland calculus	1	0
Salivary gland disorder	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Lip ulceration	1	0
Mouth ulceration	7	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Glossitis	1	0
Tongue disorder	2	0
<i>Tongue signs and symptoms</i>		
Glossodynia	3	0
Swollen tongue	6	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue dry	2	0
Gastrointestinal disorders SOC TOTAL	638	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	39	0
Chronic fatigue syndrome	4	0
Decreased activity	1	0
Fatigue	407	0
Malaise	103	0
<i>Complications associated with device NEC</i>		
Injury associated with device	1	0
<i>Death and sudden death</i>		
Death	2	2
<i>Febrile disorders</i>		
Pyrexia	411	0
<i>Feelings and sensations NEC</i>		
Chills	325	0
Feeling abnormal	31	0
Feeling cold	41	0
Feeling drunk	3	0
Feeling hot	19	0
Feeling jittery	2	0
Feeling of body temperature change	8	0
Hangover	2	0
Hunger	1	0
Sensation of foreign body	1	0
Temperature intolerance	5	0
Thirst	20	0
<i>Gait disturbances</i>		
Gait disturbance	10	0
Gait inability	1	0
Loss of control of legs	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crying	5	0
Exercise tolerance decreased	1	0
Illness	28	0
Influenza like illness	58	0
Local reaction	2	0
Peripheral swelling	47	0
Screaming	2	0
Swelling	22	0
Swelling face	9	0
<i>Inflamations</i>		
Inflammation	5	0
<i>Infusion site reactions</i>		
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site erythema	4	0
Injection site joint pain	1	0
Injection site mass	5	0
Injection site pain	32	0
Injection site pruritus	2	0
Injection site rash	1	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site reaction	1	0
Injection site swelling	4	0
Injection site warmth	3	0
<i>Mucosal findings abnormal</i>		
Mucosal haemorrhage	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
Oedema	4	0
Oedema peripheral	2	0
<i>Pain and discomfort NEC</i>		
Axillary pain	4	0
Chest discomfort	10	0
Chest pain	68	0
Discomfort	11	0
Facial pain	5	0
Non-cardiac chest pain	1	0
Pain	152	0
Tenderness	21	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	1	0
Drug ineffective	2	0
Immediate post-injection reaction	1	0
Inadequate analgesia	2	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
<i>Vaccination site reactions</i>		
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	2	0
Vaccination site inflammation	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	6	0
Vaccination site movement impairment	2	0
Vaccination site pain	18	0
Vaccination site pruritus	1	0
Vaccination site rash	1	0
Vaccination site swelling	2	0
Vaccination site vesicles	1	0
Vaccination site warmth	2	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	2009	2

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024

Data Lock Date: 06-Mar-2024 18:30:04

Earliest Reaction Date: 17-Apr-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic vascular disorders</i>		
Hepatic vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatic steatosis	1	0
Hepatitis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	5	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	14	0
Multiple allergies	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Oral allergy syndrome	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	9	0
<i>Atopic disorders</i>		
Seasonal allergy	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Cytokine release syndrome	1	0
Immune system disorder	1	0
Immune system disorders SOC TOTAL	32	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diverticulitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	7	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Candida infections</i>		
Oral candidiasis	3	0
Skin candida	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	1	0
<i>Coronavirus infections</i>		
COVID-19	35	0
Post-acute COVID-19 syndrome	2	0
Suspected COVID-19	1	0
<i>Dental and oral soft tissue infections</i>		
Gingival abscess	1	0
Gingivitis	1	0
<i>Ear infections</i>		
Ear infection	3	0
Labyrinthitis	1	0
Mastoiditis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
Eyelid boil	1	0
<i>Female reproductive tract infections</i>		
Vulval abscess	1	0
<i>Herpes viral infections</i>		
Genital herpes	1	0
Herpes zoster	14	0
Oral herpes	7	0
<i>Infections NEC</i>		
Abscess limb	1	0
Infection	9	0
Localised infection	1	0
Lymph node abscess	1	0
<i>Influenza viral infections</i>		
Influenza	39	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	7	0
Pneumonia	4	0
<i>Pseudomonal infections</i>		
Pseudomonas infection	1	0
<i>Skin structures and soft tissue infections</i>		
Dermo-hypodermatitis	1	0
Pustule	2	0
<i>Staphylococcal infections</i>		

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Furuncle	2	0
Staphylococcal infection	2	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	1
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	19	0
Sinusitis	4	0
<i>Urinary tract infections</i>		
Urinary tract infection	4	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Sweating fever	7	0
Viral rash	2	0
Infections SOC TOTAL	197	1

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Colon injury	1	0
Splenic rupture	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Chemical injuries</i>		
Chemical burn of skin	1	0
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	14	0
Maternal exposure during pregnancy	6	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Wrong drug	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle rupture	1	0
<i>Non-site specific injuries NEC</i>		
Fall	5	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	4	0
<i>Poisoning and toxicity</i>		
Metal poisoning	1	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
Inappropriate schedule of product administration	1	0
Incomplete course of vaccination	3	0
Product administered at inappropriate site	2	0
Product dose omission issue	1	0
<i>Product confusion errors and issues</i>		
Product packaging confusion	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
Limb injury	2	0
<i>Skin injuries NEC</i>		
Contusion	30	0
Hair injury	1	0
Scratch	1	0
Skin injury	1	0
<i>Thermal burns</i>		
Thermal burns of eye	2	0
Injuries SOC TOTAL	86	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation	1	0
Oxygen saturation decreased	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
Xanthochromia	1	0
<i>ECG investigations</i>		
Electrocardiogram abnormal	1	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin increased	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Swallow study	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	10	0
Heart rate abnormal	2	0
Heart rate decreased	2	0
Heart rate increased	18	0
Heart rate irregular	6	0
Pulse abnormal	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test abnormal	1	0
<i>Investigations NEC</i>		
Quality of life decreased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	3	0
Body temperature decreased	3	0
Body temperature fluctuation	1	0
Body temperature increased	8	0
Grip strength decreased	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	1	0
Weight decreased	5	0
Weight increased	3	0
<i>Platelet analyses</i>		
Platelet count decreased	2	0
<i>Reproductive hormone analyses</i>		
Blood testosterone decreased	1	0
Oestradiol	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	1	0
Pulmonary function test decreased	1	0
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Tri-iodothyronine decreased	1	0
<i>Triglyceride analyses</i>		
Blood triglycerides	1	0
<i>Urinalysis NEC</i>		

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood urine present	4	0
<i>Urinary tract function analyses NEC</i>		
Urine output	3	0
Urine output increased	2	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure diastolic decreased	1	0
Blood pressure increased	2	0
Blood pressure measurement	1	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
SARS-CoV-2 antibody test	1	0
Investigations SOC TOTAL	102	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	57	0
Food refusal	1	0
<i>Disorders of purine metabolism</i>		
Gout	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	2	0
Feeding disorder	3	0
Poor feeding infant	1	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
<i>Water soluble vitamin deficiencies</i>		
Vitamin B12 deficiency	1	0
Metabolic disorders SOC TOTAL	76	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	7	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Bone loss	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	11	0
Pain in jaw	7	0
Spinal pain	1	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Connective tissue disorders NEC</i>		
Reynold's syndrome	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	5	0
Rotator cuff syndrome	1	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	174	0
Joint effusion	1	0
Joint stiffness	3	0
Joint swelling	7	0
Joint warmth	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Fibromyalgia	6	0
Myalgia	188	0
Myofascial pain syndrome	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	5	0
Muscle spasms	51	0
Muscle tightness	4	0
Muscle twitching	8	0
Trigger points	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
Nuchal rigidity	1	0
Torticollis	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	17	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	5	0
Musculoskeletal stiffness	22	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	59	0
Flank pain	2	0
Limb discomfort	22	0
Musculoskeletal chest pain	3	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	1	0
Neck pain	28	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Pain in extremity	216	0
Osteoarthropathies		
Osteoarthritis	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	2	0
Soft tissue disorders NEC		
Axillary mass	1	0
Groin pain	5	0
Spine and neck deformities		
Cervical spinal stenosis	1	0
Kyphosis	1	0
Spondyloarthropathies		
Arthritis reactive	1	0
Synovial disorders		
Synovial cyst	1	0
Tendon disorders		
Tendon pain	1	0
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	883	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
Triple negative breast cancer	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	2	0
<i>Metastases to specified sites</i>		
Metastases to lung	1	1
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	1	0
<i>Reproductive neoplasms male benign NEC</i>		
Testicle adenoma	2	0
<i>Skin melanomas (excl ocular)</i>		
Metastatic malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Skin papilloma	1	0
Neoplasms SOC TOTAL	12	1

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Hyporeflexia	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebrovascular accident	5	0
Subarachnoid haemorrhage	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	9	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	4	0
Dysgraphia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	37	0
Loss of consciousness	13	0
Somnolence	20	0
Syncope	34	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Fine motor skill dysfunction	1	0
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	13	0
Facial nerve disorder	1	0
Facial paralysis	4	0
Facial paresis	3	0
Facial spasm	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Cluster headache	8	0
Headache	660	0
Sinus headache	11	0
Tension headache	21	0
Vascular headache	2	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	3	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
Memory impairment	6	0
Transient global amnesia	1	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	3	0
Disturbance in attention	11	0
<i>Migraine headaches</i>		
Migraine	76	0
Migraine with aura	5	0
Retinal migraine	2	0
<i>Motor neurone diseases</i>		
Motor neurone disease	1	0
<i>Muscle tone abnormal</i>		
Drop attacks	1	0
Hypertonia	1	0
Hypotonia	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	4	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	2	0
Narcolepsy	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	2	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	1	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	19	0
Dizziness	204	0
Dizziness exertional	2	0
Dizziness postural	16	0
Head discomfort	9	0
Neurological symptom	3	0
Persistent postural-perceptual dizziness	1	0
Presyncope	4	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	4	0
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	2	0
Burning sensation	13	0
Formication	2	0
Hyperaesthesia	3	0
Hypoaesthesia	76	0
Paraesthesia	125	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Monoparesis	2	0
Monoplegia	2	0
Paralysis	3	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
<i>Partial complex seizures</i>		
Dreamy state	1	0
<i>Peripheral neuropathies NEC</i>		

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Lumbosacral plexopathy	1	0
Neuropathy peripheral	2	0
Seizures and seizure disorders NEC		
Epilepsy	3	0
Seizure	8	0
Seizure anoxic	1	0
Status epilepticus	1	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Ageusia	13	0
Allodynia	1	0
Dysgeusia	16	0
Electric shock sensation	1	0
Neuralgia	10	0
Restless legs syndrome	6	0
Sensory disturbance	4	0
Sensory loss	4	0
Sensory overload	1	0
Taste disorder	1	0
Sleep disturbances NEC		
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	2	0
Slow speech	1	0
Speech disorder	2	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Radiculopathy	1	0
Structural brain disorders NEC		
Brain injury	1	0
Transient cerebrovascular events		
Transient ischaemic attack	3	0
Tremor (excl congenital)		
Tremor	74	0
Trigeminal disorders		
Trigeminal neuralgia	4	0
Nervous system disorders SOC TOTAL	1648	1

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	1
Pregnancy conditions SOC TOTAL	7	1

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Amnesic symptoms</i>		
Paramnesia	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	22	0
Nervousness	6	0
Stress	3	0
Tension	2	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Paranoia	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	2	0
<i>Confusion and disorientation</i>		
Confusional state	22	0
Disorientation	3	0
<i>Deliria</i>		
Delirium	5	0
<i>Depressive disorders</i>		
Depression	7	0
Major depression	1	0
<i>Dissociative states</i>		
Dissociation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	33	0
Middle insomnia	1	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	7	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	4	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Social anxiety disorder	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	8	0
Hallucination, auditory	2	0
Hallucination, olfactory	1	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	3	0
Tearfulness	2	0
<i>Mood disorders NEC</i>		
Apathy	3	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Panic reaction	1	0
Parasomnias		
Abnormal dreams	3	0
Nightmare	5	0
Psychiatric elimination disorders		
Enuresis	1	0
Psychiatric symptoms NEC		
Hypervigilance	2	0
Sexual desire disorders		
Libido decreased	1	0
Loss of libido	4	0
Sleep disorders NEC		
Sleep disorder	8	0
Somatic symptom disorders		
Conversion disorder	2	0
Speech articulation and rhythm disturbances		
Dysphemia	2	0
Suicidal and self-injurious behaviour		
Suicidal ideation	4	0
Thinking disturbances		
Thought blocking	1	0
Tic disorders		
Tic	2	0
Psychiatric disorders SOC TOTAL	190	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Incontinence	1	0
Pollakiuria	3	0
Urinary incontinence	1	0
Urinary retention	2	0
<i>Myoneurogenic bladder disorders</i>		
Hypertonic bladder	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal infarct	1	0
Renal vein thrombosis	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Nocturia	2	0
Renal pain	12	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	28	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Breast mass	1	0
<i>Breast signs and symptoms</i>		
Breast pain	9	0
Breast tenderness	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	2	0
<i>Lactation disorders</i>		
Lactation puerperal increased	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	4	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	28	0
Intermenstrual bleeding	10	0
Menstrual disorder	20	0
Menstruation irregular	38	0
Premenstrual syndrome	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	9	0
Hypomenorrhoea	8	0
Menstruation delayed	59	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	94	0
Polymenorrhoea	22	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
Pruritus genital	1	0
<i>Sexual function and fertility disorders NEC</i>		
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0
Testicular retraction	1	0
Testis discomfort	1	0
<i>Testicular and epididymal infections and inflammations</i>		
Orchitis noninfective	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	23	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Vaginal odour	1	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024

Data Lock Date: 06-Mar-2024 18:30:04

Earliest Reaction Date: 17-Apr-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	2	0
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	352	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	86	0
Grunting	1	0
Hypopnoea	1	0
Respiration abnormal	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Chronic obstructive pulmonary disease	1	0
Wheezing	6	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	38	0
Haemoptysis	5	0
Productive cough	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	7	0
<i>Nasal disorders NEC</i>		
Epistaxis	29	0
Nasal disorder	1	0
Nasal dryness	1	0
Nasal oedema	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	1
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
Pharyngeal ulceration	1	0
Tonsillar hypertrophy	4	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	2	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	5	0
Pulmonary thrombosis	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Choking	1	0
Dry throat	3	0
Dysphonia	3	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	41	0
Paranasal sinus discomfort	1	0
Rhinalgia	3	0
Rhinorrhoea	13	0
Sinus pain	6	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024

Data Lock Date: 06-Mar-2024 18:30:04

Earliest Reaction Date: 17-Apr-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Sneezing	8	0
Throat irritation	2	0
Throat tightness	2	0
Yawning	3	0
Respiratory disorders SOC TOTAL	292	1

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	3	0
<i>Alopecias</i>		
Alopecia	10	0
<i>Angioedemas</i>		
Angioedema	6	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	17	0
Hyperhidrosis	68	0
Miliaria	4	0
Night sweats	15	0
<i>Bullous conditions</i>		
Blister	5	0
Blood blister	5	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	14	0
Papule	7	0
Sensitive skin	4	0
Skin burning sensation	6	0
Skin discolouration	6	0
Skin reaction	2	0
Skin swelling	1	0
Skin warm	8	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	3	0
Dermatitis atopic	1	0
Eczema	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	30	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	4	0
<i>Hyperpigmentation disorders</i>		
Solar lentigo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Splinter haemorrhages	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	1	0
<i>Pruritus NEC</i>		
Pruritus	90	0
<i>Psoriatic conditions</i>		
Psoriasis	2	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash	89	0
Rash erythematous	28	0
Rash macular	6	0
Rash papular	3	0
Rash pruritic	20	0
Rash vesicular	2	0
Systemic lupus erythematosus rash	1	0
Rosaceas		
Rosacea	4	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin cysts and polyps		
Dermal cyst	1	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Idiopathic urticaria	2	0
Urticaria	36	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	522	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Immobile	1	0
Impaired driving ability	1	0
<i>Educational issues</i>		
Illiteracy	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	1	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
Social circumstances SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
 Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Immunisations</i>		
COVID-19 immunisation	2	0
Immunisation	1	0
Tuberculosis immunisation	1	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	2	0
Physical fitness training	1	0
Surgical & medical procedures SOC TOTAL	9	0

Case Series Drug Analysis Print

Name: FOI 24/163 COVID-19 Vaccine AstraZeneca (Batch PV46674) Vaccine Analysis Print

Report Run Date: 13-Mar-2024
Earliest Reaction Date: 17-Apr-2020

Data Lock Date: 06-Mar-2024 18:30:04
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
Haemorrhage	25	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	13	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	1	0
Vascular compression	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary fragility	1	0
Vascular pain	1	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	10	0
Jugular vein thrombosis	1	0
Peripheral embolism	1	0
Superficial vein thrombosis	3	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	5	0
Hot flush	18	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	9	0
Raynaud's phenomenon	2	0
<i>Site specific necrosis and vascular insufficiency NEC</i>		
Coeliac artery occlusion	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	7	0
<i>Varicose veins NEC</i>		
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Hypotension	8	0
Vascular disorders SOC TOTAL	129	0
TOTAL REACTIONS FOR DRUG	7706	7
TOTAL REPORTS	2135	
TOTAL FATAL OUTCOME REPORTS		7