

## COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021  
Data Lock Date: 10-Feb-2021 19:00:04

All UK spontaneous reports received between 4/01/21 and 31/01/21 for  
COVID-19 vaccine Oxford University/AstraZeneca

## Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 05-Jan-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Haematological disorders</b></i>		
Bone marrow oedema	1	0
<i><b>Leukopenias NEC</b></i>		
Leukopenia	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	18	0
Lymphadenitis	3	0
Lymphadenopathy	171	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Pancytopenia	1	0
<i><b>Neutropenias</b></i>		
Neutropenia	6	0
<i><b>Thrombocytopenias</b></i>		
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>202</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	1	1
Cardiac disorder	1	0
Cardiovascular insufficiency	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	1	0
Palpitations	214	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Angina pectoris	6	0
Myocardial infarction	5	2
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	1	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	2	0
Bradycardia	7	0
Cardiac flutter	5	0
Extrasystoles	2	0
Tachyarrhythmia	1	0
Tachycardia	141	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	1	0
Sinus tachycardia	6	0
Supraventricular tachycardia	2	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	6	3
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>406</b>	<b>6</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	5	0
Ear pain	88	0
Ear swelling	4	0
<i>Hearing losses</i>		
Deafness	5	0
Deafness transitory	1	0
Deafness unilateral	1	0
Hypoacusis	5	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	6	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	3	0
Tinnitus	40	0
Vertigo	41	0
Vertigo positional	3	0
<b>Ear disorders SOC TOTAL</b>	<b>203</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Endocrine disorders</b>		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	2	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	1	0
<i><b>Eyelid movement disorders</b></i>		
Eyelid ptosis	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	11	0
Lacrimation increased	10	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Erythema of eyelid	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye pain	191	0
Eye swelling	27	0
Ocular discomfort	1	0
Periorbital oedema	1	0
Periorbital swelling	6	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	1	0
Eye irritation	9	0
Eye pruritus	11	0
Ocular hyperaemia	11	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	3	0
<i><b>Ocular sensation disorders</b></i>		
Abnormal sensation in eye	1	0
Asthenopia	7	0
Foreign body sensation in eyes	2	0
Photophobia	59	0
<i><b>Pupil disorders</b></i>		
Miosis	1	0
Mydriasis	1	0
Pupils unequal	2	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Vitreoretinal traction syndrome	1	0
<i><b>Scleral infections, irritations and inflammations</b></i>		
Episcleritis	1	0
<i><b>Visual colour distortions</b></i>		
Chromatopsia	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	7	0
Metamorphopsia	1	0
Photopsia	6	0
Vision blurred	53	0
Visual snow syndrome	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	8	0
Blindness transient	2	0
Visual acuity reduced	1	0
Visual impairment	15	0
<b>Eye disorders SOC TOTAL</b>	<b>456</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	2	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ischaemic	1	0
Colitis ulcerative	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	1	0
Toothache	7	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	479	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	26	0
Epigastric discomfort	1	0
Eructation	2	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	1	0
Faeces discoloured	1	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	6	0
Flatulence	16	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
<i>Gastritis (excl infective)</i>		
Gastritis	4	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	235	0
Abdominal pain lower	6	0
Abdominal pain upper	218	0
Abdominal rigidity	4	0
Abdominal tenderness	1	0
Gastrointestinal pain	21	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	8	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	8	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	3	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	64	0
Acute abdomen	1	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Anal incontinence	1	0
Dysphagia	8	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	2	0
Irritable bowel syndrome	4	0
Oesophageal spasm	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	2	0
Gingival oedema	1	0
Gingival pain	10	0
Gingival pruritus	1	0
Gingival swelling	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	3	0
<b><i>Intestinal haemorrhages</i></b>		
Rectal haemorrhage	3	0
Small intestinal haemorrhage	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	1	0
Nausea	2320	0
Retching	14	0
Vomiting	862	0
Vomiting projectile	7	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematemesis	1	0
Haematochezia	4	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	61	0
Lip dry	3	0
Salivary hypersecretion	3	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Cheilitis	1	0
Lip blister	1	0
Lip disorder	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	26	0
Lip pain	5	0
Lip pruritus	1	0
Oral discomfort	4	0
Oral mucosal blistering	1	0
Oral pain	13	0
Oral pruritus	2	0
Paraesthesia oral	51	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	54	0
Mouth swelling	7	0
Palatal swelling	1	0
<b><i>Salivary gland disorders NEC</i></b>		
Salivary gland pain	2	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	3	0
Mouth ulceration	17	0
Stomatitis	2	0



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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
<i><b>Tongue disorders</b></i>		
Plicated tongue	1	0
<i><b>Tongue signs and symptoms</b></i>		
Glossodynia	9	0
Scalloped tongue	1	0
Swollen tongue	28	0
Tongue blistering	2	0
Tongue discolouration	1	0
Tongue discomfort	1	0
Tongue dry	1	0
Tongue pruritus	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>4683</b>	<b>1</b>

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<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	1	0
Administration site pain	1	0
Administration site urticaria	1	0
Puncture site bruise	1	0
Puncture site pain	1	0
Puncture site reaction	1	0
<b><i>Adverse effect absent</i></b>		
No adverse event	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site bruise	1	0
Application site erythema	2	0
Application site pain	1	0
<b><i>Asthenic conditions</i></b>		
Asthenia	264	1
Chronic fatigue syndrome	1	0
Fatigue	2658	0
Malaise	647	2
Sluggishness	1	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	1	0
Hypothermia	5	0
Temperature regulation disorder	2	0
<b><i>Death and sudden death</i></b>		
Death	56	56
Sudden death	6	6
<b><i>Febrile disorders</i></b>		
Hyperpyrexia	8	0
Masked fever	1	0
Pyrexia	4562	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	2971	0
Feeling abnormal	117	0
Feeling cold	314	0
Feeling drunk	3	0
Feeling hot	121	0
Feeling jittery	1	0
Feeling of body temperature change	86	0
Hangover	1	0
Hunger	3	0
Sensation of foreign body	5	0
Temperature intolerance	3	0
Thirst	82	0
<b><i>Fibrosis NEC</i></b>		
Fibrosis	1	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	14	0
Gait inability	10	0
Loss of control of legs	4	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	2	0
Crying	3	0
Energy increased	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
General physical health deterioration	4	0
Illness	321	0
Influenza like illness	579	0
Local reaction	18	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	243	0
Secretion discharge	2	0
Swelling	121	0
Swelling face	39	0
<b>Implant and catheter site reactions</b>		
Implant site warmth	1	0
<b>Inflamations</b>		
Inflammation	17	0
<b>Infusion site reactions</b>		
Infusion site pain	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	2	0
Injection site bruising	1	0
Injection site erythema	36	0
Injection site hypoaesthesia	2	0
Injection site inflammation	7	0
Injection site joint pain	4	0
Injection site mass	78	0
Injection site oedema	5	0
Injection site pain	269	0
Injection site papule	1	0
Injection site paraesthesia	1	0
Injection site pruritus	22	0
Injection site rash	15	0
Injection site reaction	10	0
Injection site swelling	15	0
Injection site warmth	25	0
<b>Interactions</b>		
Drug interaction	1	0
<b>Mass conditions NEC</b>		
Mass	1	0
<b>Mucosal findings abnormal</b>		
Mucosal pain	1	0
<b>Oedema NEC</b>		
Face oedema	1	0
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	5	0
<b>Pain and discomfort NEC</b>		
Axillary pain	23	0
Chest discomfort	116	0
Chest pain	200	0
Discomfort	12	0
Facial discomfort	1	0
Facial pain	10	0
Inflammatory pain	1	0
Non-cardiac chest pain	1	0
Pain	1077	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Tenderness	93	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	56	0
Adverse event	1	0
Adverse reaction	3	0
Drug ineffective	2	0
No reaction on previous exposure to drug	5	0
Therapeutic response unexpected	1	0
<b><i>Vaccination site reactions</i></b>		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	4	0
Vaccination site discomfort	2	0
Vaccination site erythema	31	0
Vaccination site induration	4	0
Vaccination site inflammation	3	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	6	0
Vaccination site joint swelling	1	0
Vaccination site mass	26	0
Vaccination site pain	100	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	6	0
Vaccination site rash	5	0
Vaccination site swelling	20	0
Vaccination site vesicles	1	0
Vaccination site warmth	13	0
<b>General disorders SOC TOTAL</b>	<b>15644</b>	<b>65</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	39	0
Serum sickness	3	0
Serum sickness-like reaction	3	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	4	0
Drug hypersensitivity	5	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	28	0
Anaphylactoid reaction	2	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	2	0
Immune system disorder	1	0
Sensitisation	1	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>90</b>	<b>0</b>

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<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Gastroenteritis	1	0
<b><i>Bacterial infections NEC</i></b>		
Administration site cellulitis	1	0
Cellulitis	35	1
Vaccination site cellulitis	3	0
<b><i>Breast infections</i></b>		
Mastitis	2	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	1	0
<b><i>Coronavirus infections</i></b>		
COVID-19	40	2
Suspected COVID-19	2	0
<b><i>Coxiella infections</i></b>		
Q fever	8	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	1	0
Gingival abscess	1	0
Gingivitis	1	0
Oral pustule	1	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
Labyrinthitis	3	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	2	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	3	0
Eye infection	1	0
Eyelid infection	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	1	0
<b><i>Herpes viral infections</i></b>		
Herpes simplex	2	0
Herpes zoster	16	0
Oral herpes	25	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Abscess limb	1	0
Infection	11	1
Injection site infection	1	0
Localised infection	4	0
Vaccination site infection	2	0
<b><i>Influenza viral infections</i></b>		
H2N2 influenza	1	0
Influenza	357	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	6	1
Pneumonia	4	2
<b><i>Pneumocystis infections</i></b>		
Pneumocystis jirovecii pneumonia	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	6	0
Urosepsis	2	1

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<b>Infections</b>		
Infections cont'd		
<b><i>Skin structures and soft tissue infections</i></b>		
Skin infection	2	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	1	0
Staphylococcal scalded skin syndrome	1	0
<b><i>Tuberculous infections</i></b>		
Tuberculosis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	1	0
Nasopharyngitis	61	0
Rhinitis	2	0
Sinusitis	6	0
Tonsillitis	4	0
<b><i>Urinary tract infections</i></b>		
Cystitis	1	0
Kidney infection	1	0
Urinary tract infection	4	0
<b><i>Vascular infections</i></b>		
Infected lymphocele	1	0
<b><i>Viral infections NEC</i></b>		
Gastroenteritis viral	4	0
Post viral fatigue syndrome	2	0
Sweating fever	51	0
Viral pharyngitis	1	0
Viral rash	2	0
<b>Infections SOC TOTAL</b>	<b>695</b>	<b>8</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Atmospheric pressure injuries</b></i>		
Barotrauma	1	0
<i><b>Conditions caused by cold</b></i>		
Chillblains	2	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	2	0
Maternal exposure during pregnancy	10	0
Maternal exposure timing unspecified	1	0
<i><b>Exposures to agents or circumstances NEC</b></i>		
Exposure to SARS-CoV-2	1	0
<i><b>Gastrointestinal and hepatobiliary procedural complications</b></i>		
Procedural nausea	2	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Device use issue	1	0
Medication error	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	2	0
<i><b>Non-site specific injuries NEC</b></i>		
Electric shock	1	0
Fall	8	0
<i><b>Non-site specific procedural complications</b></i>		
Infusion related reaction	1	0
Injection related reaction	33	0
Post procedural complication	4	0
<i><b>Product administration errors and issues</b></i>		
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	29	0
<i><b>Thermal burns</b></i>		
Thermal burns of eye	2	0
<i><b>Underdoses NEC</b></i>		
Intentional underdose	1	0
<i><b>Vaccination related complications</b></i>		
Vaccination complication	7	0
<b>Injuries SOC TOTAL</b>	<b>112</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Adrenal cortex tests</b></i>		
Cortisol increased	1	0
<i><b>Autoimmunity analyses</b></i>		
Cold agglutinins positive	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation	6	0
Oxygen saturation decreased	13	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	1	0
Blood glucose fluctuation	1	0
Blood glucose increased	3	0
Glycosylated haemoglobin increased	1	0
<i><b>Central nervous system imaging procedures</b></i>		
Magnetic resonance imaging brain	5	0
<i><b>Coagulation and bleeding analyses</b></i>		
International normalised ratio decreased	2	0
International normalised ratio increased	3	0
<i><b>Gastrointestinal function diagnostic procedures</b></i>		
Gastrointestinal stoma output increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	41	0
Heart rate decreased	4	0
Heart rate increased	101	0
Heart rate irregular	8	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	1	0
<i><b>Immunology skin tests NEC</b></i>		
Allergy alert test	1	0
<i><b>Metabolism tests NEC</b></i>		
Blood ketone body	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	92	0
Body temperature abnormal	10	0
Body temperature decreased	13	0
Body temperature fluctuation	17	0
Body temperature increased	102	0
Breath sounds abnormal	1	0
Grip strength decreased	2	0
Respiratory rate decreased	1	0
Respiratory rate increased	6	0
Skin temperature	18	0
Weight decreased	4	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	1	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Forced expiratory volume	1	0
Peak expiratory flow rate	1	0
<i><b>Therapeutic drug monitoring analyses</b></i>		
Analgesic drug level	3	0
<i><b>Urinalysis NEC</b></i>		
Cells in urine	1	0
<i><b>Urinary tract function analyses NEC</b></i>		

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 05-Jan-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Urine output	4	0
Urine output decreased	2	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure decreased	3	0
Blood pressure increased	12	0
<b><i>Virus identification and serology</i></b>		
SARS-CoV-2 test	2	0
SARS-CoV-2 test negative	1	0
SARS-CoV-2 test positive	7	0
<b>Investigations SOC TOTAL</b>	<b>501</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021  
 Earliest Reaction Date: 05-Jan-2020

Data Lock Date: 10-Feb-2021 19:00:04  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	430	0
Food refusal	1	0
Hypophagia	2	0
Increased appetite	3	0
Salt craving	1	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	1	1
<i><b>Disorders of purine metabolism</b></i>		
Gout	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	6	0
Food aversion	3	0
Starvation	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	4	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	4	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Ketosis	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	32	0
<b>Metabolic disorders SOC TOTAL</b>	<b>491</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021  
Earliest Reaction Date: 05-Jan-2020

Data Lock Date: 10-Feb-2021 19:00:04  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	6	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	65	0
Pain in jaw	26	0
Spinal pain	12	0
<i><b>Connective tissue disorders NEC</b></i>		
Polymyalgia rheumatica	1	0
<i><b>Extremity deformities</b></i>		
Hand deformity	1	0
<i><b>Joint related disorders NEC</b></i>		
Joint lock	3	0
Patellofemoral pain syndrome	1	0
Periarthritis	2	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	1281	0
Joint noise	2	0
Joint stiffness	15	0
Joint swelling	23	0
Joint warmth	2	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	1	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	4	0
Myalgia	1983	0
Myofascial pain syndrome	2	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle disorder	1	0
Muscle fatigue	51	0
Muscle mass	1	0
Muscle oedema	1	0
Muscle spasms	120	0
Muscle swelling	3	0
Muscle tightness	7	0
Muscle twitching	17	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	2	0
Trismus	6	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	94	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Limb mass	1	0
Mobility decreased	5	0
Musculoskeletal stiffness	103	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	400	0
Flank pain	4	0
Growing pains	1	0
Limb discomfort	102	0
Musculoskeletal chest pain	19	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	6	0
Neck pain	156	0

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Earliest Reaction Date: 05-Jan-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Pain in extremity	880	0
<b>Myopathies</b>		
Myopathy	1	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	1	0
Still's disease	1	0
<b>Soft tissue disorders NEC</b>		
Groin pain	4	0
Neck mass	1	0
Soft tissue mass	1	0
<b>Spondyloarthropathies</b>		
Arthritis reactive	1	0
<b>Synovial disorders</b>		
Synovitis	1	0
<b>Tendon disorders</b>		
Tendonitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>5427</b>	<b>0</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 05-Jan-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021  
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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem stroke	1	0
Cerebrovascular accident	11	4
Haemorrhagic stroke	1	0
Ischaemic stroke	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	44	0
Coordination abnormal	3	0
Dysstasia	7	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
<i>Dementia (excl Alzheimer's type)</i>		
Senile dementia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Consciousness fluctuating	2	0
Depressed level of consciousness	1	0
Lethargy	289	0
Loss of consciousness	26	0
Somnolence	100	0
Syncope	121	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Clumsiness	4	0
Dyskinesia	4	0
Extrapyramidal disorder	1	0
Hypokinesia	1	0
Motor dysfunction	1	0
Movement disorder	1	0
Psychomotor hyperactivity	2	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	1	0
<i>Eye movement disorders</i>		
IIIrd nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	13	0
Facial paresis	2	0
Facial spasm	2	0
<i>Headaches NEC</i>		
Cluster headache	33	0
Cold-stimulus headache	1	0
Drug withdrawal headache	1	0
Exertional headache	1	0
External compression headache	1	0



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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Headache	5112	0
Medication overuse headache	1	0
Sinus headache	32	0
Tension headache	80	0
Thunderclap headache	2	0
Vascular headache	3	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Intracranial pressure increased	1	0
<b>Memory loss (excl dementia)</b>		
Amnesia	8	0
Memory impairment	6	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	4	0
Disturbance in attention	25	0
Mental impairment	5	0
<b>Migraine headaches</b>		
Migraine	364	0
Migraine with aura	7	0
Migraine without aura	2	0
Retinal migraine	1	0
<b>Mononeuropathies</b>		
Ulnar nerve palsy	1	0
<b>Muscle tone abnormal</b>		
Hypotonia	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	3	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	8	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	1	0
<b>Neurologic visual problems NEC</b>		
Tunnel vision	1	0
Visual field defect	1	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	1207	1
Dizziness exertional	2	0
Dizziness postural	114	0
Drooling	1	0
Head discomfort	18	0
Myoclonus	1	0
Neurological symptom	6	0
Presyncope	34	0
Unresponsive to stimuli	6	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	3	0
Muscle spasticity	1	0
Neuromuscular pain	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	17	0
Hyposmia	1	0
Parosmia	15	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning feet syndrome	1	0
Burning sensation	18	0
Formication	3	0
Hyperaesthesia	28	0
Hypoaesthesia	178	0
Lhermitte's sign	1	0
Paraesthesia	305	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	2	0
Hemiparesis	3	0
Monoparesis	2	0
Monoplegia	2	0
Paralysis	5	0
Paraplegia	1	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	9	0
Parkinsonism	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	3	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	6	0
Febrile convulsion	4	0
Seizure	40	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Tonic convulsion	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	43	0
Allodynia	7	0
Aura	1	0
Dysgeusia	93	0
Hypogeusia	1	0
Neuralgia	40	0
Phantom limb syndrome	1	0
Post herpetic neuralgia	1	0
Restless legs syndrome	35	0
Sensory disturbance	4	0
Sensory loss	5	0
Taste disorder	24	0
<b><i>Sleep disturbances NEC</i></b>		
Poor quality sleep	34	0
Sleep deficit	4	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	11	0
Slow speech	1	0
Speech disorder	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	6	0
<b><i>Tremor (excl congenital)</i></b>		
Intention tremor	1	0
Tremor	610	0
<b><i>Trigeminal disorders</i></b>		

# Case Series Drug Analysis Print

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Earliest Reaction Date: 05-Jan-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Trigeminal neuralgia	4	0
<b>Nervous system disorders SOC TOTAL</b>	<b>9328</b>	<b>5</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Pregnancy conditions</b>		
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	3	0
<i><b>Labour onset and length abnormalities</b></i>		
Premature labour	1	0
Premature rupture of membranes	1	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Morning sickness	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Pregnancy	3	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device malfunction events NEC</i>		
Oversensing	2	0
<b>null SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Affect alterations NEC</b></i>		
Inappropriate affect	1	0
<i><b>Anxiety symptoms</b></i>		
Agitation	14	0
Anxiety	20	0
Nervousness	35	0
Tension	7	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Aggression	1	0
Indifference	1	0
Social avoidant behaviour	1	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Daydreaming	1	0
Mental fatigue	15	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	92	0
Disorientation	43	0
<i><b>Deliria</b></i>		
Delirium	25	0
<i><b>Delusional symptoms</b></i>		
Delusion	2	0
<i><b>Depressive disorders</b></i>		
Depression	6	0
Major depression	1	0
<i><b>Dissociative states</b></i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	3	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	195	0
Middle insomnia	1	0
<i><b>Eating disorders NEC</b></i>		
Eating disorder	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Emotional disorder	5	0
Euphoric mood	1	0
Frustration tolerance decreased	1	0
Irritability	16	0
Mood altered	2	0
<i><b>Factitious disorders</b></i>		
Factitious disorder	2	0
<i><b>Fear symptoms and phobic disorders (incl social phobia)</b></i>		
Fear of disease	1	0
<i><b>Fluctuating mood symptoms</b></i>		
Mood swings	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	64	0
Hallucination, auditory	1	0
Hallucination, visual	2	0
Hallucinations, mixed	1	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	31	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Anhedonia	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Decreased interest	2	0
Depressed mood	10	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	6	0
<b>Mood alterations with manic symptoms</b>		
Mania	1	0
<b>Mood disorders NEC</b>		
Apathy	3	0
Listless	5	0
<b>Panic attacks and disorders</b>		
Panic attack	11	0
Panic reaction	2	0
<b>Parasomnias</b>		
Abnormal dreams	23	0
Exploding head syndrome	1	0
Nightmare	28	0
Sleep talking	2	0
Sleep terror	3	0
<b>Perception disturbances NEC</b>		
Autoscopy	3	0
Illusion	1	0
<b>Psychiatric symptoms NEC</b>		
Psychological trauma	1	0
<b>Sexual desire disorders</b>		
Loss of libido	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	26	0
<b>Somatic symptom disorders</b>		
Conversion disorder	1	0
Habit cough	2	0
Somatic symptom disorder	1	0
<b>Speech and language usage disturbances</b>		
Logorrhoea	1	0
<b>Stereotypies and automatisms</b>		
Bruxism	1	0
Head banging	3	0
<b>Stress disorders</b>		
Hyperarousal	1	0
<b>Suicidal and self-injurious behaviour</b>		
Suicidal ideation	2	0
<b>Thinking disturbances</b>		
Bradyphrenia	4	0
Tachyphrenia	3	0
Thinking abnormal	3	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>748</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	1	0
Dysuria	4	0
Incontinence	4	0
Micturition urgency	6	0
Pollakiuria	22	0
Urinary hesitation	1	0
Urinary incontinence	5	0
Urinary retention	4	0
Urine flow decreased	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	1	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephropathy	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	3	0
<i><b>Structural and obstructive urethral disorders (excl congenital)</b></i>		
Urethral spasm	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	2	0
Urine abnormality	2	0
Urine odour abnormal	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	1	0
Nocturia	1	0
Polyuria	3	0
Renal pain	48	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>112</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast disorders NEC</b></i>		
Breast mass	2	0
<i><b>Breast signs and symptoms</b></i>		
Breast oedema	1	0
Breast pain	12	0
Breast swelling	1	0
Breast tenderness	2	0
Nipple pain	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	5	0
Menstrual disorder	1	0
Menstruation irregular	3	0
Metrorrhagia	1	0
Premenstrual pain	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Hypomenorrhoea	2	0
Menstruation delayed	3	0
<i><b>Menstruation with increased bleeding</b></i>		
Menorrhagia	8	0
<i><b>Reproductive tract disorders NEC (excl neoplasms)</b></i>		
Genital ulceration	2	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	10	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal pain	1	0
Scrotal swelling	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular pain	3	0
<i><b>Uterine disorders NEC</b></i>		
Uterine pain	1	0
<i><b>Uterine tone disorders</b></i>		
Uterine spasm	2	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	13	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vaginal discharge	2	0
Vaginal lesion	1	0
Vulvovaginal pain	2	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>83</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	282	1
Dyspnoea at rest	1	0
Hyperventilation	4	0
Hypopnoea	10	0
Orthopnoea	1	0
Respiration abnormal	6	0
Respiratory arrest	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	9	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	12	0
Bronchospasm	1	0
Chronic obstructive pulmonary disease	1	1
Wheezing	35	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	8	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	169	0
Haemoptysis	1	0
Productive cough	5	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
Pleuritic pain	1	0
Pulmonary pain	10	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	26	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	42	0
Nasal dryness	3	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	1	0
Sinus congestion	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Oropharyngeal swelling	1	0
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	9	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	5	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	2	0
<i><b>Respiratory signs and symptoms NEC</b></i>		

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 05-Jan-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Respiratory symptom	2	0
<b><i>Respiratory tract disorders NEC</i></b>		
Aspiration	2	1
Lung disorder	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	3	0
Catarrh	2	0
Choking	1	0
Dry throat	20	0
Dysphonia	1	0
Nasal discomfort	2	0
Oropharyngeal pain	209	0
Paranasal sinus discomfort	1	0
Rhinalgia	3	0
Rhinorrhoea	60	0
Sinus pain	20	0
Sneezing	14	0
Throat clearing	1	0
Throat irritation	15	0
Throat tightness	10	0
Upper-airway cough syndrome	1	0
Yawning	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>1030</b>	<b>3</b>

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
<b><i>Alopecias</i></b>		
Alopecia	1	0
<b><i>Angioedemas</i></b>		
Angioedema	22	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	129	0
Hyperhidrosis	615	0
Miliaria	7	0
Night sweats	98	0
<b><i>Bullous conditions</i></b>		
Blister	15	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	6	0
Pain of skin	77	0
Scab	1	0
Scar pain	1	0
Sensitive skin	39	0
Skin burning sensation	29	0
Skin discolouration	3	0
Skin disorder	1	0
Skin odour abnormal	1	0
Skin reaction	13	0
Skin sensitisation	8	0
Skin swelling	2	0
Skin warm	31	0
Yellow skin	2	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	11	0
Dermatitis allergic	16	1
Eczema	1	0
Eczema asteatotic	1	0
Skin irritation	6	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	2	0
<b><i>Erythemas</i></b>		
Erythema	160	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	5	0
<b><i>Lipodystrophies</i></b>		
Lipohypertrophy	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	12	0
<b><i>Pilar disorders NEC</i></b>		
Piloerection	5	0
<b><i>Pruritus NEC</i></b>		
Pruritus	224	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	2	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	1	0
Rash	271	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash erythematous	52	0
Rash macular	19	0
Rash maculo-papular	2	0
Rash papular	5	0
Rash pruritic	40	0
Systemic lupus erythematosus rash	1	0
<b>Rosaceas</b>		
Rosacea	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Skin mass	1	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin erosion	2	0
Skin ulcer	1	0
<b>Skin haemorrhages</b>		
Skin haemorrhage	1	0
<b>Skin injuries and mechanical dermatoses</b>		
Needle track marks	1	0
<b>Skin vasculitides</b>		
Vasculitic rash	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	3	0
<b>Urticarias</b>		
Urticaria	102	0
<b>Skin disorders SOC TOTAL</b>	<b>2052</b>	<b>1</b>

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	4	0
Immobile	2	0
Impaired work ability	2	0
Sight disability	1	0
<b>Social circumstances SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	10	0
Immunisation	3	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	2	0
Limb operation	1	0
<i>Muscle therapeutic procedures</i>		
Muscle relaxant therapy	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Hospitalisation	1	0
Injection	2	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>22</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Arterial infections and inflammations</b></i>		
Giant cell arteritis	3	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	4	0
Shock	3	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	3	0
Haemorrhage	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	1	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Thrombosis	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Deep vein thrombosis	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	9	0
Flushing	34	0
Hot flush	121	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Ischaemic limb pain	1	0
Peripheral coldness	57	0
Raynaud's phenomenon	2	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	33	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	32	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	30	0
Orthostatic hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>337</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>42649</b>	<b>90</b>
<b>TOTAL REPORTS</b>	<b>11748</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>90</b>