

**Case Series Drug Analysis Print**  
**Name: FOI 21/1254 Cervarix Vaccine VAP**

Report Run Date: 13-Dec-2021  
Data Lock Date: 09-Dec-2021 18:30:07  
Earliest Reaction Date: 17-Oct-2007  
MedDRA Version: MedDRA 24.1  
FOI 21/1254 Cervarix Vaccine VAP: All UK Spontaneously received Adverse Drug Reaction (ADR) reports associated with the Cervarix Vaccine

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Anaemia vitamin B12 deficiency	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	4	0
<i><b>Anaemias haemolytic mechanical factor</b></i>		
Haemolytic uraemic syndrome	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	2	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	1	0
<i><b>Haematological disorders</b></i>		
Mast cell activation syndrome	2	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymphadenopathy	28	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Aplastic anaemia	1	0
Pancytopenia	1	0
<i><b>Neutropenias</b></i>		
Neutropenia	1	0
<i><b>Spleen disorders</b></i>		
Splenomegaly	2	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	2	0
<b>Blood disorders SOC TOTAL</b>	<b>49</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	19	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Angina pectoris	2	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	1	0
<i><b>Pulmonary valvular disorders</b></i>		
Pulmonary valve stenosis	2	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	1	0
Bradycardia	6	0
Postural orthostatic tachycardia syndrome	30	0
Tachycardia	30	0
<i><b>Supraventricular arrhythmias</b></i>		
Sinus tachycardia	6	0
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>101</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Anorectal disorders congenital</b></i>		
Preternatural anus	2	0
<i><b>Cardiac septal defects congenital</b></i>		
Atrioventricular septal defect	2	0
<i><b>Cerebral disorders congenital</b></i>		
Cerebral palsy	1	0
<i><b>Congenital disorders NEC</b></i>		
Congenital anomaly	1	0
VACTERL syndrome	2	0
<i><b>Connective tissue disorders congenital</b></i>		
Ehlers-Danlos syndrome	5	0
<i><b>Great vessel disorders congenital</b></i>		
Double outlet right ventricle	2	0
<i><b>Male reproductive tract disorders congenital</b></i>		
Hypospadias	1	0
<i><b>Musculoskeletal and connective tissue disorders of limbs congenital</b></i>		
Limb hypoplasia congenital	2	0
Limb reduction defect	2	0
Talipes	1	0
<i><b>Musculoskeletal and connective tissue disorders of spine congenital</b></i>		
Spine malformation	2	0
<i><b>Non-site specific bone disorders congenital</b></i>		
Osteopetrosis	1	0
<i><b>Palate disorders congenital</b></i>		
Cleft palate	1	0
High arched palate	1	0
<i><b>Pulmonary and bronchial disorders congenital</b></i>		
Pulmonary aplasia	2	0
Pulmonary hypoplasia	2	0
<i><b>Renal disorders congenital</b></i>		
Congenital cystic kidney disease	2	0
<i><b>Skin and subcutaneous tissue disorders congenital NEC</b></i>		
Birth mark	1	0
Congenital skin dimples	2	0
Ichthyosis	1	0
Sebaceous naevus	1	0
<i><b>Tongue disorders congenital</b></i>		
Ankyloglossia congenital	2	0
<i><b>Vascular anomalies congenital NEC</b></i>		
Arteriovenous malformation	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>40</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	10	0
<i>Hearing losses</i>		
Deafness	9	0
Deafness bilateral	1	0
Deafness transitory	3	0
Hypoacusis	11	0
<i>Hyperacusia</i>		
Hyperacusis	12	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	11	0
Vertigo	9	0
<b>Ear disorders SOC TOTAL</b>	<b>72</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	5	0
<b>Endocrine disorders SOC TOTAL</b>	<b>11</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>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	2	0
<i><b>Conjunctival infections, irritations and inflammations</b></i>		
Conjunctival hyperaemia	2	0
<i><b>Eyelid movement disorders</b></i>		
Excessive eye blinking	2	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	2	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Swelling of eyelid	8	0
<i><b>Ocular disorders NEC</b></i>		
Dark circles under eyes	2	0
Eye disorder	2	0
Eye pain	8	0
Eye swelling	28	0
Eyelid disorder	1	0
Eyelids pruritus	1	0
Periorbital oedema	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye discharge	1	0
Eye irritation	1	0
Eye pruritus	3	0
Ocular hyperaemia	5	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Extraocular muscle paresis	1	0
Eye movement disorder	15	0
Gaze palsy	2	0
Strabismus	1	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
Foreign body sensation in eyes	1	0
Photophobia	31	0
<i><b>Orbital structural change, deposit and degeneration</b></i>		
Lid sulcus deepened	1	0
<i><b>Pupil disorders</b></i>		
Mydriasis	16	0
Pupil fixed	3	0
<i><b>Refractive and accommodative disorders</b></i>		
Accommodation disorder	1	0
Altered visual depth perception	1	0
<i><b>Retinal, choroid and vitreous infections and inflammations</b></i>		
Choroiditis	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	6	0
Metamorphopsia	1	0
Photopsia	1	0
Vision blurred	84	0
<i><b>Visual field disorders</b></i>		
Visual field defect	5	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	6	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Blindness transient	12	0
Blindness unilateral	1	0
Visual impairment	34	0
<b>Eye disorders SOC TOTAL</b>	<b>296</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	3	0
<i>Dental disorders NEC</i>		
Tooth erosion	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	82	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	5	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	6	0
Flatulence	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	1	0
Gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	1	0
Abdominal pain	122	0
Abdominal pain lower	5	0
Abdominal pain upper	112	0
Abdominal tenderness	1	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	5	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	7	0
Impaired gastric emptying	5	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastric disorder	2	0
Gastrointestinal disorder	8	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	32	0
Dysphagia	13	0
Odynophagia	1	0
Oesophageal discomfort	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
Irritable bowel syndrome	9	0
<i>Gastrointestinal ulcers and perforation, site unspecified</i>		
Gastrointestinal ulcer	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	2	0
Gingival swelling	1	0
<i>Intestinal haemorrhages</i>		

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Rectal haemorrhage	1	0
<b><i>Malabsorption syndromes</i></b>		
Coeliac disease	1	0
Malabsorption	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	1129	0
Regurgitation	1	0
Retching	3	0
Vomiting	472	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	1	0
Haematemesis	3	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	4	0
Saliva altered	1	0
Salivary hypersecretion	3	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Cheilitis	1	0
Lip blister	2	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	8	0
Lip pain	1	0
Oral discomfort	2	0
Oral mucosal blistering	1	0
Oral pain	3	0
Oral pruritus	2	0
Paraesthesia oral	24	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	46	0
Mouth swelling	7	0
<b><i>Pancreatic disorders NEC</i></b>		
Pancreatic disorder	1	0
<b><i>Stomatitis and ulceration</i></b>		
Lip ulceration	1	0
Mouth ulceration	5	0
<b><i>Tongue signs and symptoms</i></b>		
Swollen tongue	20	0
Tongue coated	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>2187</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Puncture site reaction	1	0
<i>Asthenic conditions</i>		
Asthenia	82	0
Chronic fatigue syndrome	46	0
Decreased activity	1	0
Fatigue	423	0
Malaise	454	0
<i>Body temperature altered</i>		
Temperature regulation disorder	6	0
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	288	0
<i>Feelings and sensations NEC</i>		
Chills	59	0
Feeling abnormal	39	0
Feeling cold	51	0
Feeling drunk	3	0
Feeling hot	148	0
Feeling jittery	2	0
Feeling of body temperature change	15	0
Sensation of foreign body	2	0
Thirst	3	0
<i>Gait disturbances</i>		
Gait disturbance	14	0
Gait inability	12	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	6	0
Crying	6	0
Exercise tolerance decreased	1	0
Foaming at mouth	1	0
Ill-defined disorder	2	0
Illness	42	0
Induration	2	0
Influenza like illness	84	0
Local reaction	24	0
Organ failure	1	0
Peripheral swelling	222	0
Screaming	1	0
Swelling	53	0
Swelling face	64	0
<i>Inflammations</i>		
Inflammation	15	0
Systemic inflammatory response syndrome	1	0
<i>Infusion site reactions</i>		
Infusion site hypoaesthesia	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	2	0
Injection site bruising	24	0
Injection site coldness	1	0
Injection site discharge	3	0
Injection site discolouration	4	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site discomfort	2	0
Injection site erythema	105	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	8	0
Injection site induration	9	0
Injection site inflammation	27	0
Injection site irritation	6	0
Injection site joint movement impairment	1	0
Injection site joint pain	1	0
Injection site mass	48	0
Injection site movement impairment	1	0
Injection site nodule	8	0
Injection site pain	104	0
Injection site papule	1	0
Injection site paraesthesia	1	0
Injection site pruritus	16	0
Injection site rash	49	0
Injection site reaction	30	0
Injection site scab	2	0
Injection site scar	1	0
Injection site swelling	140	0
Injection site urticaria	5	0
Injection site vesicles	5	0
Injection site warmth	24	0
<b>Mass conditions NEC</b>		
Mass	1	0
Nodule	1	0
<b>Oedema NEC</b>		
Face oedema	4	0
Oedema peripheral	7	0
<b>Pain and discomfort NEC</b>		
Axillary pain	2	0
Chest discomfort	41	0
Chest pain	53	0
Discomfort	13	0
Facial pain	2	0
Non-cardiac chest pain	1	0
Pain	136	0
Tenderness	12	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	1	0
Vaccination failure	2	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	2	0
Vaccination site hypersensitivity	1	0
Vaccination site pain	1	0
<b>General disorders SOC TOTAL</b>	<b>3088</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Liver disorder	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergy to animal	1	0
Hypersensitivity	42	0
Multiple allergies	2	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	3	0
Type IV hypersensitivity reaction	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Food allergy	3	0
Reaction to excipient	1	0
Reaction to food additive	1	0
Reaction to preservatives	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	55	0
Anaphylactic shock	5	0
Anaphylactoid reaction	3	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	5	0
Overlap syndrome	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Immune system disorder	2	0
Immunisation reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>130</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	1	0
Peritonitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	1	0
Folliculitis	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
<b><i>Breast infections</i></b>		
Mastitis	1	0
<b><i>Candida infections</i></b>		
Candida infection	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	2	0
Encephalitis lethargica	1	0
<b><i>Coronavirus infections</i></b>		
Severe acute respiratory syndrome	1	0
<b><i>Ear infections</i></b>		
Labyrinthitis	2	0
Otitis media chronic	1	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	9	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	1	0
Hordeolum	4	0
<b><i>Herpes viral infections</i></b>		
Herpes virus infection	1	0
Herpes zoster	5	0
Varicella	1	0
<b><i>Infections NEC</i></b>		
Infection	4	0
Infection susceptibility increased	3	0
Injection site abscess	1	0
Injection site infection	4	0
Purulent discharge	1	0
Respiratory tract infection	1	0
<b><i>Infectious transmissions</i></b>		
Suspected transmission of an infectious agent via product	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	2	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	2	0
Lower respiratory tract infection	12	0
Pneumonia	1	0
<b><i>Molluscum contagiosum viral infections</i></b>		
Molluscum contagiosum	1	0
<b><i>Papilloma viral infections</i></b>		
Papilloma viral infection	1	0
Vulvovaginal human papilloma virus infection	1	0
<b><i>Respiratory syncytial viral infections</i></b>		
Respiratory syncytial virus infection	1	0

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<b>Infections</b>		
Infections cont'd		
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	2	0
Viraemia	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Application site pustules	1	0
Impetigo	1	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	3	0
Staphylococcal infection	1	0
<b><i>Streptococcal infections</i></b>		
Beta haemolytic streptococcal infection	1	0
Streptococcal sepsis	1	1
<b><i>Upper respiratory tract infections</i></b>		
Laryngitis	1	0
Nasopharyngitis	27	0
Pharyngitis	5	0
Tonsillitis	5	0
Upper respiratory tract infection	2	0
<b><i>Urinary tract infections</i></b>		
Kidney infection	1	0
Urinary tract infection	4	0
<b><i>Viral infections NEC</i></b>		
Hepatitis viral	1	0
Meningitis viral	1	0
Pneumonia viral	1	0
Post viral fatigue syndrome	27	0
Viral infection	14	0
Viral pharyngitis	1	0
<b>Infections SOC TOTAL</b>	<b>175</b>	<b>1</b>



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<b>Injuries</b>		
<i><b>Abdominal and gastrointestinal injuries NEC</b></i>		
Mouth injury	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	20	0
Foetal exposure during pregnancy	6	0
Maternal exposure before pregnancy	2	0
Maternal exposure during pregnancy	1	0
Maternal exposure timing unspecified	11	0
<i><b>Fractures and dislocations NEC</b></i>		
Joint dislocation	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Wrong technique in product usage process	1	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Muscle injury	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	2	0
<i><b>Neurological and psychiatric procedural complications</b></i>		
Procedural dizziness	2	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	11	0
Wound	1	0
<i><b>Off label uses</b></i>		
Off label use	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	1	0
<i><b>Product administration errors and issues</b></i>		
Extra dose administered	1	0
Inappropriate schedule of product administration	4	0
Wrong product administered	1	0
<i><b>Site specific injuries NEC</b></i>		
Face injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	38	0
Dermatitis artefacta	1	0
Scar	1	0
Skin abrasion	1	0
<b>Injuries SOC TOTAL</b>	<b>110</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Adrenal cortex tests</b></i>		
Cortisol decreased	1	0
<i><b>Autoimmunity analyses</b></i>		
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
<i><b>Blood counts NEC</b></i>		
Full blood count abnormal	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Blood pH increased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	1	0
Blood glucose increased	6	0
<i><b>Cell marker analyses</b></i>		
Cell marker increased	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF cell count increased	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram abnormal	1	0
<i><b>Endocrine analyses and imaging NEC</b></i>		
Hormone level abnormal	1	0
<i><b>Foetal and neonatal diagnostic procedures</b></i>		
Foetal heart rate abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	5	0
Heart rate increased	26	0
Heart rate irregular	7	0
Pulse abnormal	5	0
Pulse absent	1	0
<i><b>Investigations NEC</b></i>		
Quality of life decreased	2	0
<i><b>Liver function analyses</b></i>		
Alanine aminotransferase increased	1	0
Liver function test increased	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood iron decreased	1	0
Serum ferritin decreased	2	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	1	0
Body temperature decreased	4	0
Body temperature fluctuation	1	0
Body temperature increased	73	0
Breath sounds abnormal	1	0
Grip strength decreased	3	0
Respiratory rate decreased	1	0
Respiratory rate increased	7	0
Weight decreased	17	0
Weight increased	4	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	2	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Peak expiratory flow rate decreased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output decreased	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure increased	4	0
Blood pressure systolic decreased	1	0
<b><i>Vitamin analyses</i></b>		
Vitamin B12 decreased	1	0
Vitamin D decreased	1	0
<b><i>White blood cell analyses</i></b>		
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>201</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	35	0
Increased appetite	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus inadequate control	1	0
Type 1 diabetes mellitus	3	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	1	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	5	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	1	0
Food intolerance	5	0
Gluten sensitivity	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	10	0
Cachexia	1	0
Feeding disorder	1	0
Underweight	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	2	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	2	0
<i><b>Iron deficiencies</b></i>		
Iron deficiency	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	4	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Vitamin B12 deficiency	2	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>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	3	0
Arthropathy	4	0
Palindromic rheumatism	1	0
<i><b>Bone disorders NEC</b></i>		
Osteitis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	2	0
Pain in jaw	2	0
Spinal pain	2	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	2	0
<i><b>Connective tissue disorders NEC</b></i>		
Mixed connective tissue disease	1	0
Reynold's syndrome	1	0
Sjogren's syndrome	1	0
<i><b>Extremity deformities</b></i>		
Hand deformity	1	0
<i><b>Joint related disorders NEC</b></i>		
Hypermobility syndrome	6	0
Joint contracture	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	107	0
Joint noise	1	0
Joint stiffness	4	0
Joint swelling	18	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
<i><b>Metabolic bone disorders</b></i>		
Osteoporosis	1	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	1	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	12	0
Myalgia	100	0
Myalgia intercostal	1	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle discomfort	2	0
Muscle fatigue	5	0
Muscle spasms	13	0
Muscle swelling	1	0
Muscle tightness	3	0
Muscle twitching	21	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	15	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	46	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Growth retardation	2	0
Mobility decreased	4	0
Muscle contracture	1	0
Musculoskeletal stiffness	59	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Weight bearing difficulty	2	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	40	0
Flank pain	2	0
Growing pains	1	0
Limb discomfort	151	0
Musculoskeletal chest pain	3	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	34	0
Pain in extremity	840	0
<b><i>Rheumatoid arthropathies</i></b>		
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	4	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	1	0
Groin pain	3	0
Neck mass	1	0
Soft tissue disorder	1	0
<b><i>Spine and neck deformities</i></b>		
Scoliosis	2	0
<b><i>Spondyloarthropathies</i></b>		
Arthritis reactive	1	0
<b><i>Tendon disorders</i></b>		
Tendon pain	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>1540</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Bladder neoplasms malignant</i>		
Bladder cancer	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Pituitary tumour	1	0
<i>Glial tumours malignant</i>		
Medulloblastoma	1	0
<i>Hepatobiliary neoplasms benign</i>		
Focal nodular hyperplasia	1	0
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	0
<i>Leukaemias chronic myeloid</i>		
Chronic myeloid leukaemia	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	1
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	1
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Salivary gland neoplasms malignant</i>		
Salivary gland cancer stage I	1	0
<i>Skin neoplasms benign</i>		
Anogenital warts	2	0
Melanocytic naevus	1	0
Skin papilloma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>15</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Abnormal reflexes</i></b>		
Areflexia	5	0
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	4	0
<b><i>Acute polyneuropathies</i></b>		
Guillain-Barre syndrome	4	0
<b><i>Autonomic nervous system disorders</i></b>		
Autonomic nervous system imbalance	6	0
<b><i>Central nervous system vascular disorders NEC</i></b>		
Cerebrovascular disorder	1	0
<b><i>Chronic polyneuropathies</i></b>		
Demyelinating polyneuropathy	1	0
<b><i>Coordination and balance disturbances</i></b>		
Ataxia	1	0
Balance disorder	13	0
Coordination abnormal	1	0
Dysstasia	11	0
<b><i>Cortical dysfunction NEC</i></b>		
Agnosia	1	0
Aphasia	4	0
Dyspraxia	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Altered state of consciousness	2	0
Consciousness fluctuating	3	0
Depressed level of consciousness	1	0
Lethargy	120	0
Loss of consciousness	64	0
Sedation	1	0
Somnolence	96	0
Syncope	489	0
<b><i>Disturbances in sleep phase rhythm</i></b>		
Circadian rhythm sleep disorder	1	0
Irregular sleep wake rhythm disorder	2	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Clumsiness	2	0
Dyskinesia	23	0
Hypokinesia	7	0
Movement disorder	1	0
Psychomotor hyperactivity	4	0
<b><i>Dystonias</i></b>		
Dystonia	1	0
Opisthotonus	1	0
<b><i>Encephalitis NEC</i></b>		
Encephalitis autoimmune	3	0
<b><i>Eye movement disorders</i></b>		
IVth nerve paralysis	1	0
VIth nerve paralysis	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	6	0
Facial paralysis	5	0
Facial paresis	1	0
Facial spasm	1	0
<b><i>Generalised tonic-clonic seizures</i></b>		



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Generalised tonic-clonic seizure	10	0
<b>Headaches NEC</b>		
Cluster headache	2	0
Headache	1138	0
Tension headache	1	0
<b>Increased intracranial pressure disorders</b>		
Intracranial pressure increased	1	0
<b>Memory loss (excl dementia)</b>		
Amnesia	7	0
Memory impairment	14	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	8	0
Disturbance in attention	25	0
Mental impairment	2	0
<b>Migraine headaches</b>		
Migraine	47	0
Migraine with aura	1	0
Migraine without aura	3	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	1	0
<b>Muscle tone abnormal</b>		
Hypertonia	1	0
Hypotonia	2	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	3	0
Hypersomnia	9	0
Narcolepsy	5	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	1	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	1446	0
Dizziness postural	18	0
Drooling	1	0
Head discomfort	10	0
Meningism	1	0
Myoclonus	2	0
Neurological symptom	1	0
Presyncope	35	0
Slow response to stimuli	3	0
Unresponsive to stimuli	23	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	2	0
<b>Olfactory nerve disorders</b>		
Parosmia	2	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	2	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	3	0
Hyperaesthesia	4	0
Hypoaesthesia	248	0
Paraesthesia	146	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	3	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Hemiparesis	4	0
Monoparesis	1	0
Monoplegia	4	0
Paralysis	6	0
Quadriparesis	1	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Reduced facial expression	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Peripheral sensory neuropathy	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Clonic convulsion	1	0
Epilepsy	10	0
Myoclonic epilepsy	1	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	79	0
Seizure anoxic	4	0
Seizure like phenomena	2	0
Status epilepticus	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	1	0
Complex regional pain syndrome	6	0
Dysgeusia	7	0
Electric shock sensation	1	0
Neuralgia	1	0
Sensory disturbance	11	0
Sensory loss	14	0
Taste disorder	3	0
<b><i>Sleep disturbances NEC</i></b>		
Sudden onset of sleep	2	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	12	0
Incoherent	3	0
Speech disorder	8	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	1	0
Spinal cord oedema	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	112	0
<b>Nervous system disorders SOC TOTAL</b>	<b>4422</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	15	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	5	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	5	0
<i>Unintended pregnancies</i>		
Pregnancy with injectable contraceptive	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	3	0
Behaviour disorder	1	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	4	0
Anxiety	31	0
Nervousness	17	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	5	0
Disturbance in social behaviour	1	0
Indifference	1	0
Paranoia	1	0
Personality change	3	0
Social avoidant behaviour	2	0
<b><i>Bipolar disorders</i></b>		
Bipolar disorder	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	17	0
Disorientation	15	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	1	0
<b><i>Depressive disorders</i></b>		
Depression	14	0
<b><i>Dissociative states</i></b>		
Dissociation	2	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	25	0
Middle insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	3	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	1	0
Emotional disorder	8	0
Emotional distress	6	0
Emotional poverty	1	0
Euphoric mood	1	0
Irritability	1	0
Mood altered	2	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Autophobia	1	0
Fear	3	0
Fear of crowded places	1	0
Social anxiety disorder	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	2	0
<b><i>Hallucinations (excl sleep-related)</i></b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <sup>Psychiatric disorders cont'd</sup>		
Hallucination	9	0
Hallucination, auditory	3	0
Hallucination, visual	1	0
<b>Impulse control disorders</b>		
Impulse-control disorder	1	0
<b>Increased physical activity levels</b>		
Restlessness	1	0
<b>Mental disorders NEC</b>		
Mental disorder	1	0
<b>Mood alterations with depressive symptoms</b>		
Decreased interest	2	0
Depressed mood	6	0
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	1	0
Negative thoughts	1	0
Tearfulness	18	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	1	0
<b>Mood disorders NEC</b>		
Apathy	1	0
Listless	2	0
<b>Narcolepsy and associated conditions</b>		
Sleep attacks	1	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Obsessive thoughts	1	0
<b>Panic attacks and disorders</b>		
Panic attack	22	0
Panic reaction	5	0
<b>Parasomnias</b>		
Abnormal dreams	1	0
Abnormal sleep-related event	1	0
<b>Perception disturbances NEC</b>		
Illusion	1	0
<b>Personality disorders NEC</b>		
Self esteem decreased	2	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	1	0
<b>Psychiatric symptoms NEC</b>		
Psychiatric symptom	1	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic disorder	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	10	0
<b>Somatic symptom disorders</b>		
Somatic symptom disorder	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	1	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	2	0
<b>Stereotypies and automatisms</b>		
Bruxism	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Head banging	1	0
<b><i>Stress disorders</i></b>		
Burnout syndrome	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Intentional self-injury	2	0
Self-injurious ideation	1	0
Suicidal ideation	3	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	2	0
Thinking abnormal	2	0
Thought blocking	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>298</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 pain	1	0
Bladder spasm	1	0
Dysuria	1	0
Incontinence	1	0
Micturition urgency	2	0
Pollakiuria	5	0
Urinary incontinence	9	0
Urinary retention	2	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	2	0
Bladder fibrosis	1	0
Bladder mass	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
IgA nephropathy	1	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Contracted bladder	1	0
Hypertonic bladder	1	0
Neurogenic bladder	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	1	0
<i><b>Renal failure and impairment</b></i>		
Renal failure	1	0
<i><b>Renal lithiasis</b></i>		
Nephrolithiasis	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>33</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	1	0
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	1	0
Breast pain	2	0
Breast swelling	1	0
Breast tenderness	2	0
<i><b>Cervix infections and inflammations</b></i>		
Cervix inflammation	1	0
<i><b>Menopausal effects NEC</b></i>		
Premature menopause	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	10	0
Intermenstrual bleeding	1	0
Menstrual disorder	7	0
Menstruation irregular	13	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	14	0
Menstruation delayed	4	0
Oligomenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	10	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	2	0
Polycystic ovaries	4	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovarian failure	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital pain	1	0
Pelvic pain	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	8	0
Vaginal mucosal blistering	1	0
Vulval disorder	1	0
Vulval ulceration	2	0
Vulvar dysplasia	1	0
Vulvovaginal disorder	1	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vaginal discharge	1	0
Vaginal lesion	1	0
Vulval oedema	2	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	2	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>101</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	97	0
Grunting	2	0
Hyperventilation	34	0
Hypopnoea	6	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Tachypnoea	2	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	13	0
Bronchospasm	1	0
Wheezing	17	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	25	0
Haemoptysis	2	0
Productive cough	2	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngeal oedema	4	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	3	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	16	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal oedema	1	0
Pharyngeal swelling	10	0
Tonsillar disorder	1	0
Tonsillar hypertrophy	2	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pneumothorax	1	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	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory disorder	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	4	0
Dry throat	5	0
Nasal obstruction	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	76	0
Rhinorrhoea	4	0
Sneezing	3	0
Throat irritation	15	0
Throat tightness	28	0
<i><b>Vascular pulmonary disorders NEC</b></i>		
Pulmonary arteriopathy	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>384</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	3	0
<b><i>Alopecias</i></b>		
Alopecia	21	0
Alopecia areata	3	0
Alopecia totalis	1	0
Diffuse alopecia	2	0
<b><i>Angioedemas</i></b>		
Angioedema	11	0
Circumoral oedema	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	57	0
Hyperhidrosis	56	0
Miliaria	1	0
Night sweats	2	0
<b><i>Bullous conditions</i></b>		
Blister	14	0
Erythema multiforme	5	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	2	0
Pain of skin	3	0
Scab	1	0
Skin discolouration	68	0
Skin disorder	3	0
Skin lesion	3	0
Skin reaction	8	0
Skin sensitisation	1	0
Skin warm	12	0
Yellow skin	2	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	1	0
Dermatitis allergic	13	0
Dermatitis contact	3	0
Dyshidrotic eczema	1	0
Eczema	7	0
Eczema vesicular	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	6	0
<b><i>Erythemas</i></b>		
Erythema	155	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	3	0
<b><i>Hyperkeratoses</i></b>		
Hyperkeratosis	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	3	0
Panniculitis	1	0
<b><i>Papulosquamous conditions</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Pityriasis lichenoides et varioliformis acuta	1	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	7	0
<b>Pigmentation changes NEC</b>		
Pigmentation disorder	1	0
<b>Pilar disorders NEC</b>		
Piloerection	1	0
Trichorrhexis	1	0
<b>Pruritus NEC</b>		
Pruritus	115	0
<b>Psoriatic conditions</b>		
Guttate psoriasis	1	0
Psoriasis	2	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	2	0
Petechiae	5	0
Purpura	2	0
<b>Pustular conditions</b>		
Rash follicular	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	301	0
Rash erythematous	14	0
Rash macular	54	0
Rash maculo-papular	4	0
Rash papular	2	0
Rash pruritic	44	0
Rash vesicular	1	0
Systemic lupus erythematosus rash	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Skin mass	2	0
<b>Skin haemorrhages</b>		
Skin haemorrhage	1	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Skin hypoplasias and atrophies</b>		
Skin striae	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	17	0
<b>Urticarias</b>		
Urticaria	130	0
Urticaria chronic	3	0
<b>Skin disorders SOC TOTAL</b>	<b>1195</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Puberty	1	0
<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	4	0
<i>Educational issues</i>		
Educational problem	2	0
<b>Social circumstances SOC TOTAL</b>	<b>13</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	5	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	4	0
<i>Vascular therapeutic procedures NEC</i>		
Vasodilation procedure	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	6	0
Peripheral circulatory failure	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	3	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Peripheral venous disease	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	3	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	23	0
Erythromelalgia	1	0
Flushing	90	0
Hot flush	11	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	71	0
Poor peripheral circulation	6	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	215	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	8	0
<i>Vascular hypotensive disorders</i>		
Hypotension	23	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>472</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>15057</b>	<b>3</b>
<b>TOTAL REPORTS</b>	<b>6340</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>3</b>