

# **COVID-19 Vaccine AstraZeneca batch PV46678**

## **Vaccine Analysis Print**

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

All UK spontaneous reports received up to and including 23/02/2024 for COVID-19 Vaccine AstraZeneca batch PV46678

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.

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Anaemia folate deficiency	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	3	0
Blood loss anaemia	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	3	0
<i><b>Coagulopathies</b></i>		
Coagulopathy	1	0
<i><b>Haematological disorders</b></i>		
Mast cell activation syndrome	1	0
<i><b>Leukopenias NEC</b></i>		
Leukopenia	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	6	0
Lymphadenitis	1	0
Lymphadenopathy	50	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	4	0
Thrombosis with thrombocytopenia syndrome	3	0
<b>Blood disorders SOC TOTAL</b>	<b>75</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Aortic valvular disorders</b></i>		
Aortic valve sclerosis	1	0
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block first degree	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	2	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	59	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	3	0
Ventricular failure	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	1	0
Angina pectoris	1	0
Angina unstable	2	0
Myocardial infarction	10	0
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	1	0
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
Myocardial injury	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	6	0
Myopericarditis	1	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	7	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	1	0
Bradycardia	1	0
Cardiac flutter	1	0
Extrasystoles	3	0
Postural orthostatic tachycardia syndrome	2	0
Tachyarrhythmia	1	0
Tachycardia	17	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	3	0
Sinus bradycardia	1	0
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	1	0
Ventricular extrasystoles	1	0
Ventricular tachycardia	4	0
<b>Cardiac disorders SOC TOTAL</b>	<b>138</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Non-site specific muscle disorders congenital</i>		
Myotonic dystrophy	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear disorder	1	0
Ear pain	16	0
Ear swelling	2	0
<i><b>Hearing losses</b></i>		
Deafness	7	0
Deafness unilateral	1	0
Hypoacusis	2	0
Sudden hearing loss	2	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	1	0
<i><b>Inner ear disorders NEC</b></i>		
Meniere's disease	1	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	3	0
Tinnitus	57	0
Vertigo	32	0
Vertigo labyrinthine	1	0
Vertigo positional	5	0
<b>Ear disorders SOC TOTAL</b>	<b>131</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i><b>Adrenal gland disorders NEC</b></i>		
Haemorrhagic adrenal infarction	1	0
<i><b>Endocrine abnormalities of puberty</b></i>		
Premature menarche	2	0
<i><b>Female gonadal function disorders</b></i>		
Ovulation delayed	2	0
<i><b>Thyroid disorders NEC</b></i>		
Goitre	1	0
<i><b>Thyroid hyperfunction disorders</b></i>		
Graves' disease	3	0
Hyperthyroidism	2	0
<i><b>Thyroid hypofunction disorders</b></i>		
Hypothyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Vitreous haemorrhage	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous detachment	3	0
Vitreous floaters	4	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	3	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	2	0
Eyelid ptosis	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	6	0
Lacrimation increased	3	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	2	0
Swelling of eyelid	6	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	35	0
Eye swelling	5	0
Ocular discomfort	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	1	0
Eye irritation	1	0
Eye pruritus	3	0
Limbal swelling	1	0
Ocular hyperaemia	10	0
<i><b>Ocular sensation disorders</b></i>		
Abnormal sensation in eye	1	0
Asthenopia	4	0
Photophobia	10	0
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal artery occlusion	1	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Epiretinal membrane	1	0
Retinal tear	2	0
<i><b>Scleral infections, irritations and inflammations</b></i>		
Episcleritis	1	0
Scleritis	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Dysmetropsia	1	0
Photopsia	7	0
Vision blurred	35	0
<i><b>Visual field disorders</b></i>		
Visual field defect	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	2	0
Visual impairment	4	0
<b>Eye disorders SOC TOTAL</b>	<b>162</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Anal and rectal signs and symptoms</i>		
Rectal spasm	1	0
<i>Benign oral cavity neoplasms</i>		
Tongue cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	3	0
Crohn's disease	3	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	3	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	81	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
Epigastric discomfort	1	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	18	0
Flatulence	2	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	41	0
Abdominal pain lower	8	0
Abdominal pain upper	57	0
Gastrointestinal pain	6	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	0
Gastrooesophageal reflux disease	4	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
Neurogenic bowel	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
Anal incontinence	2	0
Dysphagia	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	3	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		



## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gingival blister	1	0
Gingival disorder	1	0
Gingival pain	3	0
Noninfective gingivitis	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	4	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoids	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	1	0
Rectal haemorrhage	3	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	215	0
Regurgitation	1	0
Retching	2	0
Vomiting	62	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematochezia	1	0
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophagitis	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	7	0
Lip dry	2	0
Salivary hypersecretion	2	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Oral blood blister	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	5	0
Oral discomfort	2	0
Oral mucosal blistering	1	0
Oral pain	5	0
Paraesthesia oral	10	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	8	0
Mouth swelling	2	0
<b><i>Salivary gland disorders NEC</i></b>		
Salivary gland pain	2	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	1	0
Mouth ulceration	11	0
Stomatitis	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	4	0
Swollen tongue	8	0
<b><i>Tooth missing</i></b>		
Tooth loss	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>646</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Administration site reactions NEC</b></i>		
Administration site pain	1	0
Puncture site bruise	1	0
Puncture site pain	1	0
<i><b>Application and instillation site reactions</b></i>		
Application site pain	1	0
Application site vesicles	1	0
<i><b>Asthenic conditions</b></i>		
Asthenia	38	0
Chronic fatigue syndrome	9	0
Fatigue	392	0
Malaise	101	0
<i><b>Death and sudden death</b></i>		
Death	1	1
<i><b>Febrile disorders</b></i>		
Pyrexia	331	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	258	0
Feeling abnormal	25	0
Feeling cold	37	0
Feeling drunk	2	0
Feeling hot	23	0
Feeling jittery	1	0
Feeling of body temperature change	3	0
Hangover	1	0
Hunger	1	0
Sensation of blood flow	1	0
Sensation of foreign body	2	0
Temperature intolerance	2	0
Thirst	8	0
<i><b>Fibrosis NEC</b></i>		
Fibrosis	1	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	5	0
Gait inability	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	4	0
Crying	2	0
Developmental delay	1	0
General physical health deterioration	1	0
Illness	40	0
Influenza like illness	50	0
Local reaction	1	0
Peripheral swelling	42	0
Sensitivity to weather change	1	0
Swelling	26	0
Swelling face	9	0
<i><b>Inflammations</b></i>		
Inflammation	7	0
<i><b>Infusion site reactions</b></i>		
Infusion site urticaria	1	0
<i><b>Injection site reactions</b></i>		
Injected limb mobility decreased	1	0

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site bruising	1	0
Injection site erythema	3	0
Injection site inflammation	1	0
Injection site injury	1	0
Injection site joint pain	1	0
Injection site mass	4	0
Injection site pain	31	0
Injection site reaction	1	0
Injection site swelling	3	0
<b>Mass conditions NEC</b>		
Nodule	1	0
<b>Oedema NEC</b>		
Oedema	1	0
Oedema peripheral	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	7	0
Chest discomfort	17	0
Chest pain	66	0
Discomfort	8	0
Facial pain	4	0
First bite syndrome	1	0
Inflammatory pain	1	0
Non-cardiac chest pain	3	0
Pain	156	0
Tenderness	11	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	6	0
Inadequate analgesia	2	0
Therapeutic product effect decreased	1	0
Vaccination failure	1	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	1	0
Vaccination site erythema	6	0
Vaccination site inflammation	1	0
Vaccination site mass	2	0
Vaccination site movement impairment	1	0
Vaccination site pain	13	0
Vaccination site pruritus	1	0
Vaccination site rash	3	0
Vaccination site swelling	4	0
Vaccination site warmth	1	0
<b>Withdrawal and rebound effects</b>		
Withdrawal syndrome	2	0
<b>General disorders SOC TOTAL</b>	<b>1805</b>	<b>1</b>

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Gallbladder disorders NEC</i>		
Gallbladder polyp	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hypertransaminasaemia	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Hypersensitivity	16	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	1	0
Food allergy	2	0
Oral allergy syndrome	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	7	0
Anaphylactoid reaction	1	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	3	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorder	1	0
Sensitisation	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>36</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Gastroenteritis	1	0
Peritonitis	1	0
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	6	0
<i><b>Breast infections</b></i>		
Mastitis	2	0
<i><b>Central nervous system and spinal infections</b></i>		
Myelitis	1	0
<i><b>Coronavirus infections</b></i>		
COVID-19	45	0
Post-acute COVID-19 syndrome	2	0
<i><b>Dental and oral soft tissue infections</b></i>		
Gingivitis	1	0
<i><b>Ear infections</b></i>		
Labyrinthitis	2	0
Otitis media chronic	1	0
<i><b>Epstein-Barr viral infections</b></i>		
Infectious mononucleosis	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	1	0
Hordeolum	2	0
<i><b>Fungal infections NEC</b></i>		
Fungal infection	1	0
Pneumonia fungal	1	0
<i><b>Herpes viral infections</b></i>		
Genital herpes	3	0
Herpes simplex reactivation	1	0
Herpes zoster	21	0
Oral herpes	5	0
Varicella	1	0
<i><b>Infections NEC</b></i>		
Abscess	2	0
Infection	6	0
<i><b>Influenza viral infections</b></i>		
Influenza	48	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	6	0
Pneumonia	3	0
Sputum purulent	1	0
<i><b>Neisseria infections</b></i>		
Gonorrhoea	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Septic rash	1	0
Viraemia	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Skin infection	1	0
<i><b>Tinea infections</b></i>		
Tinea cruris	1	0
<i><b>Upper respiratory tract infections</b></i>		
Laryngitis	2	0
Nasopharyngitis	20	0
Sinusitis	1	0

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Tonsillitis	1	0
<b>Urinary tract infections</b>		
Cystitis	2	0
Urinary tract infection	4	0
<b>Viral infections NEC</b>		
Meningitis viral	2	0
Sweating fever	9	0
Viral infection	3	0
Viral myelitis	1	0
<b>Infections SOC TOTAL</b>	<b>215</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	17	0
Maternal exposure during pregnancy	4	0
<i>Eye injuries NEC</i>		
Eyelid contusion	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	2	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	3	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
Injury	1	0
Wound complication	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	2	0
<i>Off label uses</i>		
Off label use	3	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	1	0
Incorrect route of product administration	1	0
Product administration error	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Site specific injuries NEC</i>		
Limb crushing injury	1	0
Limb injury	4	0
<i>Skin injuries NEC</i>		
Contusion	40	0
<i>Spinal fractures and dislocations</i>		
Spinal fracture	1	0
<b>Injuries SOC TOTAL</b>	<b>93</b>	<b>0</b>



## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
Antineutrophil cytoplasmic antibody positive	1	0
<b><i>Blood counts NEC</i></b>		
Full blood count abnormal	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Oxygen saturation decreased	3	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose increased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Activated partial thromboplastin time prolonged	1	0
Fibrin D dimer increased	1	0
International normalised ratio increased	1	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	3	0
<b><i>Fertility analyses and other reproductive function procedures</i></b>		
Semen volume decreased	1	0
<b><i>Gastrointestinal function diagnostic procedures</i></b>		
Swallow study	1	0
<b><i>Haematological analyses NEC</i></b>		
Red blood cell sedimentation rate increased	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	6	0
Heart rate abnormal	1	0
Heart rate decreased	1	0
Heart rate increased	17	0
Heart rate irregular	7	0
<b><i>Hepatobiliary function diagnostic procedures</i></b>		
Alanine aminotransferase increased	1	0
Liver function test abnormal	3	0
Transaminases increased	1	0
<b><i>Immunology analyses NEC</i></b>		
Antibody test	1	0
<b><i>Investigations NEC</i></b>		
Blood test abnormal	3	0
<b><i>Microbiology and serology tests NEC</i></b>		
Blood culture negative	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood iron decreased	1	0
Blood phosphorus increased	1	0
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Discogram abnormal	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body mass index increased	1	0
Body temperature	4	0
Body temperature fluctuation	2	0
Body temperature increased	6	0
Temperature difference of extremities	1	0
Weight decreased	5	0
Weight increased	1	0
<b><i>Pituitary analyses anterior</i></b>		
Blood corticotrophin abnormal	1	0
Blood prolactin increased	1	0
<b><i>Platelet analyses</i></b>		

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Platelet count abnormal	1	0
Platelet count decreased	2	0
<b>Protein analyses NEC</b>		
Blood albumin abnormal	1	0
C-reactive protein increased	1	0
Protein total abnormal	1	0
<b>Red blood cell analyses</b>		
Haematocrit	1	0
Red blood cell count increased	1	0
<b>Reproductive hormone analyses</b>		
Female sex hormone level	1	0
Pregnancy test	1	0
<b>Respiratory and pulmonary function diagnostic procedures</b>		
Peak expiratory flow rate decreased	1	0
<b>Skeletal and cardiac muscle analyses</b>		
Troponin increased	1	0
<b>Toxicology laboratory analyses</b>		
Blood carbon monoxide increased	1	0
<b>Urinalysis NEC</b>		
Blood urine	1	0
Blood urine present	1	0
Protein urine	1	0
White blood cells urine positive	1	0
pH urine	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure increased	4	0
Blood pressure measurement	1	0
<b>Virus identification and serology</b>		
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 test negative	1	0
<b>Vitamin analyses</b>		
Vitamin B12 abnormal	1	0
<b>White blood cell analyses</b>		
Eosinophil count increased	1	0
Lymphocyte count abnormal	1	0
Monocyte count increased	1	0
Neutrophil count abnormal	1	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>113</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	37	0
Hyperphagia	1	0
Hypophagia	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	3	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	3	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	2	0
Abnormal weight gain	1	0
Feeding disorder	5	0
Food aversion	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	2	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Lactic acidosis	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	4	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	3	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Vitamin B12 deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>68</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	6	0
Autoimmune arthritis	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	11	0
Pain in jaw	7	0
Spinal pain	6	0
<b><i>Bursal disorders</i></b>		
Bursitis	1	0
<b><i>Cartilage disorders</i></b>		
Costochondritis	2	0
<b><i>Connective tissue disorders NEC</i></b>		
Polymyalgia rheumatica	1	0
<b><i>Extremity deformities</i></b>		
Foot deformity	1	0
<b><i>Intervertebral disc disorders NEC</i></b>		
Intervertebral disc degeneration	1	0
<b><i>Joint related disorders NEC</i></b>		
Joint contracture	1	0
Periarthritis	4	0
Rotator cuff syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	192	0
Joint noise	1	0
Joint stiffness	6	0
Joint swelling	15	0
<b><i>Muscle infections and inflammations</i></b>		
Myositis	2	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	2	0
Myalgia	194	0
Myofascial pain syndrome	1	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	2	0
Muscle fatigue	9	0
Muscle haemorrhage	1	0
Muscle oedema	1	0
Muscle spasms	46	0
Muscle swelling	1	0
Muscle tightness	3	0
Muscle twitching	10	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	26	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Dupuytren's contracture	1	0
Mobility decreased	6	0
Musculoskeletal stiffness	26	0
Winged scapula	1	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Connective tissue inflammation	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	51	0
Flank pain	1	0

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Limb discomfort	21	0
Musculoskeletal chest pain	4	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	2	0
Neck pain	27	0
Pain in extremity	228	0
<b>Myopathies</b>		
Muscle necrosis	1	0
Myopathy	1	0
<b>Osteoarthropathies</b>		
Osteoarthritis	4	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	1	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	2	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	2	0
Groin pain	1	0
Neck mass	1	0
<b>Spine and neck deformities</b>		
Kyphosis	1	0
<b>Spondyloarthropathies</b>		
Arthritis reactive	2	0
<b>Synovial disorders</b>		
Synovitis	2	0
<b>Tendon disorders</b>		
Tendonitis	1	0
Tenosynovitis stenosaurs	1	0
Trigger finger	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>946</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Histiocytic necrotising lymphadenitis	1	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Seborrhoeic keratosis	1	0
Skin papilloma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	1	0
<b>Neoplasms SOC TOTAL</b>	<b>11</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Poor sucking reflex	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	4	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebellar stroke	1	1
Cerebral haemorrhage	2	0
Cerebral infarction	2	0
Cerebral ischaemia	1	0
Cerebrovascular accident	13	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	2	1
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	0
Sigmoid sinus thrombosis	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	2	0
<i>Coordination and balance disturbances</i>		
Balance disorder	12	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
Apraxia	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	45	0
Loss of consciousness	15	0
Somnolence	23	0
Syncope	26	0
<i>Dyskinesias and movement disorders NEC</i>		
Akinesia	1	0
Bradykinesia	1	0
Dyskinesia	1	0
Hypokinesia	2	0
Movement disorder	1	0
<i>Dystonias</i>		
Dystonia	1	0
Dystonic tremor	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	6	0
Facial paralysis	4	0
Facial paresis	2	0
Facial spasm	1	0
<i>Generalised tonic-clonic seizures</i>		

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Generalised tonic-clonic seizure	1	0
<b>Headaches NEC</b>		
Cluster headache	6	0
Drug withdrawal headache	1	0
Headache	558	0
Occipital neuralgia	1	0
Primary headache associated with sexual activity	1	0
Primary stabbing headache	3	0
Sinus headache	6	0
Tension headache	12	0
Thunderclap headache	1	0
<b>Increased intracranial pressure disorders</b>		
Brain oedema	1	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Cauda equina syndrome	1	0
Lumbar radiculopathy	1	0
Sciatica	4	0
<b>Memory loss (excl dementia)</b>		
Amnesia	6	0
Memory impairment	5	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	5	0
Disturbance in attention	16	0
Mental impairment	3	0
<b>Migraine headaches</b>		
Hemiplegic migraine	2	0
Migraine	77	0
Migraine with aura	5	0
Retinal migraine	1	0
Vestibular migraine	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	3	0
Long thoracic nerve palsy	1	0
<b>Muscle tone abnormal</b>		
Stiff leg syndrome	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	5	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	1	0
Narcolepsy	1	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	1	0
<b>Neurological signs and symptoms NEC</b>		
Brain fog	11	0
Dizziness	211	0
Dizziness exertional	1	0
Dizziness postural	17	0
Head discomfort	8	0
Neurological symptom	1	0
Pleocytosis	1	0
Presyncope	9	0
Unresponsive to stimuli	2	0
<b>Neuromuscular disorders NEC</b>		



## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	2	0
Parosmia	4	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	1	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	10	0
Dysaesthesia	1	0
Formication	2	0
Hyperaesthesia	1	0
Hypoesthesia	68	0
Paraesthesia	124	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	1	0
Hemiparesis	1	0
Hemiplegia	1	0
Monoparesis	1	0
Paralysis	3	0
<b>Partial simple seizures NEC</b>		
Simple partial seizures	1	0
<b>Peripheral neuropathies NEC</b>		
Neuropathy peripheral	5	0
Small fibre neuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	5	0
Febrile convulsion	1	0
Partial seizures	1	0
Seizure	21	0
Tonic convulsion	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	10	0
Allodynia	2	0
Aura	1	0
Dysgeusia	19	0
Electric shock sensation	1	0
Neuralgia	23	0
Restless legs syndrome	6	0
Sensory disturbance	1	0
Sensory loss	4	0
Taste disorder	3	0
<b>Speech and language abnormalities</b>		
Dysarthria	3	0
Speech disorder	2	0
<b>Spinal cord and nerve root disorders NEC</b>		
Spinal cord disorder	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	2	0
White matter lesion	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	2	0
<b>Tremor (excl congenital)</b>		

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Tremor	50	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	2	0
<b>Vertigos NEC</b>		
Vertigo CNS origin	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1569</b>	<b>2</b>

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>4</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b><i>Device incompatibility issues</i></b>		
Patient-device incompatibility	1	0
<b><i>Product distribution and storage issues</i></b>		
Product temperature excursion issue	1	0
<b><i>Product label issues</i></b>		
Product barcode issue	1	0
<b><i>Product physical issues</i></b>		
Product taste abnormal	1	0
<b><i>Product quality issues NEC</i></b>		
Product quality issue	1	0
<b>null SOC TOTAL</b>	<b>5</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
Constricted affect	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1	0
Anxiety	27	0
Nervousness	4	0
Stress	4	0
Tension	2	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Violence-related symptom	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	23	0
Disorientation	3	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Depressive disorders</i></b>		
Depression	8	0
Major depression	1	0
Mixed anxiety and depressive disorder	1	0
<b><i>Dissociative states</i></b>		
Dissociation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	29	0
Middle insomnia	1	0
Terminal insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	9	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	2	0
Emotional disorder	1	0
Emotional distress	2	0
Irritability	6	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Phonophobia	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	3	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	3	0
Hallucination, visual	1	0
<b><i>Impulse control disorders</i></b>		
Pyromania	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	9	0
Feeling guilty	1	0
Tearfulness	2	0
<b><i>Mood alterations with manic symptoms</i></b>		

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Mania	1	0
<b><i>Orgasmic disorders and disturbances</i></b>		
Premature ejaculation	1	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	8	0
Panic disorder	1	0
Panic reaction	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	3	0
Nightmare	2	0
Rapid eye movements sleep abnormal	1	0
<b><i>Psychiatric symptoms NEC</i></b>		
Psychiatric symptom	1	0
<b><i>Sexual desire disorders</i></b>		
Loss of libido	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	8	0
<b><i>Somatic symptom disorders</i></b>		
Conversion disorder	2	0
<b><i>Stereotypies and automatisms</i></b>		
Head banging	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Suicidal ideation	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	1	0
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>190</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Dysuria	1	0
Incontinence	3	0
Pollakiuria	4	0
Urinary incontinence	2	0
Urinary retention	2	0
Urine flow decreased	1	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
<i>Urinary abnormalities</i>		
Haematuria	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Nocturia	1	0
Renal pain	8	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	10	0
Breast tenderness	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	4	0
<i><b>Lactation disorders</b></i>		
Lactation insufficiency	1	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	1	0
Premature menopause	3	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	6	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	35	0
Intermenstrual bleeding	17	0
Menstrual discomfort	1	0
Menstrual disorder	31	0
Menstruation irregular	52	0
Premenstrual pain	2	0
Premenstrual syndrome	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	8	0
Hypomenorrhoea	9	0
Menstruation delayed	73	0
Oligomenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	88	0
Polymenorrhoea	13	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovarian enlargement	1	0
Ovarian oedema	1	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	2	0
<i><b>Penile and scrotal infections and inflammations</b></i>		
Balanoposthitis	1	0
<i><b>Reproductive tract disorders NEC (excl neoplasms)</b></i>		
Genital haemorrhage	1	0
Genital ulceration	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Spermatogenesis and semen disorders</b></i>		
Haematospermia	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular disorder	1	0
Testicular pain	2	0
<i><b>Uterine disorders NEC</b></i>		
Uterine haemorrhage	2	0
<i><b>Uterine tone disorders</b></i>		
Uterine spasm	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	17	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vaginal odour	1	0



# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
Reproductive & breast disorders cont'd		
Vulvovaginal burning sensation	1	0
Vulvovaginal discomfort	1	0
Vulvovaginal pain	2	0
Vulvovaginal rash	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>396</b>	<b>0</b>

# Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	100	0
Dyspnoea at rest	1	0
Dyspnoea exertional	2	0
Hypopnoea	1	0
Respiration abnormal	2	0
Respiratory arrest	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	4	0
Wheezing	4	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	33	0
Haemoptysis	2	0
Productive cough	2	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Vocal cord dysfunction	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngospasm	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
Pulmonary haemorrhage	1	1
Pulmonary pain	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	33	0
Nasal disorder	1	0
Nasal ulcer	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	2	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Atelectasis	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal paraesthesia	1	0
Tonsillar erythema	1	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary hypertensions</b></i>		
Pulmonary hypertension	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	15	1
Pulmonary infarction	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Allergic respiratory symptom	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	3	0
Dry throat	2	0
Dysphonia	1	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	30	0
Paranasal sinus discomfort	1	0

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Rhinorrhoea	13	0
Sinus pain	7	0
Sneezing	4	0
Throat irritation	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>283</b>	<b>2</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	2	0
<b><i>Alopecias</i></b>		
Alopecia	5	0
Androgenetic alopecia	1	0
<b><i>Angioedemas</i></b>		
Angioedema	6	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	16	0
Hidradenitis	1	0
Hyperhidrosis	71	0
Miliaria	1	0
Night sweats	15	0
<b><i>Bullous conditions</i></b>		
Blister	4	0
Blood blister	1	0
Dermatitis bullous	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	7	0
Pain of skin	4	0
Papule	1	0
Scab	2	0
Scar pain	1	0
Sensitive skin	5	0
Skin burning sensation	5	0
Skin lesion	1	0
Skin swelling	1	0
Skin warm	9	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis allergic	3	0
Dermatitis atopic	1	0
Dermatitis contact	1	0
Dyshidrotic eczema	3	0
Eczema	8	0
Neurodermatitis	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	1	0
Fixed eruption	1	0
<b><i>Erythemas</i></b>		
Erythema	22	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	2	0
<b><i>Hypopigmentation disorders</i></b>		
Vitiligo	1	0
<b><i>Papulosquamous conditions</i></b>		
Pityriasis rosea	1	0
<b><i>Pigmentation changes NEC</i></b>		
Haemosiderin stain	1	0
<b><i>Pilar disorders NEC</i></b>		
Hair colour changes	1	0

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Hair growth abnormal	1	0
Piloerection	1	0
<b>Pruritus NEC</b>		
Pruritus	72	0
Senile pruritus	1	0
<b>Psoriatic conditions</b>		
Palmoplantar pustulosis	1	0
Psoriasis	5	0
Pustular psoriasis	1	0
<b>Purpura and related conditions</b>		
Petechiae	3	0
Purpura	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	1	0
Rash	75	0
Rash erythematous	17	0
Rash macular	5	0
Rash maculo-papular	1	0
Rash papular	5	0
Rash pruritic	24	0
<b>Rosaceas</b>		
Erythematotelangiectatic rosacea	1	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	1	0
Skin mass	1	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin erosion	2	0
<b>Skin haemorrhages</b>		
Skin haemorrhage	1	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	20	0
Urticaria chronic	3	0
<b>Skin disorders SOC TOTAL</b>	<b>457</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Postmenopause	2	0
<i>Disability issues</i>		
Bedridden	1	0
Impaired work ability	1	0
Loss of personal independence in daily activities	1	0
<b>Social circumstances SOC TOTAL</b>	<b>5</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Dental and gingival therapeutic procedures</i>		
Tooth restoration	2	0
<i>Immunisations</i>		
COVID-19 immunisation	1	0
Immunisation	1	0
<i>Limb therapeutic procedures</i>		
Leg amputation	1	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	4	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>9</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/191 COVID AZ vaccine PV46678**

Report Run Date: 07-Mar-2024  
Earliest Reaction Date: 01-Jun-2001

Data Lock Date: 23-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Arterial infections and inflammations</i></b>		
Arteritis	1	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	1	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	3	0
<b><i>Haemorrhages NEC</i></b>		
Haematoma	1	0
Haemorrhage	25	0
Internal haemorrhage	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	1	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Arterial thrombosis	1	0
Embolism	3	0
Thrombosis	19	0
Venous thrombosis	1	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Vasospasm	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Capillary fragility	1	0
Vascular pain	4	0
Vasodilatation	1	0
Vein rupture	1	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Deep vein thrombosis	16	0
Subclavian artery embolism	1	0
Thrombophlebitis	2	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	1	0
Flushing	4	0
Hot flush	21	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
Peripheral coldness	14	0
Peripheral ischaemia	2	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	2	0
<b><i>Phlebitis NEC</i></b>		
Phlebitis	4	0
Phlebitis superficial	1	0
<b><i>Site specific vascular disorders NEC</i></b>		
Pallor	5	0
<b><i>Varicose veins NEC</i></b>		
Spider vein	2	0
Varicose vein	2	0
<b><i>Vascular hypertensive disorders NEC</i></b>		
Hypertension	11	0
Labile hypertension	1	0
Secondary hypertension	1	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	1	0
Hypotension	6	0
<b><i>Vasculitides NEC</i></b>		



# Case Series Drug Analysis Print

Name: FOI 24/191 COVID AZ vaccine PV46678

Report Run Date: 07-Mar-2024

Data Lock Date: 23-Feb-2024 18:30:04

Earliest Reaction Date: 01-Jun-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>164</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>7565</b>	<b>5</b>
<b>TOTAL REPORTS</b>	<b>2175</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>5</b>