

## Case Series Drug Analysis Print

### Name: FOI 22/405: Engerix B Vaccine Analysis Print

Report Run Date: 24-Feb-2022  
Data Lock Date: 20-Feb-2022 18:30:04  
Earliest Reaction Date: 08-Sep-1987  
MedDRA Version: MedDRA 24.1

FOI 22/405: Engerix B Engerix Vaccine Analysis Print. All UK, spontaneous Vaccine Analysis Print: suspected reports associated with the Engerix B brand up to and including the 20th February 2022.

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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	3	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>Eosinophilic disorders</b></i>		
Eosinophilia	2	0
<i><b>Haemolyses NEC</b></i>		
Jaundice acholuric	1	0
<i><b>Leukocytoses NEC</b></i>		
Leukaemoid reaction	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
Lymphadenitis	3	0
Lymphadenopathy	57	0
Pseudolymphoma	1	0
<i><b>Neutropenias</b></i>		
Agranulocytosis	1	0
Autoimmune neutropenia	1	0
Granulocytopenia	2	0
Neutropenia	2	0
<i><b>Platelet disorders NEC</b></i>		
Platelet disorder	1	0
<i><b>Spleen disorders</b></i>		
Splenomegaly	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	6	0
<b>Blood disorders SOC TOTAL</b>	<b>98</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	23	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Angina pectoris	1	0
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	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	2	0
Bradycardia	5	0
Extrasystoles	4	0
Tachycardia	27	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	1	1
Ventricular extrasystoles	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>77</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 21	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
<i>Hearing disorders congenital</i>		
Deafness congenital	1	0
<i>Inborn errors of bilirubin metabolism</i>		
Gilbert's syndrome	1	0
<i>Intestinal disorders congenital</i>		
Ileal atresia	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	2	0
<b>Congenital disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear pain	7	0
<i>Hearing losses</i>		
Deafness	3	0
Deafness neurosensory	2	0
Deafness transitory	1	0
Hypoacusis	1	0
Sudden hearing loss	1	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	14	0
Vertigo	24	0
<b>Ear disorders SOC TOTAL</b>	<b>57</b>	<b>0</b>

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<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	3	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	5	0
Myxoedema	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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<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
<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	2	0
Uveitis	1	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	3	0
Lacrimation increased	1	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Eyelid oedema	1	0
Eyelid rash	1	0
Swelling of eyelid	6	0
<b><i>Ocular disorders NEC</i></b>		
Eye disorder	3	0
Eye pain	18	0
Eye swelling	25	0
Eyelid disorder	1	0
Periorbital oedema	10	0
Periorbital swelling	3	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		
Eye discharge	1	0
Eye irritation	2	0
Eye pruritus	4	0
Ocular hyperaemia	5	0
<b><i>Ocular nerve and muscle disorders</i></b>		
Eye movement disorder	2	0
<b><i>Ocular sensation disorders</i></b>		
Abnormal sensation in eye	2	0
Photophobia	17	0
<b><i>Optic disc abnormalities NEC</i></b>		
Papilloedema	1	0
<b><i>Pupil disorders</i></b>		
Miosis	2	0
Mydriasis	3	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>		
Xanthopsia	1	0
<b><i>Visual disorders NEC</i></b>		
Diplopia	6	0
Photopsia	4	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Vision blurred	27	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	2	0
Blindness transient	3	0
Visual acuity reduced	1	0
Visual impairment	30	0
<b>Eye disorders SOC TOTAL</b>	<b>200</b>	<b>0</b>



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<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	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	2	0
Inflammatory bowel disease	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	145	0
Diarrhoea haemorrhagic	2	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	2	0
Faeces pale	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	6	0
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	104	0
Abdominal pain lower	2	0
Abdominal pain upper	39	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastric disorder	1	0
Gastrointestinal disorder	4	0
Stomach mass	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	6	0
Anal incontinence	1	0
Dysphagia	13	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Irritable bowel syndrome	1	0
Oesophageal spasm	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	1	0
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Rectal haemorrhage	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	409	0
Retching	2	0
Vomiting	224	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematochezia	1	0
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophagitis	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	13	0
Lip dry	1	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Cheilitis	1	0
Lip blister	3	0
Oral lichen planus	1	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	7	0
Oral mucosal blistering	2	0
Oral pain	2	0
Paraesthesia oral	14	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	28	0
Mouth swelling	4	0
<b><i>Salivary gland disorders NEC</i></b>		
Salivary gland pain	1	0
<b><i>Salivary gland enlargements</i></b>		
Salivary gland enlargement	2	0
<b><i>Stomatitis and ulceration</i></b>		
Lip ulceration	2	0
Mouth ulceration	6	0
Stomatitis	1	0
<b><i>Tongue disorders</i></b>		
Tongue disorder	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	2	0
Swollen tongue	17	0
Tongue blistering	1	0
Tongue coated	1	0
Tongue discomfort	1	0
Tongue oedema	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>1105</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
Administration site papule	1	0
Administration site rash	3	0
<i>Application and instillation site reactions</i>		
Application site reaction	1	0
<i>Asthenic conditions</i>		
Asthenia	58	0
Chronic fatigue syndrome	14	0
Fatigue	216	0
Malaise	360	0
<i>Death and sudden death</i>		
Sudden infant death syndrome	1	1
<i>Febrile disorders</i>		
Pyrexia	296	0
<i>Feelings and sensations NEC</i>		
Chills	69	0
Feeling abnormal	28	0
Feeling cold	14	0
Feeling drunk	3	0
Feeling hot	37	0
Feeling of body temperature change	16	0
Temperature intolerance	1	0
Thirst	5	0
<i>Gait disturbances</i>		
Gait disturbance	13	0
Gait inability	1	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	5	0
Crying	5	0
Developmental delay	1	0
General physical health deterioration	1	0
Ill-defined disorder	3	0
Illness	10	0
Induration	1	0
Influenza like illness	358	0
Local reaction	45	0
Nonspecific reaction	1	0
Peripheral swelling	65	0
Swelling	35	0
Swelling face	41	0
<i>Healing abnormal NEC</i>		
Impaired healing	1	0
<i>Inflammations</i>		
Inflammation	14	0
<i>Injection site reactions</i>		
Injection site atrophy	2	0
Injection site dermatitis	1	0
Injection site discharge	1	0
Injection site erythema	7	0
Injection site exfoliation	1	0
Injection site haematoma	1	0

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<b>General disorders</b> General disorders cont'd		
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	2	0
Injection site induration	2	0
Injection site inflammation	34	0
Injection site mass	6	0
Injection site nodule	1	0
Injection site pain	59	0
Injection site pruritus	2	0
Injection site rash	12	0
Injection site reaction	112	0
Injection site scar	1	0
Injection site swelling	7	0
Injection site vesicles	1	0
Injection site warmth	5	0
<b>Interactions</b>		
Alcohol interaction	1	0
Drug interaction	1	0
<b>Oedema NEC</b>		
Face oedema	10	0
Generalised oedema	1	0
Gravitational oedema	2	0
Oedema	9	0
Oedema peripheral	22	0
<b>Pain and discomfort NEC</b>		
Axillary pain	3	0
Chest discomfort	37	0
Chest pain	56	0
Discomfort	7	0
Facial pain	4	0
Non-cardiac chest pain	1	0
Pain	115	0
Tenderness	4	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	2	0
Drug ineffective	4	0
Therapeutic response decreased	4	0
Therapy non-responder	11	0
Vaccination failure	4	0
<b>Vaccination site reactions</b>		
Vaccination site bruising	4	0
Vaccination site discomfort	1	0
Vaccination site erythema	3	0
Vaccination site haemorrhage	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	1	0
Vaccination site joint erythema	1	0
Vaccination site mass	4	0
Vaccination site movement impairment	1	0
Vaccination site pain	11	0
Vaccination site pruritus	1	0
Vaccination site rash	1	0
Vaccination site swelling	5	0
Vaccination site vesicles	1	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site warmth	1	0
<b>General disorders SOC TOTAL</b>	<b>2318</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	1	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	1	0
Hepatitis cholestatic	1	0
Hyperbilirubinaemia	3	0
Jaundice	31	1
<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	6	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	2	0
Hepatomegaly	1	0
Liver tenderness	2	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	2	0
Hepatitis	5	0
Hepatitis acute	2	0
Hepatitis fulminant	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>61</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	3	0
<i>Allergic conditions NEC</i>		
Allergic oedema	2	0
Hypersensitivity	49	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	2	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	51	0
Anaphylactic shock	4	0
Anaphylactoid reaction	11	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immunisation reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>132</b>	<b>0</b>

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<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Diverticulitis	2	0
<b><i>Arenaviral infections</i></b>		
Choriomeningitis lymphocytic	1	0
<b><i>Bacterial infections NEC</i></b>		
Bronchitis bacterial	1	0
Cellulitis	4	0
Folliculitis	1	0
Injection site cellulitis	1	0
<b><i>Candida infections</i></b>		
Oral candidiasis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	4	0
Encephalomyelitis	3	0
Meningitis	4	0
Myelitis	4	0
<b><i>Coronavirus infections</i></b>		
COVID-19	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Parotitis	3	0
<b><i>Ear infections</i></b>		
Labyrinthitis	4	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	3	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	8	0
<b><i>Hepatitis virus infections</i></b>		
Chronic hepatitis B	1	0
Hepatitis A	1	0
<b><i>Hepatobiliary and spleen infections</i></b>		
Liver abscess	1	0
<b><i>Herpes viral infections</i></b>		
Herpes simplex	4	0
Herpes zoster	4	0
Oral herpes	1	0
<b><i>Infections NEC</i></b>		
Infection	1	0
Pyuria	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	3	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	1	0
Lower respiratory tract infection	7	0
Pneumonia	3	0
<b><i>Muscle and soft tissue infections</i></b>		
Necrotising fasciitis	1	0
<b><i>Rubeola viral infections</i></b>		
Measles	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	2	0
Septic rash	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Infected dermal cyst	1	0



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<b>Infections</b>		
Infections cont'd		
Pustule	1	0
Rash pustular	4	0
Skin infection	1	0
Subcutaneous abscess	1	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	2	0
<b><i>Tuberculous infections</i></b>		
Tuberculosis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Laryngitis	6	0
Nasopharyngitis	17	0
Pharyngitis	10	0
Rhinitis	11	0
Tonsillitis	2	0
Tracheitis	1	0
Upper respiratory tract infection	4	0
<b><i>Urinary tract infections</i></b>		
Urinary tract infection	2	0
<b><i>Viral infections NEC</i></b>		
Encephalitis viral	1	1
Hepatitis viral	1	0
Post viral fatigue syndrome	12	0
Vestibular neuronitis	3	0
Viral infection	3	0
<b>Infections SOC TOTAL</b>	<b>162</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	4	0
Maternal exposure before pregnancy	1	0
Maternal exposure during pregnancy	1	0
Maternal exposure timing unspecified	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Fall	4	0
<b><i>Non-site specific procedural complications</i></b>		
Injection related reaction	1	0
<b><i>Overdoses NEC</i></b>		
Intentional overdose	1	0
Overdose	1	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	17	0
Incomplete course of vaccination	6	0
Incorrect dose administered	2	0
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
<b><i>Radiation injuries</i></b>		
Sunburn	1	0
<b><i>Site specific injuries NEC</i></b>		
Head injury	4	0
<b><i>Skin injuries NEC</i></b>		
Contusion	11	0
Scar	1	0
Skin abrasion	1	0
<b><i>Underdoses NEC</i></b>		
Underdose	2	0
<b><i>Vaccination related complications</i></b>		
Adverse event following immunisation	1	0
Vaccination complication	2	0
<b>Injuries SOC TOTAL</b>	<b>70</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/405: Engerix B Vaccine Analysis Print

Report Run Date: 24-Feb-2022

Data Lock Date: 20-Feb-2022 18:30:04

Earliest Reaction Date: 08-Sep-1987

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b>Autoimmunity analyses</b>		
Antinuclear antibody positive	2	0
<b>Blood counts NEC</b>		
Full blood count abnormal	1	0
<b>Blood gas and acid base analyses</b>		
Oxygen saturation decreased	1	0
<b>Carbohydrate tolerance analyses (incl diabetes)</b>		
Blood glucose decreased	1	0
Blood glucose increased	1	0
<b>Cholesterol analyses</b>		
Blood cholesterol increased	1	0
<b>Coagulation and bleeding analyses</b>		
Coagulation time prolonged	1	0
<b>ECG investigations</b>		
Electrocardiogram PR shortened	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
<b>Haematological analyses NEC</b>		
Blood viscosity increased	1	0
Red blood cell sedimentation rate abnormal	1	0
Red blood cell sedimentation rate increased	2	0
<b>Heart rate and pulse investigations</b>		
Heart rate decreased	5	0
Heart rate increased	11	0
Heart rate irregular	5	0
Pulse abnormal	5	0
<b>Immunoglobulin analyses</b>		
Immunoglobulins increased	1	0
<b>Immunology skin tests NEC</b>		
Skin test positive	1	0
<b>Investigations NEC</b>		
Laboratory test interference	1	0
<b>Liver function analyses</b>		
Alanine aminotransferase increased	4	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase increased	8	0
Hepatic enzyme increased	1	0
Liver function test abnormal	17	0
Liver function test increased	6	0
<b>Mineral and electrolyte analyses</b>		
Blood sodium increased	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	17	0
Grip strength decreased	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	1	0
Weight decreased	8	0
Weight increased	1	0
<b>Protein analyses NEC</b>		
Alpha 1 foetoprotein increased	1	0
Blood albumin abnormal	1	0

## Case Series Drug Analysis Print

### Name: FOI 22/405: Engerix B Vaccine Analysis Print

Report Run Date: 24-Feb-2022  
 Earliest Reaction Date: 08-Sep-1987

Data Lock Date: 20-Feb-2022 18:30:04  
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
C-reactive protein abnormal	1	0
Globulin abnormal	1	0
Protein total abnormal	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase abnormal	1	0
Blood creatine phosphokinase increased	2	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood alkaline phosphatase increased	2	0
<b><i>Urinalysis NEC</i></b>		
Blood urine present	1	0
Urine analysis abnormal	1	0
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output increased	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure abnormal	1	0
Blood pressure decreased	7	0
Blood pressure diastolic decreased	1	0
Blood pressure increased	8	0
Blood pressure systolic normal	1	0
<b><i>Virus identification and serology</i></b>		
Hepatitis B antibody abnormal	1	0
Hepatitis B antibody negative	1	0
<b>Investigations SOC TOTAL</b>	<b>146</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022  
Earliest Reaction Date: 08-Sep-1987

Data Lock Date: 20-Feb-2022 18:30:04  
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	35	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Type 1 diabetes mellitus	1	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	6	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>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	2	0
<i><b>Potassium imbalance</b></i>		
Hypokalaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>55</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022  
Earliest Reaction Date: 08-Sep-1987

Data Lock Date: 20-Feb-2022 18:30:04  
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	33	0
Arthropathy	13	0
Polyarthritis	9	0
Seronegative arthritis	2	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	1	0
Pain in jaw	10	0
Spinal pain	1	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	1	0
<i><b>Connective tissue disorders NEC</b></i>		
Mixed connective tissue disease	1	0
Myofascitis	2	0
Polymyalgia rheumatica	3	0
<i><b>Extremity deformities</b></i>		
Hand deformity	1	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	4	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	361	0
Joint noise	1	0
Joint stiffness	20	0
Joint swelling	39	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Systemic lupus erythematosus	4	0
<i><b>Metabolic bone disorders</b></i>		
Osteopenia	1	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	3	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	2	0
Myalgia	210	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	1	0
Muscle discomfort	2	0
Muscle disorder	1	0
Muscle mass	1	0
Muscle spasms	21	0
Muscle tightness	6	0
Muscle twitching	4	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	2	0
Trismus	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	33	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Mobility decreased	4	0
Musculoskeletal stiffness	42	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	38	0
Limb discomfort	19	0
Musculoskeletal discomfort	1	0

## Case Series Drug Analysis Print

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Data Lock Date: 20-Feb-2022 18:30:04  
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Musculoskeletal pain	1	0
Neck pain	38	0
Pain in extremity	129	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	5	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	17	0
<b><i>Soft tissue disorders NEC</i></b>		
Groin pain	2	0
Neck mass	1	0
<b><i>Spondyloarthropathies</i></b>		
Arthritis reactive	8	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>1102</b>	<b>0</b>

# Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022

Data Lock Date: 20-Feb-2022 18:30:04

Earliest Reaction Date: 08-Sep-1987

MedDRA Version: MedDRA 24.1

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>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
Skin cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>6</b>	<b>0</b>



## Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022  
Earliest Reaction Date: 08-Sep-1987

Data Lock Date: 20-Feb-2022 18:30:04  
MedDRA Version: MedDRA 24.1

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	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	13	0
<i>Autonomic nervous system disorders</i>		
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	3	1
<i>Central nervous system vascular disorders NEC</i>		
Central nervous system vasculitis	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	4	0
Balance disorder	19	0
Coordination abnormal	5	0
Dysstasia	3	0
Nystagmus	4	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	3	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Consciousness fluctuating	2	0
Depressed level of consciousness	1	0
Lethargy	81	0
Loss of consciousness	17	0
Somnolence	38	0
Syncope	98	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	3	0
Hyperkinesia	1	0
Hypokinesia	6	0
Movement disorder	1	0
<i>Dystonias</i>		
Opisthotonus	1	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	12	0
Facial paralysis	7	0
Facial paresis	3	0

## Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022

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Earliest Reaction Date: 08-Sep-1987

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	12	0
<b>Headaches NEC</b>		
Cluster headache	1	0
Headache	452	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	8	0
Memory impairment	4	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	2	0
Disturbance in attention	12	0
<b>Migraine headaches</b>		
Migraine	23	0
Ophthalmic migraine	1	0
Typical aura without headache	1	0
<b>Mononeuropathies</b>		
Peroneal nerve palsy	2	0
<b>Motor neurone diseases</b>		
Motor neurone disease	1	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis	16	0
<b>Muscle tone abnormal</b>		
Drop attacks	1	0
Hypertonia	5	0
Hypotonia	3	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	2	0
<b>Nervous system disorders NEC</b>		
Cerebral disorder	1	0
Meningeal disorder	1	0
Nervous system disorder	1	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
Tunnel vision	2	0
<b>Neurological signs and symptoms NEC</b>		
Clonus	1	0
Dizziness	342	0
Head discomfort	2	0
Meningism	5	0
Neurological symptom	3	0
Persistent postural-perceptual dizziness	1	0
Presyncope	15	0
Slow response to stimuli	1	0
Unresponsive to stimuli	6	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	3	0
<b>Olfactory nerve disorders</b>		
Anosmia	1	0

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Earliest Reaction Date: 08-Sep-1987

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Parosmia	1	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	10	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	13	0
Dysaesthesia	1	0
Hyperaesthesia	4	0
Hypoaesthesia	64	0
Lhermitte's sign	2	0
Paraesthesia	164	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	1	0
Monoplegia	3	0
Paralysis	3	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuralgic amyotrophy	4	0
Neuritis	2	0
Neuropathy peripheral	4	0
Peripheral motor neuropathy	1	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	13	0
Partial seizures	1	0
Seizure	39	0
Status epilepticus	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Dysgeusia	16	0
Neuralgia	3	0
Sensory disturbance	1	0
Sensory loss	4	0
Taste disorder	5	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	6	0
Speech disorder	7	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	2	0
<b><i>Structural brain disorders NEC</i></b>		
Brain injury	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	3	0
<b><i>Tremor (excl congenital)</i></b>		
Head titubation	1	0
Tremor	41	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1706</b>	<b>1</b>

## Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortion related conditions and complications</b></i>		
Anembryonic gestation	1	0
Retained products of conception	1	0
<i><b>Abortions not specified as induced or spontaneous</b></i>		
Abortion	1	0
Abortion missed	1	0
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	9	0
<i><b>Foetal complications NEC</b></i>		
Foetal cardiac disorder	1	0
<i><b>Gestational age and weight conditions</b></i>		
Premature baby	1	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Haemorrhage in pregnancy	1	0
<i><b>Labour onset and length abnormalities</b></i>		
Premature rupture of membranes	1	0
<i><b>Neonatal hepatobiliary disorders</b></i>		
Jaundice neonatal	2	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Live birth	2	0
<i><b>Postpartum complications NEC</b></i>		
Postpartum haemorrhage	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>22</b>	<b>0</b>

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Earliest Reaction Date: 08-Sep-1987

MedDRA Version: MedDRA 24.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device physical property and chemical issues</i>		
Syringe issue	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product quality issue	1	0
<b>null SOC TOTAL</b>	<b>3</b>	<b>0</b>

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Abnormal behaviour NEC</i>		
Staring	1	0
<i>Anxiety disorders NEC</i>		
Generalised anxiety disorder	1	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	3	0
Anxiety	14	0
Nervousness	5	0
<i>Behaviour and socialisation disturbances</i>		
Paranoia	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	10	0
Disorientation	16	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	12	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	8	0
Middle insomnia	1	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	2	0
Irritability	4	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	2	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	4	0
Hallucination, auditory	1	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
Feeling of despair	1	0
Tearfulness	2	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	1	0

## Case Series Drug Analysis Print

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Data Lock Date: 20-Feb-2022 18:30:04  
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i><b>Panic attacks and disorders</b></i>		
Panic attack	1	0
Panic reaction	5	0
<i><b>Parasomnias</b></i>		
Nightmare	1	0
<i><b>Pervasive developmental disorders NEC</b></i>		
Autism spectrum disorder	1	0
<i><b>Psychotic disorder NEC</b></i>		
Psychotic disorder	1	0
<i><b>Schizophrenia NEC</b></i>		
Schizophrenia	1	0
<i><b>Sleep disorders NEC</b></i>		
Sleep disorder	6	0
<i><b>Somatic symptom disorders</b></i>		
Conversion disorder	1	0
<i><b>Substance related and addictive disorders</b></i>		
Drug dependence	1	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Suicidal ideation	1	0
<i><b>Thinking disturbances</b></i>		
Thinking abnormal	4	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>127</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022  
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Data Lock Date: 20-Feb-2022 18:30:04  
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Incontinence	2	0
Micturition disorder	1	0
Micturition urgency	1	0
Pollakiuria	3	0
Urinary incontinence	5	0
Urinary retention	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	3	0
<i>Renal disorders NEC</i>		
Renal disorder	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Renal failure	1	0
Renal impairment	1	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal necrosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Glycosuria	2	0
Haematuria	8	0
Proteinuria	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Nocturia	1	0
Polyuria	2	0
Renal pain	8	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>49</b>	<b>0</b>



## Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022

Data Lock Date: 20-Feb-2022 18:30:04

Earliest Reaction Date: 08-Sep-1987

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	4	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	1	0
Menstrual disorder	2	0
Menstruation irregular	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
Menstruation delayed	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	4	0
Polymenorrhoea	1	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital rash	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/405: Enderix B Vaccine Analysis Print

Report Run Date: 24-Feb-2022  
Earliest Reaction Date: 08-Sep-1987

Data Lock Date: 20-Feb-2022 18:30:04  
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	72	0
Dyspnoea exertional	1	0
Hyperventilation	7	0
Hypopnoea	3	0
Orthopnoea	1	0
Respiration abnormal	1	0
Respiratory distress	2	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	19	0
Bronchospasm	21	0
Obstructive airways disorder	1	0
Wheezing	14	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	27	0
Haemoptysis	1	0
Productive cough	4	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngospasm	1	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
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	2	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	6	0
<i><b>Neonatal hypoxic conditions</b></i>		
Neonatal asphyxia	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	19	0
Tonsillar hypertrophy	1	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 tract disorders NEC</b></i>		
Respiratory tract congestion	4	0
Respiratory tract oedema	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	2	0
Catarrh	1	0
Dry throat	9	0
Dysphonia	3	0
Laryngeal pain	1	0
Nasal discomfort	2	0
Oropharyngeal pain	58	0
Rhinorrhoea	5	0
Sneezing	2	0
Throat irritation	7	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Throat tightness	22	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>329</b>	<b>0</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
<b><i>Alopecias</i></b>		
Alopecia	6	0
Alopecia areata	2	0
<b><i>Angioedemas</i></b>		
Angioedema	19	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	19	0
Hyperhidrosis	89	0
Night sweats	8	0
<b><i>Bullous conditions</i></b>		
Blister	7	0
Blood blister	4	0
Dermatitis bullous	2	0
Erythema multiforme	19	0
Stevens-Johnson syndrome	4	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	1	0
Papule	3	0
Sensitive skin	1	0
Skin burning sensation	3	0
Skin discolouration	6	0
Skin disorder	4	0
Skin induration	4	0
Skin necrosis	2	0
Skin reaction	4	0
Skin tightness	2	0
Skin warm	3	0
Yellow skin	2	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	2	0
Dermatitis allergic	6	0
Dermatitis contact	1	0
Dyshidrotic eczema	2	0
Eczema	18	0
Eczema nummular	1	0
Skin irritation	6	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	52	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	1	0
Skin exfoliation	3	0
<b><i>Hyperkeratoses</i></b>		
Lichenoid keratosis	3	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin hyperpigmentation	1	0
<b>Hypopigmentation disorders</b>		
Skin hypopigmentation	1	0
<b>Nail and nail bed conditions (excl infections and infestations)</b>		
Nail discolouration	1	0
<b>Panniculitides</b>		
Erythema nodosum	23	0
Panniculitis	1	0
Panniculitis lobular	1	0
<b>Papulosquamous conditions</b>		
Lichen planus	2	0
Lichen sclerosus	1	0
Lichenification	1	0
Pityriasis rosea	3	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	7	0
Solar dermatitis	1	0
<b>Pigmentation changes NEC</b>		
Pigmentation disorder	1	0
<b>Pruritus NEC</b>		
Pruritus	133	0
<b>Psoriatic conditions</b>		
Psoriasis	11	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	1	0
Petechiae	4	0
Purpura	15	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	232	0
Rash erythematous	50	0
Rash macular	30	0
Rash maculo-papular	36	0
Rash morbilliform	4	0
Rash papular	16	0
Rash pruritic	43	0
Rash rubelliform	2	0
Rash vesicular	7	0
Systemic lupus erythematosus rash	2	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 ulcer	2	0
<b>Skin vasculitides</b>		
Capillaritis	2	0
Cutaneous vasculitis	1	0
Vasculitic rash	2	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	2	0
<b>Urticarias</b>		
Mechanical urticaria	1	0
Urticaria	200	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Urticarial vasculitis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>1164</b>	<b>0</b>

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

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Skin lesion excisions</i>		
Sebaceous cyst excision	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>2</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Blood pressure disorders NEC</b></i>		
Labile blood pressure	1	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	19	0
Peripheral circulatory failure	1	0
<i><b>Haemorrhages NEC</b></i>		
Haemorrhage	2	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Vasodilatation	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Deep vein thrombosis	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	8	0
Flushing	30	0
Hot flush	10	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	7	0
Peripheral ischaemia	1	0
Raynaud's phenomenon	2	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	38	0
<i><b>Varicose veins NEC</b></i>		
Varicose vein	1	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	13	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	19	0
Orthostatic hypotension	2	0
<i><b>Vasculitides NEC</b></i>		
Polyarteritis nodosa	1	0
Vasculitis	6	0
<b>Vascular disorders SOC TOTAL</b>	<b>163</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>9197</b>	<b>5</b>
<b>TOTAL REPORTS</b>	<b>3363</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>5</b>