

## Case Series Drug Analysis Print

**Name: FOI 21/1164 Hepatitis B Vaccine DAP**

Report Run Date: 24-Nov-2021  
Data Lock Date: 17-Oct-2021 22:57:05  
Earliest Reaction Date: 01-Jul-1982  
MedDRA Version: MedDRA 24.0

FOI 21/1164 Hepatitis B Vaccine DAP: All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with Hepatitis B vaccine

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Iron deficiency anaemia	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	5	0
<i><b>Anaemias haemolytic NEC</b></i>		
Haemolytic anaemia	4	0
<i><b>Anaemias haemolytic immune</b></i>		
Autoimmune haemolytic anaemia	1	0
Coombs positive haemolytic anaemia	1	0
<i><b>Coagulopathies</b></i>		
Disseminated intravascular coagulation	1	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	3	0
<i><b>Haemolyses NEC</b></i>		
Jaundice acholuric	1	0
<i><b>Leukocytoses NEC</b></i>		
Leukaemoid reaction	1	0
Leukocytosis	1	0
Lymphocytosis	1	0
<i><b>Leukopenias NEC</b></i>		
Leukopenia	2	0
Lymphopenia	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Hilar lymphadenopathy	1	0
Lymph node pain	2	0
Lymphadenitis	3	0
Lymphadenopathy	89	0
Pseudolymphoma	1	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Pancytopenia	2	0
<i><b>Neutropenias</b></i>		
Agranulocytosis	1	0
Autoimmune neutropenia	1	0
Granulocytopenia	2	0
Neutropenia	3	0
<i><b>Platelet disorders NEC</b></i>		
Platelet disorder	2	0
<i><b>Sickle cell trait and disorders</b></i>		
Sickle cell anaemia with crisis	1	0
<i><b>Spleen disorders</b></i>		
Splenomegaly	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	5	0
Thrombocytopenia	8	0
<b>Blood disorders SOC TOTAL</b>	<b>145</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Long QT syndrome	1	0
Wolff-Parkinson-White syndrome	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	48	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	1	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Myocardial infarction	2	0
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	1	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	2	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	2	0
Bradycardia	10	0
Extrasystoles	6	0
Tachycardia	38	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	1	0
Sinus bradycardia	1	0
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	2	1
Ventricular extrasystoles	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>122</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Autosomal chromosomal abnormalities</b></i>		
Trisomy 21	1	0
<i><b>Cardiac malpositions congenital</b></i>		
Ectopia cordis	1	0
<i><b>Cerebellar disorders congenital</b></i>		
Cerebellar hypoplasia	2	0
<i><b>Congenital disorders NEC</b></i>		
Congenital anomaly	1	0
<i><b>Dental disorders congenital</b></i>		
Tooth hypoplasia	1	0
<i><b>Hearing disorders congenital</b></i>		
Deafness congenital	1	0
<i><b>Inborn errors of bilirubin metabolism</b></i>		
Gilbert's syndrome	1	0
<i><b>Intestinal disorders congenital</b></i>		
Ileal atresia	1	0
<i><b>Musculoskeletal and connective tissue disorders of limbs congenital</b></i>		
Congenital hand malformation	1	0
Limb malformation	2	0
Limb reduction defect	1	0
Polydactyly	1	0
<i><b>Ocular disorders congenital NEC</b></i>		
Congenital eye disorder	1	0
<i><b>Palate disorders congenital</b></i>		
Cleft palate	2	0
<i><b>Tongue disorders congenital</b></i>		
Ankyloglossia congenital	2	0
<i><b>Viral infections congenital</b></i>		
Congenital herpes simplex infection	1	1
<b>Congenital disorders SOC TOTAL</b>	<b>20</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear discomfort	4	0
Ear pain	11	0
<i><b>Hearing losses</b></i>		
Deafness	3	0
Deafness neurosensory	2	0
Deafness transitory	3	0
Deafness unilateral	1	0
Hypoacusis	5	0
Sudden hearing loss	2	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	1	0
<i><b>Inner ear disorders NEC</b></i>		
Inner ear disorder	1	0
Vestibular disorder	1	0
<i><b>Inner ear signs and symptoms</b></i>		
Tinnitus	23	0
Vertigo	41	0
<b>Ear disorders SOC TOTAL</b>	<b>98</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	2	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
Thyroid disorder	3	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	6	0
Myxoedema	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<b><i>Choroid and vitreous structural change, deposit and degeneration</i></b>		
Vitreous floaters	1	0
<b><i>Conjunctival structural change, deposit and degeneration</i></b>		
Conjunctival discolouration	2	0
Conjunctival disorder	1	0
<b><i>Corneal infections, oedemas and inflammations</i></b>		
Keratitis	1	0
<b><i>Iris and uveal tract infections, irritations and inflammations</i></b>		
Iridocyclitis	3	0
Iritis	3	0
Uveitis	2	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	3	0
Lacrimation increased	4	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Eyelid oedema	1	0
Eyelid rash	1	0
Swelling of eyelid	9	0
<b><i>Ocular disorders NEC</i></b>		
Eye disorder	4	0
Eye pain	27	0
Eye swelling	38	0
Eyelid disorder	1	0
Periorbital oedema	13	0
Periorbital swelling	3	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		
Eye discharge	2	0
Eye irritation	4	0
Eye pruritus	6	0
Ocular hyperaemia	7	0
<b><i>Ocular nerve and muscle disorders</i></b>		
Eye movement disorder	8	0
Gaze palsy	1	0
Ophthalmoplegia	1	0
<b><i>Ocular sensation disorders</i></b>		
Abnormal sensation in eye	2	0
Foreign body sensation in eyes	1	0
Photophobia	26	0
<b><i>Optic disc abnormalities NEC</i></b>		
Papilloedema	1	0
<b><i>Pupil disorders</i></b>		
Miosis	2	0
Mydriasis	6	0
<b><i>Refractive and accommodative disorders</i></b>		
Accommodation disorder	1	0
<b><i>Retinal bleeding and vascular disorders (excl retinopathy)</i></b>		
Retinal haemorrhage	1	0
Retinal vein occlusion	1	0
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Retinal pigmentation	1	0
<b><i>Retinopathies NEC</i></b>		
Retinopathy	1	0
<b><i>Visual colour distortions</i></b>		

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Xanthopsia	1	0
<b>Visual disorders NEC</b>		
Diplopia	10	0
Photopsia	5	0
Vision blurred	46	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	4	0
Blindness transient	5	0
Visual acuity reduced	1	0
Visual impairment	47	0
<b>Eye disorders SOC TOTAL</b>	<b>308</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 wall conditions NEC</i>		
Abdominal wall disorder	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	2	0
<i>Anal and rectal signs and symptoms</i>		
Rectal tenesmus	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	1	0
Crohn's disease	3	0
Inflammatory bowel disease	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	230	0
Diarrhoea haemorrhagic	4	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	2	0
Faeces pale	2	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	10	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	161	0
Abdominal pain lower	4	0
Abdominal pain upper	54	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	6	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastric disorder	2	0
Gastrointestinal disorder	6	0
Stomach mass	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	9	0
Anal incontinence	1	0
Dysphagia	28	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Irritable bowel syndrome	3	0
Oesophageal spasm	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		

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<b>Gastrointestinal disorders</b>		
Gingival blister	1	0
Gingival swelling	1	0
<b>Gingival haemorrhages</b>		
Gingival bleeding	2	0
<b>Intestinal haemorrhages</b>		
Rectal haemorrhage	2	0
<b>Nausea and vomiting symptoms</b>		
Nausea	594	0
Retching	3	0
Vomiting	353	0
Vomiting projectile	1	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Haematochezia	2	0
<b>Oesophagitis (excl infective)</b>		
Oesophagitis	1	0
<b>Oral dryness and saliva altered</b>		
Dry mouth	19	0
Lip dry	1	0
Salivary hypersecretion	1	0
<b>Oral soft tissue disorders NEC</b>		
Chapped lips	1	0
Cheilitis	1	0
Lip blister	3	0
Oral disorder	2	0
Oral lichen planus	1	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	1	0
<b>Oral soft tissue infections</b>		
Angular cheilitis	1	0
<b>Oral soft tissue signs and symptoms</b>		
Hypoaesthesia oral	15	0
Oral mucosal blistering	2	0
Oral pain	2	0
Paraesthesia oral	26	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	1	0
Lip swelling	41	0
Mouth swelling	7	0
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland pain	2	0
<b>Salivary gland enlargements</b>		
Salivary gland enlargement	3	0
<b>Stomatitis and ulceration</b>		
Lip ulceration	2	0
Mouth ulceration	11	0
Stomatitis	1	0
<b>Tongue disorders</b>		
Tongue disorder	1	0
<b>Tongue signs and symptoms</b>		
Glossodynia	3	0
Swollen tongue	31	0

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Tongue blistering	1	0
Tongue coated	1	0
Tongue discolouration	2	0
Tongue oedema	2	0
<i>Tooth missing</i>		
Tooth loss	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>1702</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Administration site reactions NEC</b></i>		
Administration site erythema	1	0
Administration site papule	1	0
Administration site rash	3	0
<i><b>Adverse effect absent</b></i>		
No adverse event	2	0
<i><b>Application and instillation site reactions</b></i>		
Application site reaction	2	0
<i><b>Asthenic conditions</b></i>		
Asthenia	95	0
Chronic fatigue syndrome	23	0
Fatigue	337	0
Malaise	539	0
<i><b>Death and sudden death</b></i>		
Sudden infant death syndrome	1	1
<i><b>Febrile disorders</b></i>		
Hyperpyrexia	1	0
Pyrexia	457	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	107	0
Feeling abnormal	46	0
Feeling cold	21	0
Feeling drunk	3	0
Feeling hot	74	0
Feeling jittery	1	0
Feeling of body temperature change	18	0
Hunger	1	0
Sensation of foreign body	1	0
Temperature intolerance	1	0
Thirst	9	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	16	0
Gait inability	4	0
Loss of control of legs	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	8	0
Crying	5	0
Developmental delay	1	0
General physical health deterioration	2	0
Ill-defined disorder	3	0
Illness	15	0
Induration	1	0
Influenza like illness	530	0
Local reaction	60	0
Nonspecific reaction	1	0
Peripheral swelling	105	0
Screaming	1	0
Swelling	66	0
Swelling face	63	0
<i><b>Healing abnormal NEC</b></i>		
Impaired healing	1	0
<i><b>Inflammations</b></i>		
Granuloma	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Inflammation	16	0
<b><i>Injection site reactions</i></b>		
Injected limb mobility decreased	2	0
Injection site atrophy	2	0
Injection site bruising	1	0
Injection site coldness	1	0
Injection site dermatitis	1	0
Injection site discharge	1	0
Injection site discolouration	2	0
Injection site discomfort	1	0
Injection site dryness	1	0
Injection site erythema	18	0
Injection site exfoliation	1	0
Injection site haematoma	1	0
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	3	0
Injection site induration	2	0
Injection site inflammation	52	0
Injection site irritation	1	0
Injection site joint pain	1	0
Injection site mass	9	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site pain	93	0
Injection site pruritus	4	0
Injection site rash	17	0
Injection site reaction	175	0
Injection site scar	1	0
Injection site swelling	19	0
Injection site vesicles	1	0
Injection site warmth	8	0
<b><i>Interactions</i></b>		
Alcohol interaction	1	0
Drug interaction	3	0
<b><i>Mass conditions NEC</i></b>		
Mass	2	0
Nodule	2	0
<b><i>Oedema NEC</i></b>		
Face oedema	13	0
Generalised oedema	2	0
Gravitational oedema	3	0
Localised oedema	2	0
Oedema	17	0
Oedema peripheral	26	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	4	0
Chest discomfort	65	0
Chest pain	79	0
Discomfort	11	0
Facial pain	5	0
Non-cardiac chest pain	2	0
Pain	177	0
Tenderness	7	0

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<b>General disorders</b> General disorders cont'd		
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse drug reaction	5	0
Adverse event	1	0
Drug ineffective	6	0
Therapeutic product effect delayed	1	0
Therapeutic response decreased	5	0
Therapy non-responder	74	0
Vaccination failure	17	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site bruising	4	0
Vaccination site discomfort	2	0
Vaccination site erythema	5	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	1	0
Vaccination site inflammation	1	0
Vaccination site joint erythema	1	0
Vaccination site mass	3	0
Vaccination site movement impairment	1	0
Vaccination site nerve damage	1	0
Vaccination site pain	16	0
Vaccination site pruritus	1	0
Vaccination site rash	1	0
Vaccination site swelling	7	0
Vaccination site vesicles	1	0
Vaccination site warmth	5	0
<b>General disorders SOC TOTAL</b>	<b>3646</b>	<b>1</b>

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<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	2	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	2	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	1	0
Hepatitis cholestatic	1	0
Hyperbilirubinaemia	3	0
Jaundice	46	1
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder enlargement	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Hepatic cyst	1	0
Liver disorder	1	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	12	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	5	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	1	0
Hepatitis	7	0
Hepatitis acute	2	0
Hepatitis fulminant	1	0
Hepatocellular injury	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>91</b>	<b>1</b>

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<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	3	0
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	68	0
Serum sickness	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
Food allergy	3	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	77	0
Anaphylactic shock	3	0
Anaphylactoid reaction	15	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	5	0
Immunisation reaction	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunosuppression	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>189</b>	<b>0</b>



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<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	1	0
Diverticulitis	2	0
Gastroenteritis	3	0
<b><i>Arenaviral infections</i></b>		
Choriomeningitis lymphocytic	1	0
<b><i>Bacterial infections NEC</i></b>		
Bronchitis bacterial	1	0
Cellulitis	5	0
Folliculitis	2	0
Injection site cellulitis	2	0
<b><i>Candida infections</i></b>		
Candida infection	1	0
Oral candidiasis	2	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	5	0
Encephalomyelitis	3	0
Meningitis	4	0
Myelitis	5	0
<b><i>Coronavirus infections</i></b>		
COVID-19	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	1	0
Parotitis	3	0
<b><i>Ear infections</i></b>		
Labyrinthitis	5	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	6	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	11	0
Hordeolum	1	0
<b><i>Hepatitis virus infections</i></b>		
Chronic hepatitis B	3	0
Hepatitis A	1	0
Hepatitis B	4	0
Hepatitis B reactivation	1	0
<b><i>Hepatobiliary and spleen infections</i></b>		
Liver abscess	1	0
<b><i>Herpes viral infections</i></b>		
Herpes simplex	5	0
Herpes zoster	11	0
Oral herpes	4	0
<b><i>Infections NEC</i></b>		
Infection	3	0
Pyuria	1	0
<b><i>Infectious disorders carrier</i></b>		
Viral hepatitis carrier	1	0
<b><i>Infectious transmissions</i></b>		
Vertical infection transmission	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	6	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	1	0

## Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2021  
Earliest Reaction Date: 01-Jul-1982

Data Lock Date: 17-Oct-2021 22:57:05  
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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Lower respiratory tract infection	13	0
Pneumonia	4	0
<b>Muscle and soft tissue infections</b>		
Necrotising fasciitis	1	0
<b>Rubeola viral infections</b>		
Measles	1	0
<b>Salmonella infections</b>		
Typhoid fever	1	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Sepsis	2	0
Septic rash	1	0
<b>Skin structures and soft tissue infections</b>		
Infected dermal cyst	1	0
Pustule	1	0
Rash pustular	6	0
Skin infection	1	0
Subcutaneous abscess	1	0
<b>Staphylococcal infections</b>		
Furuncle	2	0
<b>Tuberculous infections</b>		
Erythema induratum	2	0
Tuberculosis	1	0
<b>Upper respiratory tract infections</b>		
Laryngitis	6	0
Nasopharyngitis	22	0
Pharyngitis	17	0
Rhinitis	15	0
Sinusitis	1	0
Tonsillitis	3	0
Tracheitis	3	0
Upper respiratory tract infection	5	0
<b>Urinary tract infections</b>		
Cystitis	2	0
Kidney infection	1	0
Renal abscess	1	0
Urinary tract infection	5	0
<b>Viral infections NEC</b>		
Encephalitis viral	1	1
Hepatitis viral	1	0
Post viral fatigue syndrome	19	0
Vestibular neuronitis	3	0
Viral infection	5	0
Viral pericarditis	1	0
<b>Infections SOC TOTAL</b>	<b>257</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Mouth injury	1	0
Splenic rupture	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	10	0
Exposure via breast milk	1	0
Maternal exposure before pregnancy	2	0
Maternal exposure during pregnancy	2	0
Maternal exposure timing unspecified	2	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Procedural nausea	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	2	0
Product use issue	1	0
Vaccination error	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Fall	6	0
Wound secretion	1	0
<b><i>Overdoses NEC</i></b>		
Intentional overdose	1	0
Overdose	2	0
<b><i>Product administration errors and issues</i></b>		
Accidental overdose	1	0
Accidental underdose	1	0
Expired product administered	1	0
Inappropriate schedule of product administration	44	0
Incomplete course of vaccination	7	0
Incorrect dose administered	3	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><i>Product prescribing errors and issues</i></b>		
Product prescribing error	1	0
<b><i>Radiation injuries</i></b>		
Sunburn	1	0
<b><i>Reproductive system and breast injuries</i></b>		
Perineal injury	1	0
<b><i>Site specific injuries NEC</i></b>		
Head injury	4	0
<b><i>Skin injuries NEC</i></b>		
Contusion	21	0
Scar	2	0
Skin abrasion	1	0
<b><i>Underdoses NEC</i></b>		
Underdose	5	0
<b><i>Vaccination related complications</i></b>		
Adverse event following immunisation	1	0
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>134</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
Antinuclear antibody positive	2	0
<b><i>Blood counts NEC</i></b>		
Full blood count abnormal	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Oxygen saturation decreased	1	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose decreased	1	0
Blood glucose increased	2	0
<b><i>Cholesterol analyses</i></b>		
Blood cholesterol increased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Coagulation time prolonged	1	0
International normalised ratio increased	1	0
<b><i>ECG investigations</i></b>		
Electrocardiogram PR shortened	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	1	0
<b><i>Haematological analyses NEC</i></b>		
Blood viscosity increased	1	0
Red blood cell sedimentation rate abnormal	1	0
Red blood cell sedimentation rate increased	3	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate decreased	6	0
Heart rate increased	12	0
Heart rate irregular	5	0
Pulse abnormal	7	0
<b><i>Imaging procedures NEC</i></b>		
Ultrasound scan abnormal	1	0
<b><i>Immunoglobulin analyses</i></b>		
Immunoglobulins increased	1	0
<b><i>Immunology analyses NEC</i></b>		
Antibody test abnormal	2	0
<b><i>Immunology skin tests NEC</i></b>		
Skin test positive	1	0
<b><i>Investigations NEC</i></b>		
Laboratory test interference	1	0
<b><i>Liver function analyses</i></b>		
Alanine aminotransferase increased	5	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	9	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	22	0
Liver function test increased	7	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood sodium increased	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature decreased	1	0
Body temperature fluctuation	3	0
Body temperature increased	19	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Grip strength decreased	2	0
Respiratory rate decreased	1	0
Respiratory rate increased	1	0
Weight decreased	16	0
Weight increased	4	0
<b>Platelet analyses</b>		
Platelet count decreased	1	0
<b>Protein analyses NEC</b>		
Alpha 1 foetoprotein increased	1	0
Blood albumin abnormal	1	0
C-reactive protein abnormal	1	0
Globulin abnormal	1	0
Protein total abnormal	1	0
<b>Skeletal and cardiac muscle analyses</b>		
Blood creatine phosphokinase abnormal	1	0
Blood creatine phosphokinase increased	3	0
<b>Tissue enzyme analyses NEC</b>		
Blood alkaline phosphatase increased	2	0
<b>Toxicology laboratory analyses</b>		
Blood aluminium increased	1	0
<b>Urinalysis NEC</b>		
Blood urine present	1	0
Urine analysis abnormal	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output increased	2	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	1	0
Blood pressure decreased	12	0
Blood pressure diastolic decreased	1	0
Blood pressure increased	12	0
Blood pressure systolic normal	1	0
<b>Virus identification and serology</b>		
Hepatitis B antibody abnormal	46	0
Hepatitis B antibody negative	2	0
Hepatitis B surface antibody negative	1	0
<b>White blood cell analyses</b>		
Lymphocyte morphology abnormal	1	0
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>245</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	49	0
Increased appetite	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	2	0
Type 1 diabetes mellitus	3	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	7	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	3	0
Feeding disorder	2	0
Poor feeding infant	1	0
<i><b>Hyperlipidaemias NEC</b></i>		
Hyperlipidaemia	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	2	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Metabolic acidosis	1	0
<i><b>Mixed acid-base disorders</b></i>		
Acidosis	1	0
<i><b>Potassium imbalance</b></i>		
Hypokalaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	3	0
<b>Metabolic disorders SOC TOTAL</b>	<b>79</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	49	0
Arthropathy	17	0
Polyarthritis	12	0
SLE arthritis	1	0
Seronegative arthritis	3	0
<b><i>Bone disorders NEC</i></b>		
Jaw disorder	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	7	0
Pain in jaw	16	0
Spinal pain	1	0
<b><i>Cartilage disorders</i></b>		
Costochondritis	1	0
<b><i>Connective tissue disorders NEC</i></b>		
Mixed connective tissue disease	1	0
Myofascitis	5	0
Polymyalgia rheumatica	6	0
<b><i>Extremity deformities</i></b>		
Hand deformity	1	0
<b><i>Joint related disorders NEC</i></b>		
Periarthritis	6	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	549	0
Joint noise	1	0
Joint stiffness	30	0
Joint swelling	60	0
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Systemic lupus erythematosus	5	0
<b><i>Metabolic bone disorders</i></b>		
Osteopenia	1	0
<b><i>Muscle infections and inflammations</i></b>		
Myositis	3	0
Polymyositis	1	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	4	0
Myalgia	335	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	3	0
Muscle discomfort	2	0
Muscle disorder	2	0
Muscle fatigue	1	0
Muscle mass	1	0
Muscle spasms	34	0
Muscle swelling	1	0
Muscle tightness	7	0
Muscle twitching	6	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	4	0
Nuchal rigidity	1	0
Trismus	4	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	54	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Musculoskeletal and connective tissue conditions cont'd</i>		
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Extremity contracture	1	0
Mobility decreased	4	0
Musculoskeletal stiffness	65	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	65	0
Limb discomfort	27	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	54	0
Pain in extremity	216	0
<b><i>Myopathies</i></b>		
Myopathy	1	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	8	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	1	0
<b><i>Rheumatoid arthropathies</i></b>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	20	0
<b><i>Soft tissue disorders NEC</i></b>		
Groin pain	6	0
Neck mass	1	0
<b><i>Spondyloarthropathies</i></b>		
Arthritis reactive	9	0
<b><i>Tendon disorders</i></b>		
Tendon calcification	1	0
Tendonitis	1	0
Tenosynovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>1721</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	2	0
<i>Plasma cell myelomas</i>		
Plasmacytoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	2	0
Skin cancer	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	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>Abnormal reflexes</i>		
Extensor plantar response	1	0
Hyporeflexia	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	17	0
<i>Autonomic nervous system disorders</i>		
Autonomic neuropathy	1	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Intracranial aneurysm	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
Cerebral ischaemia	1	0
Cerebrovascular accident	4	1
<i>Central nervous system vascular disorders NEC</i>		
Central nervous system vasculitis	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	5	0
Balance disorder	24	0
Coordination abnormal	8	0
Dysstasia	5	0
Nystagmus	4	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
Dysgraphia	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	5	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Consciousness fluctuating	2	0
Depressed level of consciousness	1	0
Lethargy	135	0
Loss of consciousness	28	0
Somnolence	62	0
Stupor	1	0
Syncope	135	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	4	0
Dyskinesia	6	0
Extrapyramidal disorder	1	0
Hyperkinesia	1	0
Hypokinesia	8	0
Motor dysfunction	2	0
Movement disorder	4	0
<i>Dystonias</i>		
Opisthotonus	1	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	1	0
<i>Encephalopathies NEC</i>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Encephalopathy	1	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	16	0
Facial paralysis	11	0
Facial paresis	3	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	14	0
<b>Headaches NEC</b>		
Cluster headache	1	0
Headache	692	0
Tension headache	3	0
<b>Increased intracranial pressure disorders</b>		
Brain oedema	1	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	1	0
<b>Memory loss (excl dementia)</b>		
Amnesia	14	0
Memory impairment	12	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	7	0
Disturbance in attention	21	0
Mental impairment	2	0
<b>Migraine headaches</b>		
Migraine	35	0
Migraine with aura	1	0
Ophthalmic migraine	1	0
Typical aura without headache	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	1	0
Mononeuropathy multiplex	1	0
Nerve compression	1	0
Peroneal nerve palsy	2	0
<b>Motor neurone diseases</b>		
Lower motor neurone lesion	1	0
Motor neurone disease	1	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis	21	0
<b>Muscle tone abnormal</b>		
Drop attacks	1	0
Hypertonia	6	0
Hypotonia	6	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	5	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	2	0
<b>Nervous system disorders NEC</b>		
Central nervous system lesion	1	0
Cerebral disorder	1	0
Meningeal disorder	1	0
Nervous system disorder	4	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
Tunnel vision	4	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b>Neurological signs and symptoms NEC</b>		
Clonus	1	0
Dizziness	505	0
Head discomfort	4	0
Meningism	7	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	1	0
Presyncope	18	0
Slow response to stimuli	1	0
Unresponsive to stimuli	8	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	3	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	1	0
Parosmia	1	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	17	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	17	0
Dysaesthesia	1	0
Hyperaesthesia	6	0
Hypoaesthesia	104	0
Lhermitte's sign	2	0
Paraesthesia	240	0
Paraesthesia mucosal	1	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	1	0
Hemiparesis	2	0
Monoplegia	3	0
Paralysis	5	0
Paresis	1	0
<b>Peripheral neuropathies NEC</b>		
Neuralgic amyotrophy	6	0
Neuritis	3	0
Neuropathy peripheral	9	0
Peripheral motor neuropathy	1	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	15	0
Partial seizures	1	0
Seizure	54	0
Status epilepticus	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	1	0
Allodynia	1	0
Dysgeusia	25	0
Electric shock sensation	2	0
Neuralgia	3	0
Sensory disturbance	5	0
Sensory loss	8	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Taste disorder	6	0
<b>Speech and language abnormalities</b>		
Dysarthria	15	0
Speech disorder	14	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	4	0
Radiculopathy	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	3	0
<b>Tremor (excl congenital)</b>		
Head titubation	1	0
Tremor	64	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>2584</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	1	0
Retained products of conception	1	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	17	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Hydrops foetalis	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
<i>Labour onset and length abnormalities</i>		
Premature rupture of membranes	1	0
Prolonged labour	2	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	2	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	2	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>36</b>	<b>0</b>

# Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2021  
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MedDRA Version: MedDRA 24.0

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Device physical property and chemical issues</i></b>		
Syringe issue	1	0
<b><i>Product quality issues NEC</i></b>		
Product complaint	1	0
Product quality issue	1	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	1	0
<b>null SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Staring	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety disorders NEC</i></b>		
Generalised anxiety disorder	1	0
Neurosis	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	7	0
Anxiety	24	0
Nervousness	8	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Paranoia	1	0
<b><i>Bipolar disorders</i></b>		
Bipolar disorder	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	19	0
Disorientation	22	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		
Delirium	5	0
<b><i>Depressive disorders</i></b>		
Depression	21	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	2	0
Dissociation	2	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	17	0
Middle insomnia	1	0
Terminal insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	2	0
Irritability	9	0
<b><i>Factitious disorders</i></b>		
Factitious disorder	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	2	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	9	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
<b><i>Learning disorders</i></b>		
Reading disorder	1	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	2	0
Feeling of despair	1	0



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Tearfulness	2	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	1	0
Mania	1	0
<b>Mood disorders NEC</b>		
Apathy	1	0
Listless	2	0
<b>Panic attacks and disorders</b>		
Panic attack	4	0
Panic disorder	1	0
Panic reaction	5	0
<b>Parasomnias</b>		
Nightmare	1	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	1	0
<b>Psychotic disorder NEC</b>		
Psychotic behaviour	2	0
Psychotic disorder	1	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual desire disorders</b>		
Loss of libido	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	11	0
<b>Somatic symptom disorders</b>		
Conversion disorder	2	0
<b>Substance related and addictive disorders</b>		
Drug dependence	1	0
<b>Suicidal and self-injurious behaviour</b>		
Suicidal ideation	1	0
<b>Thinking disturbances</b>		
Thinking abnormal	4	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>215</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>		
Dysuria	2	0
Incontinence	2	0
Micturition disorder	1	0
Micturition urgency	4	0
Pollakiuria	5	0
Urinary incontinence	5	0
Urinary retention	2	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	2	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis	1	0
Nephrotic syndrome	3	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	2	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	2	0
Renal failure	1	0
Renal impairment	1	0
<i><b>Renal neoplasms</b></i>		
Renal cyst	1	0
<i><b>Renal vascular and ischaemic conditions</b></i>		
Renal necrosis	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	2	0
Glycosuria	2	0
Haematuria	11	0
Ketonuria	1	0
Proteinuria	4	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Nocturia	1	0
Polyuria	2	0
Renal pain	10	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>68</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	6	0
Breast tenderness	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	2	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Intermenstrual bleeding	3	0
Menstrual disorder	2	0
Menstruation irregular	2	0
Premenstrual syndrome	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
Menstruation delayed	1	0
Oligomenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	6	0
Polymenorrhoea	1	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
<i><b>Prostatic signs, symptoms and disorders NEC</b></i>		
Prostatism	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital rash	1	0
Pelvic pain	1	0
<i><b>Sexual function and fertility disorders NEC</b></i>		
Infertility	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular swelling	1	0
<i><b>Uterine disorders NEC</b></i>		
Endometriosis	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>36</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	126	0
Dyspnoea exertional	1	0
Hyperventilation	7	0
Hypopnoea	5	0
Orthopnoea	1	0
Respiration abnormal	1	0
Respiratory distress	3	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	27	0
Bronchospasm	27	0
Obstructive airways disorder	1	0
Wheezing	20	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Respiratory gas exchange disorder	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	44	0
Haemoptysis	1	0
Productive cough	4	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngospasm	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pulmonary vasculitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Increased bronchial secretion	1	0
Rales	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	7	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	11	0
<i><b>Neonatal hypoxic conditions</b></i>		
Neonatal asphyxia	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	32	0
Tonsillar hypertrophy	3	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	2	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Acute respiratory failure	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Painful respiration	2	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory disorder	1	0
Respiratory tract congestion	5	0
Respiratory tract oedema	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	5	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Catarrh	1	0
Choking sensation	1	0
Dry throat	10	0
Dysphonia	7	0
Laryngeal pain	1	0
Nasal discomfort	2	0
Oropharyngeal blistering	1	0
Oropharyngeal pain	92	0
Rhinalgia	1	0
Rhinorrhoea	8	0
Sinus pain	1	0
Sneezing	8	0
Throat irritation	12	0
Throat tightness	38	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>534</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	2	0
Dermatitis acneiform	1	0
<b><i>Alopecias</i></b>		
Alopecia	13	0
Alopecia areata	5	0
Madarosis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	28	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	22	0
Hyperhidrosis	128	0
Night sweats	10	0
Sweat discolouration	1	0
<b><i>Bullous conditions</i></b>		
Blister	16	0
Blood blister	4	0
Dermatitis bullous	2	0
Erythema multiforme	26	0
Pemphigoid	1	0
Stevens-Johnson syndrome	6	0
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	7	0
Pain of skin	4	0
Papule	6	0
Sensitive skin	1	0
Skin burning sensation	4	0
Skin discolouration	7	0
Skin disorder	7	0
Skin induration	4	0
Skin lesion	1	0
Skin necrosis	2	0
Skin reaction	4	0
Skin swelling	1	0
Skin tightness	2	0
Skin warm	6	0
Yellow skin	2	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	5	0
Dermatitis allergic	11	0
Dermatitis contact	1	0
Dermatitis diaper	1	0
Dyshidrotic eczema	2	0
Eczema	32	0
Eczema nummular	1	0
Skin irritation	8	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	1	0
Toxic skin eruption	1	0
<b><i>Erythemas</i></b>		
Erythema	81	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	1	0
Skin exfoliation	4	0
<b><i>Hyperkeratoses</i></b>		
Lichenoid keratosis	5	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	1	0
Skin hyperpigmentation	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin hypopigmentation	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	29	0
Panniculitis	1	0
Panniculitis lobular	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	6	0
Lichen sclerosus	1	0
Lichenification	1	0
Pityriasis rosea	3	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	9	0
Solar dermatitis	1	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	211	0
<b><i>Psoriatic conditions</i></b>		
Guttate psoriasis	1	0
Psoriasis	13	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	1	0
Petechiae	5	0
Purpura	19	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	387	0
Rash erythematous	67	0
Rash macular	46	0
Rash maculo-papular	47	0
Rash morbilliform	4	0
Rash papular	25	0
Rash pruritic	63	0
Rash rubelliform	2	0
Rash vesicular	7	0
Systemic lupus erythematosus rash	2	0
<b><i>Rosaceas</i></b>		
Rosacea	1	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Eosinophilic cellulitis	1	0
Skin mass	1	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin ulcer	2	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<i><b>Skin vasculitides</b></i>		
Capillaritis	2	0
Cutaneous vasculitis	1	0
Vasculitic rash	2	0
<i><b>Skin vasomotor conditions</b></i>		
Livedo reticularis	3	0
<i><b>Urticarias</b></i>		
Mechanical urticaria	2	0
Urticaria	284	0
Urticarial vasculitis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>1736</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	2	0
Disability	1	0
Immobile	2	0
Impaired work ability	1	0
Loss of personal independence in daily activities	1	0
<b>Social circumstances SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Joint therapeutic procedures</i>		
Joint stabilisation	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	4	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<i>Skin lesion excisions</i>		
Sebaceous cyst excision	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Blood pressure disorders NEC</i>		
Labile blood pressure	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	25	0
Peripheral circulatory failure	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	4	0
<i>Non-site specific vascular disorders NEC</i>		
Vasodilatation	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	12	0
Flushing	46	0
Hot flush	23	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	8	0
Peripheral ischaemia	1	0
Raynaud's phenomenon	4	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	47	0
<i>Varicose veins NEC</i>		
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	16	0
<i>Vascular hypotensive disorders</i>		
Hypotension	28	0
Orthostatic hypotension	3	0
<i>Vasculitides NEC</i>		
Polyarteritis nodosa	2	0
Vasculitis	8	0
<b>Vascular disorders SOC TOTAL</b>	<b>235</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>14249</b>	<b>6</b>
<b>TOTAL REPORTS</b>	<b>5070</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>6</b>