

## Case Series Drug Analysis Print

**Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print**

Report Run Date: 24-May-2024  
Data Lock Date: 23-May-2024 18:30:03  
Earliest Reaction Date: 07-Feb-2018  
MedDRA Version: MedDRA 27.0

FOI 2024/00093  
COVID-19 Vaccine  
AstraZeneca (Batch  
4120Z002) Vaccine  
Analysis Print: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the COVID-19 Vaccine AstraZeneca (Batch 4120Z002)

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	2	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	2	0
<i>Leukocytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	15	0
Lymphadenitis	1	0
Lymphadenopathy	147	0
<i>Neutropenias</i>		
Agranulocytosis	1	0
Neutropenia	1	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Macrocytosis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	12	0
Thrombocytopenic purpura	1	0
Thrombosis with thrombocytopenia syndrome	2	0
<i>Thrombocytoses</i>		
Thrombocytosis	1	0
<b>Blood disorders SOC TOTAL</b>	<b>197</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block complete	1	0
Trifascicular block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	2	0
Cardiac ventricular thrombosis	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	1	0
Cardiovascular symptom	1	0
Palpitations	157	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	1	0
Dilated cardiomyopathy	4	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	2	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	4	2
Angina pectoris	7	0
Arteriospasm coronary	1	0
Myocardial infarction	21	0
Myocardial ischaemia	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiac sarcoidosis	1	0
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
Ventricular hypertrophy	1	1
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	5	0
Myopericarditis	2	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	13	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial rub	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	5	1
Bradycardia	6	0
Cardiac fibrillation	1	0
Cardiac flutter	13	0
Extrasystoles	7	0
Postural orthostatic tachycardia syndrome	2	0
Tachyarrhythmia	1	0
Tachycardia	37	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	8	0
Atrial flutter	1	0
Atrial tachycardia	10	0
Sinus node dysfunction	1	0
Sinus tachycardia	1	0
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b> Cardiac disorders cont'd		
Cardiac arrest	2	0
Pulseless electrical activity	1	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	2	0
Ventricular fibrillation	1	0
Ventricular tachycardia	12	0
<b>Cardiac disorders SOC TOTAL</b>	<b>344</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 18	1	0
<i>Sex chromosomal abnormalities</i>		
Klinefelter's syndrome	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	1	0
Ear discomfort	2	0
Ear pain	54	0
Ear swelling	1	0
<i><b>Hearing losses</b></i>		
Deafness	7	0
Deafness bilateral	2	0
Hypoacusis	9	0
Sudden hearing loss	1	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	6	0
<i><b>Inner ear disorders NEC</b></i>		
Meniere's disease	3	0
Vestibular disorder	1	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	3	0
Tinnitus	140	0
Vertigo	55	0
Vertigo positional	4	0
<b>Ear disorders SOC TOTAL</b>	<b>289</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	2	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
Polycystic ovarian syndrome	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Thyroid pain	2	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
<b>Endocrine disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	3	0
Vitreous floaters	9	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	9	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
Eyelid ptosis	1	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	3	0
<i>Lacrimation disorders</i>		
Dry eye	11	0
Lacrimation increased	9	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid cyst	2	0
Eyelid rash	1	0
Swelling of eyelid	6	0
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	5	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye oedema	1	0
Eye pain	83	0
Eye swelling	15	0
Periorbital oedema	1	0
Periorbital swelling	5	0
Retinal disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye irritation	7	0
Eye pruritus	13	0
Ocular hyperaemia	13	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
Ocular myasthenia	1	0
Strabismus	1	0
Tolosa-Hunt syndrome	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	13	0
Photophobia	28	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	1	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal vascular occlusion	1	0
Retinal vein occlusion	1	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Macular hole	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	20	0
Photopsia	8	0
Scintillating scotoma	1	0
Vision blurred	83	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	13	0
Blindness transient	1	0
Visual acuity reduced	1	0
Visual impairment	36	0
<b>Eye disorders SOC TOTAL</b>	<b>421</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ischaemic	1	0
Inflammatory bowel disease	1	0
<i>Dental disorders NEC</i>		
Malpositioned teeth	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	5	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	202	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	23	0
Epigastric discomfort	1	0
Eructation	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	15	0
Flatulence	6	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	104	0
Abdominal pain lower	4	0
Abdominal pain upper	135	0
Abdominal rigidity	2	0
Gastrointestinal pain	6	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	11	0
Gastrooesophageal reflux disease	9	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Functional gastrointestinal disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Barrett's oesophagus	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	47	0
Dysphagia	8	0
Odynophagia	1	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Cardiospasm	10	0
Irritable bowel syndrome	4	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	1	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal infarction	1	0
Intestinal ischaemia	1	0
Mesenteric vein thrombosis	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	3	0
Gingival pain	6	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	2	0
Haemorrhoids thrombosed	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	2	0
Rectal haemorrhage	3	0
Small intestinal haemorrhage	1	0
<b><i>Malabsorption syndromes</i></b>		
Coeliac disease	2	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	752	0
Regurgitation	1	0
Retching	8	0
Vomiting	230	0
Vomiting projectile	2	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	1	0
Haematemesis	2	0
Haematochezia	4	0
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophagitis	2	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	36	0
Lip dry	6	0
Salivary hypersecretion	1	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Chapped lips	1	0
Oral disorder	1	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	2	0
Oral blood blister	1	0
<b><i>Oral soft tissue infections</i></b>		

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Angular cheilitis	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Burning mouth syndrome	1	0
Hypoaesthesia oral	19	0
Oral discomfort	4	0
Oral pain	5	0
Oral pruritus	1	0
Paraesthesia oral	26	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	37	0
Mouth swelling	3	0
Palatal swelling	2	0
<b><i>Peritoneal and retroperitoneal disorders</i></b>		
Ascites	1	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	5	0
Lip ulceration	1	0
Mouth ulceration	19	0
Stomatitis	2	0
<b><i>Tongue disorders</i></b>		
Trichoglossia	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	6	0
Swollen tongue	22	0
Tongue discolouration	2	0
Tongue discomfort	1	0
Tongue dry	2	0
Tongue oedema	1	0
Tongue rough	1	0
Tongue spasm	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>1863</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
Puncture site bruise	2	0
<i>Application site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	1	0
Application site pain	1	0
<i>Asthenic conditions</i>		
Asthenia	115	0
Chronic fatigue syndrome	8	0
Fatigue	1213	0
Malaise	333	0
Sluggishness	1	0
<i>Body temperature altered</i>		
Hypothermia	2	0
<i>Complications associated with device NEC</i>		
Medical device site dysaesthesia	1	0
Phantom shocks	1	0
<i>Death and sudden death</i>		
Death	2	2
Sudden death	2	2
<i>Febrile disorders</i>		
Pyrexia	1059	0
<i>Feelings and sensations NEC</i>		
Chills	858	0
Feeling abnormal	92	0
Feeling cold	115	0
Feeling drunk	4	0
Feeling hot	64	0
Feeling jittery	2	0
Feeling of body temperature change	20	0
Hangover	10	0
Hunger	1	0
Sensation of foreign body	2	0
Temperature intolerance	5	0
Thirst	36	0
<i>Gait disturbances</i>		
Gait disturbance	11	0
Gait inability	5	0
Loss of control of legs	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	8	0
Crying	3	0
Disease progression	1	0
Foaming at mouth	1	0
General physical health deterioration	1	0
High-pitched crying	1	0
Illness	93	0
Induration	3	0
Influenza like illness	229	0
Local reaction	3	0

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<b>General disorders</b> General disorders cont'd		
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	178	0
Pre-existing condition improved	1	0
Secretion discharge	1	0
Swelling	61	0
Swelling face	27	0
<b>Implant and catheter site reactions</b>		
Implant site swelling	1	0
Implant site warmth	1	0
<b>Inflamations</b>		
Inflammation	24	0
Scar inflammation	1	0
<b>Infusion site reactions</b>		
Infusion site pain	2	0
Infusion site warmth	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	3	0
Injection site bruising	3	0
Injection site coldness	1	0
Injection site erythema	22	0
Injection site inflammation	3	0
Injection site joint pain	2	0
Injection site mass	39	0
Injection site oedema	1	0
Injection site pain	120	0
Injection site paraesthesia	1	0
Injection site pruritus	7	0
Injection site rash	12	0
Injection site reaction	1	0
Injection site swelling	6	0
Injection site urticaria	1	0
Injection site vesicles	2	0
Injection site warmth	12	0
<b>Instillation site reactions</b>		
Instillation site pain	1	0
Instillation site warmth	2	0
<b>Interactions</b>		
Drug interaction	1	0
Inhibitory drug interaction	1	0
<b>Mass conditions NEC</b>		
Cyst	2	0
Mass	1	0
Nodule	1	0
<b>Mucosal findings abnormal</b>		
Oedema mucosal	1	0
<b>Necrosis NEC</b>		
Necrosis	1	0
<b>Oedema NEC</b>		
Localised oedema	1	0
Oedema	6	0
Oedema peripheral	5	0
<b>Pain and discomfort NEC</b>		

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<b>General disorders</b> General disorders cont'd		
Axillary pain	19	0
Chest discomfort	39	0
Chest pain	144	0
Discomfort	21	0
Facial pain	19	0
Inflammatory pain	1	0
Pain	460	0
Tenderness	47	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	4	0
Adverse food reaction	1	0
Drug ineffective	9	0
Therapeutic response unexpected	4	0
Vaccination failure	1	0
<b><i>Ulcers NEC</i></b>		
Ulcer	1	0
<b><i>Vaccination site reactions</i></b>		
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	3	0
Vaccination site discolouration	1	0
Vaccination site erythema	19	0
Vaccination site hypoaesthesia	1	0
Vaccination site joint pain	3	0
Vaccination site mass	16	0
Vaccination site movement impairment	4	0
Vaccination site pain	64	0
Vaccination site pruritus	4	0
Vaccination site rash	4	0
Vaccination site scar	1	0
Vaccination site swelling	9	0
Vaccination site warmth	11	0
<b><i>Withdrawal and rebound effects</i></b>		
Withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>5786</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	1	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	1	0
Jaundice	1	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	1	0
<i><b>Hepatic vascular disorders</b></i>		
Hepatic vein thrombosis	1	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	5	0
Liver tenderness	1	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Hepatic necrosis	1	0
Hepatitis	1	0
Hepatitis acute	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

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### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
 Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
 MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	48	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Drug hypersensitivity	2	0
Food allergy	2	0
Reaction to excipient	1	0
Reaction to preservatives	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	17	0
Anaphylactic shock	3	0
<i>Atopic disorders</i>		
Seasonal allergy	4	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	4	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	3	0
<b>Immune system disorders SOC TOTAL</b>	<b>89</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis perforated	1	0
Diverticulitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Bacterial infection	3	0
Cellulitis	12	0
Pneumonia bacterial	1	0
Skin bacterial infection	1	0
<b><i>Bone and joint infections</i></b>		
Bursitis infective	1	0
<b><i>Borrelial infections</i></b>		
Lyme disease	1	0
<b><i>Campylobacter infections</i></b>		
Campylobacter gastroenteritis	1	0
<b><i>Candida infections</i></b>		
Candida infection	4	0
Oral candidiasis	2	0
Vulvovaginal candidiasis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Cavernous sinus thrombosis	1	0
Encephalitis	1	0
Encephalomyelitis	1	0
Meningitis	2	0
<b><i>Coronavirus infections</i></b>		
COVID-19	68	0
Suspected COVID-19	1	0
<b><i>Coxiella infections</i></b>		
Q fever	2	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	2	0
Parotitis	1	0
<b><i>Ear infections</i></b>		
Ear infection	2	0
Labyrinthitis	9	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	4	0
Eye infection	2	0
Retinitis	1	0
<b><i>Female reproductive tract infections</i></b>		
Ovarian abscess	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	1	0
<b><i>Herpes viral infections</i></b>		
Genital herpes	1	0
Herpes simplex	1	0
Herpes virus infection	2	0
Herpes zoster	30	0
Herpes zoster oticus	2	0
Ophthalmic herpes zoster	1	0
Oral herpes	11	0

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Varicella	3	0
<b><i>Infections NEC</i></b>		
Abscess	2	0
Infected bite	1	0
Infection	20	0
Injection site infection	2	0
Localised infection	3	0
Toxic shock syndrome	1	0
<b><i>Influenza viral infections</i></b>		
H1N1 influenza	1	0
Influenza	157	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	1	0
Lower respiratory tract infection	6	0
Pneumonia	8	0
<b><i>Plasmodia infections</i></b>		
Malaria	1	0
<b><i>Retroviral infections</i></b>		
HIV infection	1	0
<b><i>Salmonella infections</i></b>		
Typhoid fever	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	7	1
<b><i>Skin structures and soft tissue infections</i></b>		
Impetigo	1	0
Pustule	1	0
Rash pustular	1	0
Skin infection	3	0
<b><i>Streptococcal infections</i></b>		
Pharyngitis streptococcal	1	0
<b><i>Tinea infections</i></b>		
Tinea pedis	1	0
<b><i>Tuberculous infections</i></b>		
Pulmonary tuberculosis	1	0
Tuberculosis	2	0
<b><i>Upper respiratory tract infections</i></b>		
Laryngitis	3	0
Nasopharyngitis	55	0
Rhinitis	1	0
Sinusitis	5	0
Tonsillitis	3	0
<b><i>Urinary tract infections</i></b>		
Cystitis	3	0
Urinary tract infection	7	0
<b><i>Viral infections NEC</i></b>		
Encephalitis viral	1	0
Gastroenteritis viral	3	0
Meningitis viral	1	0
Sweating fever	13	0
Vestibular neuronitis	3	0
Viral infection	3	0
Viral rash	1	0

# Case Series Drug Analysis Print

## Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024

Data Lock Date: 23-May-2024 18:30:03

Earliest Reaction Date: 07-Feb-2018

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<b>Infections SOC TOTAL</b>	<b>505</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Cardiac and vascular procedural complications</i></b>		
Vascular access site bruising	1	0
<b><i>Cerebral injuries NEC</i></b>		
Brain herniation	1	0
Extradural haematoma	1	0
Subdural haemorrhage	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	4	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	3	0
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	28	0
Maternal exposure during pregnancy	6	0
<b><i>Eye injuries NEC</i></b>		
Eye contusion	3	0
Eye injury	1	0
Foreign body in eye	1	0
<b><i>Fractures and dislocations NEC</i></b>		
Joint dislocation	1	0
<b><i>Intentional product misuses</i></b>		
Intentional product misuse	11	0
<b><i>Intentional product use issues</i></b>		
Intentional product use issue	8	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	1	0
Femur fracture	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Wrong technique in product usage process	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Ligament injury	1	0
Ligament rupture	1	0
Ligament sprain	1	0
Muscle injury	2	0
Tendon injury	2	0
Tendon rupture	2	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	6	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Procedural dizziness	2	0
<b><i>Non-site specific injuries NEC</i></b>		
Animal bite	1	0
Electric shock	1	0
Fall	6	0
Inflammation of wound	1	0
Injury	1	0
Wound complication	1	0
<b><i>Non-site specific procedural complications</i></b>		
Infusion related reaction	1	0
Injection related reaction	6	0
Post procedural complication	1	0

## Case Series Drug Analysis Print

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Report Run Date: 24-May-2024  
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 MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Post procedural contusion	1	0
<b>Off label uses</b>		
Off label use	11	0
<b>Overdoses NEC</b>		
Intentional overdose	1	0
<b>Pathways and sources of exposure</b>		
Exposure via body fluid	1	0
<b>Product administration errors and issues</b>		
Contraindicated product administered	1	0
Expired product administered	2	0
Inappropriate schedule of product administration	4	0
Incomplete course of vaccination	1	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
Product dose omission issue	1	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	1	0
<b>Product prescribing errors and issues</b>		
Product prescribing error	1	0
<b>Radiation injuries</b>		
Sunburn	1	0
<b>Site specific injuries NEC</b>		
Head injury	1	0
Limb injury	7	0
<b>Skin injuries NEC</b>		
Contusion	105	0
Scar	1	0
<b>Thermal burns</b>		
Thermal burns of eye	1	0
<b>Vaccination related complications</b>		
Immunisation reaction	3	0
<b>Injuries SOC TOTAL</b>	<b>260</b>	<b>0</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Auditory and vestibular diagnostic procedures</b></i>		
Acoustic stimulation tests	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Blood pH increased	1	0
Carbon dioxide increased	1	0
Oxygen saturation decreased	3	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose	1	0
Blood glucose fluctuation	2	0
Blood glucose increased	11	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
Heart sounds	1	0
<i><b>Central nervous system imaging procedures</b></i>		
Computerised tomogram head	2	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF pressure	2	0
<i><b>Coagulation and bleeding analyses</b></i>		
Activated partial thromboplastin time prolonged	2	0
Coagulation factor VIII level decreased	1	0
Coagulation time	1	0
Fibrin D dimer	1	0
International normalised ratio increased	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram	1	0
<i><b>Endocrine analyses and imaging NEC</b></i>		
Hormone level abnormal	4	0
<i><b>Faecal analyses NEC</b></i>		
Faecal calprotectin increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	26	0
Heart rate abnormal	1	0
Heart rate decreased	5	0
Heart rate increased	49	0
Heart rate irregular	7	0
Maximum heart rate	1	0
Pulse abnormal	1	0
<i><b>Hepatobiliary function diagnostic procedures</b></i>		
Liver function test abnormal	1	0
Transaminases increased	1	0
<i><b>Immunoglobulin analyses</b></i>		
Blood immunoglobulin E	1	0
<i><b>Immunology skin tests NEC</b></i>		
Allergy alert test	1	0
Skin test positive	1	0
<i><b>Investigations NEC</b></i>		
Blood test	3	0
Blood test abnormal	1	0
Laboratory test	1	0
<i><b>Metabolism tests NEC</b></i>		
Blood ketone body	1	0
N-terminal prohormone brain natriuretic peptide increased	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Mineral and electrolyte analyses</i></b>		
Blood calcium decreased	1	0
Blood iron decreased	2	0
Blood iron increased	1	0
Blood phosphorus decreased	1	0
Blood potassium decreased	1	0
Blood sodium decreased	1	0
Serum ferritin	1	0
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Skull X-ray	2	0
X-ray limb abnormal	1	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Muscle mass percentage	1	0
Tender joint count	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	1	0
Lumbar puncture	2	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Visual tracking test	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	17	0
Body temperature abnormal	2	0
Body temperature decreased	1	0
Body temperature fluctuation	5	0
Body temperature increased	37	0
Grip strength	2	0
Grip strength decreased	2	0
Menstruation normal	1	0
Respiratory rate decreased	2	0
Respiratory rate increased	4	0
Skin temperature	3	0
Weight decreased	6	0
Weight increased	2	0
<b><i>Pituitary analyses anterior</i></b>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	1	0
<b><i>Platelet analyses</i></b>		
Platelet count decreased	7	0
Platelet count increased	1	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	3	0
<b><i>Red blood cell analyses</i></b>		
Haemoglobin	1	0
Haemoglobin decreased	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Pulmonary function test decreased	1	0
Slow vital capacity	1	0
Total lung capacity decreased	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine	1	0
Blood urine present	1	0
Glucose urine	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure decreased	1	0
Blood pressure increased	7	0
Blood pressure measurement	1	0
<b><i>Virus identification and serology</i></b>		
SARS-CoV-2 antibody test	1	0
SARS-CoV-2 test positive	1	0
Viral test	1	0
<b><i>Vitamin analyses</i></b>		
Vitamin B12 increased	1	0
<b><i>White blood cell analyses</i></b>		
Eosinophil count increased	1	0
Neutrophil count decreased	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>279</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	5	0
Decreased appetite	115	0
Food craving	1	0
Hypophagia	1	0
Increased appetite	3	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus inadequate control	2	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	3	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	2	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Histamine intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	1	0
Abnormal weight gain	2	0
Feeding disorder	5	0
Food aversion	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Iron deficiencies</b></i>		
Iron deficiency	1	0
<i><b>Potassium imbalance</b></i>		
Hypokalaemic syndrome	2	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	29	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	1	0
<i><b>Vitamin deficiencies NEC</b></i>		
Hypovitaminosis	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>181</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	14	0
Arthropathy	1	0
Autoimmune arthritis	1	0
Haemarthrosis	1	0
Polyarthritits	1	0
Rheumatic fever	1	0
<i><b>Bone disorders NEC</b></i>		
Medial tibial stress syndrome	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	18	0
Bone swelling	1	0
Coccydynia	1	0
Pain in jaw	20	0
Spinal pain	4	0
<i><b>Bursal disorders</b></i>		
Bursitis	6	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	3	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	2	0
Eosinophilic fasciitis	1	0
Polymyalgia rheumatica	1	0
Sjogren's syndrome	1	0
<i><b>Joint related disorders NEC</b></i>		
Ligament laxity	1	0
Periarthritis	21	0
Rotator cuff syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	559	0
Joint stiffness	9	0
Joint swelling	16	0
Joint vibration	1	0
<i><b>Metabolic bone disorders</b></i>		
Osteoporosis	2	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	10	0
Myalgia	585	0
Myofascial pain syndrome	1	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle discomfort	1	0
Muscle fatigue	29	0
Muscle spasms	86	0
Muscle swelling	1	0
Muscle tightness	7	0
Muscle twitching	33	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	54	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Limb mass	2	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Mobility decreased	4	0
Musculoskeletal stiffness	70	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	1	0
Head deformity	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	114	0
Limb discomfort	71	0
Musculoskeletal chest pain	3	0
Musculoskeletal discomfort	4	0
Musculoskeletal pain	5	0
Neck pain	75	0
Pain in extremity	585	0
Rheumatic disorder	1	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	3	0
Spinal osteoarthritis	1	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	5	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	2	0
Groin pain	5	0
Neck mass	2	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	1	0
Spondylitis	1	0
<b><i>Tendon disorders</i></b>		
Tendon discomfort	1	0
Tendon pain	2	0
Tendonitis	5	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>2460</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
Breast cancer stage III	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma	1	0
Neoplasm malignant	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Schwannoma	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	1	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	1	0
<i>Skin neoplasms benign</i>		
Skin papilloma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>11</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	9	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	1	0
Carotid artery occlusion	10	0
Cerebral haemorrhage	5	0
Cerebral infarction	1	0
Cerebrovascular accident	35	0
Haemorrhage intracranial	2	0
Ischaemic stroke	2	0
Subarachnoid haemorrhage	14	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	1
Cerebral venous thrombosis	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
Demyelinating polyneuropathy	1	0
<i>Coma states</i>		
Coma	2	0
<i>Coordination and balance disturbances</i>		
Balance disorder	25	0
Coordination abnormal	7	0
Dysstasia	4	0
Hand-eye coordination impaired	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	5	0
Dysgraphia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	3	0
Lethargy	105	0
Loss of consciousness	29	0
Somnolence	42	0
Syncope	63	0
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Clumsiness	2	0
Dyskinesia	2	0
Hyperkinesia	3	0
Hypokinesia	3	0
Movement disorder	5	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	13	0
Facial paralysis	8	0
Facial paresis	8	0
Facial spasm	3	0
<i>Generalised tonic-clonic seizures</i>		

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Generalised tonic-clonic seizure	7	0
<b>Headaches NEC</b>		
Cluster headache	19	0
Cold-stimulus headache	1	0
Headache	1913	0
Medication overuse headache	1	0
Menstrual headache	1	0
New daily persistent headache	1	0
Occipital neuralgia	2	0
Primary stabbing headache	5	0
Sinus headache	24	0
Tension headache	43	0
Thunderclap headache	2	0
Vascular headache	4	0
<b>Increased intracranial pressure disorders</b>		
Brain oedema	1	0
Intracranial pressure increased	1	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	7	0
<b>Memory loss (excl dementia)</b>		
Amnesia	20	0
Memory impairment	20	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	13	0
Disturbance in attention	24	0
Judgement impaired	1	0
Mental impairment	1	0
<b>Migraine headaches</b>		
Hemiplegic migraine	2	0
Migraine	197	0
Migraine with aura	11	0
Migraine without aura	1	0
Retinal migraine	2	0
Typical aura without headache	1	0
Vestibular migraine	2	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	3	0
Nerve compression	1	0
Peroneal nerve palsy	2	0
<b>Motor neurone diseases</b>		
Lower motor neurone lesion	1	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis	1	0
Multiple sclerosis relapse	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	2	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	5	0
<b>Nervous system disorders NEC</b>		
Brain stem syndrome	1	0
Central nervous system lesion	1	0
Nervous system disorder	2	0

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b>Neurological signs and symptoms NEC</b>		
Brain fog	31	0
Dizziness	584	0
Dizziness postural	49	0
Drooling	2	0
Head discomfort	20	0
Myoclonus	2	0
Neurological symptom	3	0
Presyncope	22	0
Tongue biting	1	0
Unresponsive to stimuli	2	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	19	0
Parosmia	18	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	31	0
Formication	6	0
Hemiparaesthesia	1	0
Hyperaesthesia	1	0
Hypoaesthesia	180	0
Paraesthesia	287	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	2	0
Hemiplegia	1	0
Monoparesis	3	0
Monoplegia	3	0
Paralysis	10	0
<b>Partial simple seizures NEC</b>		
Simple partial seizures	2	0
<b>Peripheral neuropathies NEC</b>		
Neuropathy peripheral	4	0
Peripheral sensory neuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	13	0
Febrile convulsion	1	0
Myoclonic epilepsy	1	0
Partial seizures	1	0
Seizure	31	0
Seizure like phenomena	1	0
Tonic convulsion	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	20	0
Dysgeusia	66	0
Electric shock sensation	5	0
Hypogeusia	1	0
Neuralgia	24	0
Restless arm syndrome	1	0

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
 Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
 MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Restless legs syndrome	10	0
Sensory disturbance	5	0
Sensory loss	7	0
Taste disorder	9	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	2	0
<b>Speech and language abnormalities</b>		
Dysarthria	8	0
Incoherent	1	0
Repetitive speech	1	0
Slow speech	2	0
Speech disorder	4	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	1	0
Subacute combined cord degeneration	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	2	0
Cerebral mass effect	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	14	0
<b>Tremor (excl congenital)</b>		
Head titubation	1	0
Tremor	165	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	5	0
<b>Vagus nerve disorders</b>		
Vocal cord paralysis	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>4464</b>	<b>1</b>

# Case Series Drug Analysis Print

## Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024

Data Lock Date: 23-May-2024 18:30:03

Earliest Reaction Date: 07-Feb-2018

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>4</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024

Data Lock Date: 23-May-2024 18:30:03

Earliest Reaction Date: 07-Feb-2018

MedDRA Version: MedDRA 27.0

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device malfunction events NEC</i>		
Oversensing	1	0
<i>Product physical issues</i>		
Product after taste	1	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	1	0
<b><i>Affect alterations NEC</i></b>		
Constricted affect	1	0
Flat affect	1	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	4	0
Anxiety	32	0
Nervousness	10	0
Stress	4	0
Tension	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Paranoia	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	17	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	44	0
Disorientation	17	0
<b><i>Deliria</i></b>		
Delirium	11	0
<b><i>Delusional symptoms</i></b>		
Delusion	2	0
<b><i>Depressive disorders</i></b>		
Depression	20	0
Depression suicidal	1	0
<b><i>Dissociative states</i></b>		
Dissociation	4	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	79	0
Middle insomnia	2	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	21	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	2	0
Emotional disorder	2	0
Emotional distress	5	0
Euphoric mood	4	0
Irritability	8	0
Mood altered	3	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	8	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	23	0
Hallucination, olfactory	1	0
Hallucination, visual	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	16	0
<b><i>Mood alterations with depressive symptoms</i></b>		

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Decreased interest	1	0
Depressed mood	16	0
Tearfulness	3	0
<b>Mood disorders NEC</b>		
Listless	2	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Body dysmorphic disorder	1	0
Compulsive shopping	1	0
<b>Orgasmic disorders and disturbances</b>		
Orgasmic sensation decreased	1	0
<b>Panic attacks and disorders</b>		
Panic attack	6	0
Panic reaction	2	0
<b>Parasomnias</b>		
Abnormal dreams	5	0
Nightmare	14	0
Sleep terror	9	0
Sleep-related eating disorder	1	0
Somnambulism	1	0
<b>Perception disturbances NEC</b>		
Autoscopy	1	0
Derealisation	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	2	0
<b>Psychiatric symptoms NEC</b>		
Hypervigilance	1	0
Psychological trauma	1	0
<b>Psychotic disorder NEC</b>		
Psychotic disorder	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	2	0
<b>Sexual desire disorders</b>		
Libido decreased	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	12	0
<b>Somatic symptom disorders</b>		
Conversion disorder	1	0
Habit cough	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	1	0
<b>Stereotypies and automatisms</b>		
Head banging	1	0
<b>Substance related and addictive disorders</b>		
Drug abuse	1	0
<b>Suicidal and self-injurious behaviour</b>		
Suicidal ideation	2	0
Suicide attempt	1	0
<b>Thinking disturbances</b>		
Bradyphrenia	2	0
Impaired reasoning	1	0
Tachyphrenia	1	0
Thinking abnormal	1	0

# Case Series Drug Analysis Print

## Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024

Data Lock Date: 23-May-2024 18:30:03

Earliest Reaction Date: 07-Feb-2018

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
Thought blocking	1	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>450</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder pain	3	0
Dysuria	3	0
Incontinence	2	0
Micturition urgency	2	0
Pollakiuria	9	0
Urethral pain	1	0
Urinary incontinence	1	0
Urinary retention	3	0
Urine flow decreased	1	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	1	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Urinary tract disorder	1	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	1	0
Hypertonic bladder	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	1	0
Anuria	1	0
Oliguria	1	0
<i><b>Renal lithiasis</b></i>		
Nephrolithiasis	1	0
<i><b>Urinary abnormalities</b></i>		
Urine odour abnormal	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Polyuria	1	0
Renal pain	17	0
Urinary tract pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>54</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	13	0
Breast swelling	2	0
Breast tenderness	3	0
<i><b>Cervix neoplasms</b></i>		
Cervical polyp	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	3	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal disorder	1	0
Menopausal symptoms	3	0
Premature menopause	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	8	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	18	0
Intermenstrual bleeding	17	0
Menstrual disorder	32	0
Menstruation irregular	46	0
Premenstrual syndrome	3	0
Withdrawal bleed	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	12	0
Hypomenorrhoea	12	0
Menstruation delayed	47	0
Oligomenorrhoea	3	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	79	0
Polymenorrhoea	9	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	3	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	2	0
<i><b>Prostatic neoplasms and hypertrophy</b></i>		
Benign prostatic hyperplasia	1	0
<i><b>Prostatic signs, symptoms and disorders NEC</b></i>		
Prostatomegaly	1	0
<i><b>Reproductive tract disorders NEC (excl neoplasms)</b></i>		
Genital haemorrhage	1	0
Genital lesion	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
Pruritus genital	10	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal pain	1	0
<i><b>Sexual function and fertility disorders NEC</b></i>		
Infertility	1	0
<i><b>Uterine disorders NEC</b></i>		
Endometriosis	1	0
Uterine haemorrhage	3	0
Uterine pain	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
 Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
 MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
Vaginal haemorrhage	28	0
Vulval haemorrhage	1	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Vaginal discharge	3	0
Vulvovaginal burning sensation	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>377</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	201	0
Dyspnoea at rest	1	0
Dyspnoea exertional	2	0
Hyperventilation	3	0
Hypopnoea	2	0
Irregular breathing	1	0
Respiration abnormal	4	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	12	0
Asthma exercise induced	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	16	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypercapnia	1	0
Hypoxia	3	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	1	0
Cough	96	0
Haemoptysis	4	0
Productive cough	3	0
Sputum discoloured	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Hypersensitivity pneumonitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	2	0
Pulmonary pain	3	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	10	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	44	0
Nasal crusting	1	0
Nasal septum deviation	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	4	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Interstitial lung disease	2	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal swelling	10	0
Pharyngeal ulceration	1	0
Tonsillar hypertrophy	2	0
Tonsillar ulcer	1	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	24	1
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	2	1

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
 Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
 MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Respiratory signs and symptoms NEC</i></b>		
Allergic respiratory symptom	1	0
Diaphragmalgia	3	0
<b><i>Respiratory tract disorders NEC</i></b>		
Lung disorder	1	0
Respiratory disorder	1	0
Respiratory tract irritation	2	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	3	0
Dry throat	11	0
Dysphonia	5	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	2	0
Oropharyngeal blistering	3	0
Oropharyngeal pain	87	0
Paranasal sinus discomfort	4	0
Rhinalgia	2	0
Rhinorrhoea	43	0
Sinus pain	18	0
Sneezing	16	0
Throat irritation	8	0
Throat tightness	7	0
Upper-airway cough syndrome	2	0
Yawning	3	0
<b>Respiratory disorders SOC TOTAL</b>	<b>688</b>	<b>2</b>

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Acnes</b></i>		
Acne	3	0
Acne cystic	1	0
<i><b>Alopecias</b></i>		
Alopecia	25	0
Alopecia areata	2	0
Lichen planopilaris	1	0
<i><b>Angioedemas</b></i>		
Angioedema	20	0
Circumoral oedema	1	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	37	0
Hyperhidrosis	220	0
Miliaria	7	0
Night sweats	44	0
<i><b>Bullous conditions</b></i>		
Blister	16	0
Blood blister	3	0
Dermatitis bullous	2	0
Dermatitis herpetiformis	1	0
Erythema multiforme	3	0
Pemphigoid	2	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	20	0
Pain of skin	37	0
Papule	6	0
Scab	1	0
Scar discomfort	1	0
Scar pain	1	0
Sensitive skin	21	0
Skin burning sensation	17	0
Skin discolouration	10	0
Skin disorder	2	0
Skin induration	1	0
Skin lesion	2	0
Skin plaque	1	0
Skin reaction	5	0
Skin sensitisation	1	0
Skin swelling	2	0
Skin warm	11	0
Skin weeping	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	1	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	4	0
Dermatitis allergic	8	0
Dermatitis atopic	4	0
Dermatitis contact	4	0
Eczema	7	0
Eczema asteatotic	1	0
Intertrigo	1	0

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024  
Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Seborrhoeic dermatitis	1	0
Skin irritation	3	0
Stasis dermatitis	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	96	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	5	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Granuloma annulare	1	0
<b><i>Hyperkeratoses</i></b>		
Palmoplantar keratoderma	10	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail disorder	1	0
Nail ridging	1	0
Splinter haemorrhages	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	1	0
Parapsoriasis	1	0
Pityriasis rosea	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	3	0
Polymorphic light eruption	1	0
<b><i>Pilar disorders NEC</i></b>		
Hair colour changes	1	0
Hair texture abnormal	2	0
Piloerection	2	0
Trichodynia	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	253	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	6	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	8	0
Purpura	3	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	241	0
Rash erythematous	84	0
Rash macular	28	0
Rash morbilliform	1	0
Rash papular	25	0
Rash pruritic	55	0
Rash vesicular	5	0
<b><i>Rosaceas</i></b>		
Rosacea	2	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin ulcer	2	0

## Case Series Drug Analysis Print

### Name: FOI 2024/00093 COVID-19 Vaccine AstraZeneca (Batch 4120Z002) Vaccine Analysis Print

Report Run Date: 24-May-2024

Data Lock Date: 23-May-2024 18:30:03

Earliest Reaction Date: 07-Feb-2018

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<i><b>Skin haemorrhages</b></i>		
Haemorrhage subcutaneous	2	0
<i><b>Skin vascular conditions NEC</b></i>		
Angiodermatitis	1	0
<i><b>Skin vasculitides</b></i>		
Hypersensitivity vasculitis	1	0
<i><b>Urticarias</b></i>		
Idiopathic urticaria	1	0
Urticaria	72	0
Urticaria chronic	3	0
Urticaria contact	1	0
<b>Skin disorders SOC TOTAL</b>	<b>1490</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 24-May-2024  
 Earliest Reaction Date: 07-Feb-2018

Data Lock Date: 23-May-2024 18:30:03  
 MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menopause	2	0
<i>Disability issues</i>		
Bedridden	1	0
Immobile	1	0
Immobilisation prolonged	1	0
Impaired work ability	2	0
Physical disability	1	0
Sight disability	2	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	1	0
<i>Social issues NEC</i>		
Blood donor	1	0
Tattoo	1	0
Unhealthy lifestyle	1	0
<i>Tobacco use</i>		
Tobacco user	1	0
<b>Social circumstances SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Data Lock Date: 23-May-2024 18:30:03  
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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
<i>External ear therapeutic procedures</i>		
Cerumen removal	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	1	0
<i>Immunisations</i>		
COVID-19 immunisation	2	0
Immunisation	8	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
Limb operation	1	0
<i>Therapeutic procedures NEC</i>		
Catheter management	1	0
Interchange of vaccine products	3	0
Tumour excision	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	3	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>25</b>	<b>0</b>

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MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Aortic aneurysms and dissections</i></b>		
Aortic intramural haematoma	1	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	1	0
<b><i>Arterial infections and inflammations</i></b>		
Giant cell arteritis	1	0
<b><i>Bruising, ecchymosis and purpura</i></b>		
Achenbach syndrome	1	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	2	0
<b><i>Haemorrhages NEC</i></b>		
Haematoma	5	0
Haemorrhage	38	0
Internal haemorrhage	1	0
<b><i>Lymphangiopathies</i></b>		
Lymphorrhoea	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	1	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Embolism	2	0
Thrombosis	46	0
Venous thrombosis	1	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Ischaemia	1	0
Peripheral venous disease	3	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Vascular pain	5	0
Vasodilatation	6	0
Vein disorder	1	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Blue toe syndrome	4	0
Deep vein thrombosis	25	0
Superficial vein thrombosis	1	0
Thrombophlebitis	1	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	8	0
Flushing	23	0
Hot flush	63	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
Peripheral coldness	36	0
Peripheral ischaemia	1	1
Poor peripheral circulation	3	0
Raynaud's phenomenon	6	0
<b><i>Phlebitis NEC</i></b>		
Phlebitis	3	0
<b><i>Site specific vascular disorders NEC</i></b>		
Pallor	10	0
<b><i>Varicose veins NEC</i></b>		
Spider vein	2	0
Varicophlebitis	1	0
Varicose vein	4	0
<b><i>Vascular hypertensive disorders NEC</i></b>		

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Earliest Reaction Date: 07-Feb-2018

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Diastolic hypertension	1	0
Hypertension	29	0
White coat hypertension	3	0
<b>Vascular hypotensive disorders</b>		
Hypotension	12	0
<b>Vasculitides NEC</b>		
Vasculitis	12	0
<b>Vascular disorders SOC TOTAL</b>	<b>365</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>20650</b>	<b>13</b>
<b>TOTAL REPORTS</b>	<b>5372</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>13</b>