Case Series Drug Analysis Print Name: Human Papillomavirus (HPV) Vaccine Analysis Print

Report Run Date: 17-May-2024

Data Lock Date: 16-May-2024 18:30:03

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 27.0

Human Papillomavirus Human Papillomavirus Vaccine Analysis Print for

(HPV) Vaccine reports received up to 16th of May 2024

Ànalysis Print:

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Edillest Reaction Date. 05-May-2000 MedDRA Version. MedDRA		
Reaction Name	Total_	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia vitamin B12 deficiency	2	0
Iron deficiency anaemia	1	0
Pernicious anaemia	1	0
Anaemias NEC		
Anaemia	11	0
Anaemias haemolytic mechanical factor		
Haemolytic uraemic syndrome	1	0
Bleeding tendencies		
Increased tendency to bruise	5	0
Coagulopathies		
Coagulopathy	2	0
Eosinophilic disorders		
Eosinophilia	1	0
Haematological disorders		
Blood disorder	1	0
Mast cell activation syndrome	6	0
Lymphatic system disorders NEC		
Lymph node pain	3	0
Lymphadenitis	1	0
Lymphadenopathy	72	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Pancytopenia	1	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	3	0
Spleen disorders		
Splenomegaly	3	0
Thrombocytopenias		
Immune thrombocytopenia	10	0
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	129	0

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Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac conduction disorders		
Atrioventricular block	1	0
Bundle branch block right	1	0
Cardiac disorders NEC		
Cardiac disorder	4	0
Cardiac signs and symptoms NEC		
Palpitations	65	0
Ischaemic coronary artery disorders		
Angina pectoris	3	0
Noninfectious pericarditis		
Pericarditis lupus	1	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Pulmonary valvular disorders		
Pulmonary valve stenosis	2	0
Rate and rhythm disorders NEC		
Arrhythmia	3	0
Bradycardia	7	0
Postural orthostatic tachycardia syndrome	88	0
Tachycardia	53	0
Supraventricular arrhythmias		
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	8	0
Supraventricular tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	4	2
Pulseless electrical activity	1	0
Cardiac disorders SOC TOTAL	245	2

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Reaction Name	_ Total_	<u>Fatal</u>
Congenital disorders		
Anorectal disorders congenital		
Preternatural anus	2	C
Cardiac septal defects congenital		
Atrioventricular septal defect	2	C
Cerebral disorders congenital		
Cerebral palsy	1	C
Congenital disorders NEC		
Congenital anomaly	1	C
VACTERL syndrome	2	C
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	12	C
Hypermobility syndrome	10	C
Great vessel disorders congenital	_	_
Double outlet right ventricle	2	C
Inborn errors of bilirubin metabolism		_
Gilbert's syndrome	1	C
Male reproductive tract disorders congenital		_
Hypospadias	1	C
Musculoskeletal and connective tissue disorders of limbs congenital		
Limb hypoplasia congenital	2	C
Limb reduction defect	2	C
Talipes	1	C
Musculoskeletal and connective tissue disorders of spine congenital		
Congenital musculoskeletal disorder of spine	2	C
Non-site specific bone disorders congenital		_
Osteopetrosis	1	C
Ocular disorders congenital NEC	1	_
Colour blindness	'	C
Oral cavity disorders congenital NEC Tethered oral tissue	2	C
		C
Palate disorders congenital Cleft palate	1	C
High arched palate		C
Pulmonary and bronchial disorders congenital	'	
Pulmonary and bioricinal disorders congenital Pulmonary aplasia	2	C
Pulmonary hypoplasia	2	C
Renal disorders congenital		
Congenital cystic kidney disease	2	C
Skin and subcutaneous tissue disorders congenital NEC		
Birth mark	1	C
Congenital skin dimples	2	C
Ichthyosis	1	C
Sebaceous naevus	1	C
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	C
Congenital disorders SOC TOTAL	59	C

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	4	0
Ear pain	19	0
Eustachian tube disorders		
Eustachian tube dysfunction	1	0
Hearing disorders NEC		
Auditory disorder	1	0
Hearing losses		
Deafness	17	0
Deafness bilateral	1	0
Deafness transitory	4	0
Hypoacusis	23	0
Hyperacusia		
Hyperacusis	27	0
Inner ear disorders NEC		
Inner ear disorder	1	0
Vestibular disorder	1	0
Inner ear signs and symptoms		
Motion sickness	3	0
Tinnitus	17	0
Vertigo	16	0
Ear disorders SOC TOTAL	135	0

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Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	6	0
Thyroiditis acute	1	0
Adrenal cortical hypofunctions		
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	2	0
Endocrine abnormalities of gonadal function NEC		
Oestrogen deficiency	1	0
Endocrine abnormalities of puberty		
Delayed puberty	1	0
Endocrine disorders NEC		
Endocrine disorder	1	0
Female gonadal function disorders		
Polycystic ovarian syndrome	5	0
Hypothalamic and pituitary disorders NEC		
Lymphocytic hypophysitis	1	0
Posterior pituitary disorders		
Diabetes insipidus	1	0
Thyroid disorders NEC		
Autoimmune thyroid disorder	1	0
Goitre	1	0
Thyroid disorder	1	0
Thyroid hyperfunction disorders		
Graves' disease	1	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	2	0
Hypothyroidism	11	0
Endocrine disorders SOC TOTAL	l 38	ol

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	4	0
Colour blindness (incl acquired)		
Dyschromatopsia	2	0
Conjunctival infections, irritations and inflammations		
Conjunctival hyperaemia	2	0
Eyelid movement disorders		
Blepharospasm	3	0
Excessive eye blinking	2	0
Eyelid ptosis	3	0
Glaucomas (excl congenital)		
Glaucoma	1	0
Iris and ciliary body structural change, deposit and degeneration		
Iris adhesions	1	0
Iris and uveal tract infections, irritations and inflammations		
Iritis	1	0
Uveitis	1	0
Lacrimation disorders		
Dry eye	2	0
Lacrimation increased	3	0
Lid, lash and lacrimal infections, irritations and inflammations		
Eyelid oedema	1	0
Eyelid rash	1	0
Swelling of eyelid	20	0
Ocular disorders NEC		
Dark circles under eyes	4	0
Eye disorder	6	0
Eye pain	27	0
Eye swelling	40	0
Eyelid disorder	1	0
Eyelids pruritus	1	0
Ocular discomfort	1	0
Periorbital oedema	2	0
Periorbital pain	1	
Periorbital swelling	3	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	1	0
Eye discharge	2	0
Eye inflammation	1	0
Eye irritation	2	0
Eye pruritus	7	0
Ocular hyperaemia	11	0
Ocular nerve and muscle disorders		
Eye movement disorder	40	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Oculogyric crisis	1	0
Ophthalmoplegia	3	
Strabismus	2	0
Ocular sensation disorders		
Abnormal sensation in eye	1	0
Asthenopia	3	
Foreign body sensation in eyes	1	ő

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Photophobia	63	0
Optic disc abnormalities NEC		
Optic disc disorder	1	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	1	0
Pupil disorders		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	4	0
Pupillary disorder	1	0
Pupillary reflex impaired	1	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	1	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	1	0
Retinal, choroid and vitreous infections and inflammations		
Choroiditis	1	0
Retinal vasculitis	1	0
Visual disorders NEC		
Diplopia	14	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	7	0
Vision blurred	168	0
Visual field disorders		
Visual field defect	8	0
Visual impairment and blindness (excl colour blindness)		
Blindness	16	0
Blindness transient	22	0
Blindness unilateral	1	0
Visual acuity reduced	1	0
Visual impairment	81	0
Eve disorders SOC TOTAL	633	

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Gastrointestinal disorders		
Acute and chronic pancreatitis		
Pancreatitis	1	0
Anal and rectal disorders NEC		
Anal fissure	1	0
Colitis (excl infective)		
Colitis	2	0
Colitis ulcerative	4	0
Crohn's disease	3	0
Dental disorders NEC		
Tooth erosion	1	0
Diaphragmatic hernias		
Hiatus hernia	1	0
Diarrhoea (excl infective)		
Diarrhoea	151	0
Diarrhoea haemorrhagic	2	0
Dyspeptic signs and symptoms		
Dyspepsia	12	0
Eructation	2	0
Faecal abnormalities NEC		
Abnormal faeces	1	0
Flatulence, bloating and distension		
Abdominal distension	17	0
Flatulence	3	0
Gastric and oesophageal haemorrhages		
Oesophageal haemorrhage	1	0
Gastric ulcers and perforation		
Gastric ulcer	1	0
Gastritis erosive	1	0
Gastritis (excl infective)		
Chronic gastritis	1	0
Gastritis	7	0
Reflux gastritis	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	1	0
Abdominal pain	219	0
Abdominal pain lower	19	
Abdominal pain upper	210	
Abdominal rigidity	2	0
Abdominal tenderness	3	
Gastrointestinal pain	2	0
Oesophageal pain	1	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	19	0
Gastric dilatation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	16	
Impaired gastric emptying	5	0
Gastrointestinal disorders NEC		
Functional gastrointestinal disorder	2	0
Gastrointestinal disorder	24	
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	1	0
Dyschezia	1	0

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Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders	cont'd	
Gastrointestinal motility disorder		2 0
Gastrointestinal inflammatory disorders NE	EC	
Duodenitis		1 0
Gastrointestinal inflammation		3 0
Gastrointestinal mucosal dystrophies and	secretion disorders	
Oesophageal mucosal hyperplasia		1 0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	5	6 0
Dysphagia	2	7 0
Odynophagia		2 0
Oesophageal discomfort		1 0
Gastrointestinal spastic and hypermotility of	disorders	
Defaecation urgency		1 0
Frequent bowel movements		3 0
Irritable bowel syndrome	2	3 0
Gastrointestinal ulcers and perforation, site	e unspecified	
Gastrointestinal ulcer		1 0
Gingival disorders, signs and symptoms N	EC	
Gingival disorder		1 0
Gingival pain		2 0
Gingival swelling		1 0
Gingival ulceration		1 0
Gingival haemorrhages		
Gingival bleeding		1 0
Haemorrhoids and gastrointestinal varices	(excl oesophageal)	
Haemorrhoids	` ' ' '	1 ol
Inguinal hernias		
Inguinal hernia		2 0
Intestinal haemorrhages		
Rectal haemorrhage		2 0
Malabsorption syndromes		
Bile acid malabsorption		1 0
Coeliac disease	1	3 0
Malabsorption		2 0
Nausea and vomiting symptoms		
Cyclic vomiting syndrome		1 ol
Nausea	176	6 0
Regurgitation		1 0
Retching		8l ol
Vomiting	77	7 ol
Vomiting projectile		2 0
Non-site specific gastrointestinal haemorrh	nages	
Gastrointestinal haemorrhage		1 o
Haematemesis		6l ol
Haematochezia		1 o
Oesophagitis (excl infective)		
Eosinophilic oesophagitis		1 ol
Oral dryness and saliva altered		
Dry mouth		6 0
Lip dry		1 0
Saliva altered		1 0
Salivary hypersecretion		3 0
Oral soft tissue disorders NEC		

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Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Chapped lips	1	0
Cheilitis	1	0
Lip blister	3	0
Uvulitis	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	9	0
Lip erythema	1	0
Lip pain	1	0
Oral discomfort	3	0
Oral mucosal blistering	3	0
Oral mucosal eruption	1	0
Oral pain	6	0
Oral pruritus	2	0
Paraesthesia oral	41	0
Oral soft tissue swelling and oedema		
Lip swelling	68	0
Mouth swelling	8	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Peritoneal and retroperitoneal disorders		
Intra-abdominal fluid collection	1	0
Stomatitis and ulceration		
Lip ulceration	2	0
Mouth ulceration	13	0
Tongue disorders		
Glossitis	1	0
Tongue ulceration	1	0
Tongue signs and symptoms		
Glossodynia	2	0
Swollen tongue	33	0
Tongue coated	2	0
Tongue discomfort	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	3670	

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General disorders	Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 27.0	
Administration site reactions NEC Administration site pain 1 Administration site swelling 1 Puncture site reaction 1 Asthenic conditions 144 Asthenia 195 Chronic fatigue syndrome 144 Decreased activity 2 Fatigue 828 Malaise 799 Body temperature altered 15 Temperature regulation disorder 15 Injury associated with device NEC 1 Injury associated with device NEC	Reaction Name	Total	<u>Fatal</u>
Administration site swelling Administration site swelling Puncture site reaction Asthenic conditions Asthenia Chronic fatigue syndrome Decreased activity Fatigue Bags Malaise Malais	General disorders		
Administration site swelling Puncture site reaction Asthenia	Administration site reactions NEC		
Puncture site reaction	Administration site pain		1 0
Puncture site reaction	Administration site swelling		1 0
Asthenia 195 0 Chronic fatigue syndrome 1144 0 Decreased activity 2 2 0 Fatigue 828 0 Malaise 799 0 Body temperature altered 15 0 Temperature regulation disorder 15 0 Complications associated with device NEC Injury associated with device NEC Injury associated with device Death and sudden death Death 1 1 1 Febrile disorders 1 1 0 Febrile disorders 1 1 0 Febrile disorders 1 1 0 Feelings and sensations NEC Chills 1 115 0 Feeling abnormal 54 54 Feeling cold 83 0 Feeling cold 83 0 Feeling drunk 5 0 Feeling fittery 5 0 Feeling ittery 5 0 Feeling ittery 5 0 Feeling of body temperature change 26 0 Sensation of foreign body 7 0 Temperature intolerance 7 0 Trinist 8 0 Gait disturbances Gait inability 29 0 Gait disturbance 35 0 Gait disturbance 35 0 Gait disturbance 35 0 Gait anability 29 0 Loss of control of legs General signs and symptoms NEC Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Glassy eyes 11I-defined disorder 110 0 Influenza like illness 127 0 Influenza like i			1 o
Asthenia 195 0 Chronic fatigue syndrome 1144 0 Decreased activity 2 2 0 Fatigue 828 0 Malaise 799 0 Body temperature altered 15 0 Temperature regulation disorder 15 0 Complications associated with device NEC Injury associated with device NEC Injury associated with device Death and sudden death Death 1 1 1 Febrile disorders 1 1 0 Febrile disorders 1 1 0 Febrile disorders 1 1 0 Feelings and sensations NEC Chills 1 115 0 Feeling abnormal 54 54 Feeling cold 83 0 Feeling cold 83 0 Feeling drunk 5 0 Feeling fittery 5 0 Feeling ittery 5 0 Feeling ittery 5 0 Feeling of body temperature change 26 0 Sensation of foreign body 7 0 Temperature intolerance 7 0 Trinist 8 0 Gait disturbances Gait inability 29 0 Gait disturbance 35 0 Gait disturbance 35 0 Gait disturbance 35 0 Gait anability 29 0 Loss of control of legs General signs and symptoms NEC Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Glassy eyes 11I-defined disorder 110 0 Influenza like illness 127 0 Influenza like i			
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Complications associated with device 1 Death and sudden death 1 Death and sudden death 1 Death 1 Febrile disorders 1 Hyperpyrexia 2 Pyrexia 610 Feelings and sensations NEC 610 Chills 115 Feeling abnormal 54 Feeling cold 83 Feeling drunk 5 Feeling jittery 5 Feeling of body 223 Feeling of body temperature change 26 Sensation of foreign body 3 Temperature intolerance 7 Thirst 8 Gait disturbances 35 Gait disturbance 35 Gait disturbance 35 Gait inability 29 Loss of control of legs 5 General signs and symptoms NEC 5 Condition aggravated 16 Crying 13 Disease recurrence 1 Exercise tolerance de		1:	5l ol
Injury associated with device Death and sudden death Deat			
Death and sudden death 1 1 Febrile disorders Hyperpyrexia 2 0 Pyrexia 610 0 Feelings and sensations NEC 115 0 Chills 54 0 Feeling abnormal 54 0 Feeling cold 83 0 Feeling drunk 5 0 Feeling jittery 5 0 Feeling of body temperature change 26 0 Sensation of foreign body 3 0 Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 35 0 Gait disturbance 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 16 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased			1 0
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Febrile disorders 2 0 Hyperpyrexia 2 0 Prevings and sensations NEC 610 0 Chills 115 0 Feeling abnormal 54 0 Feeling cold 83 0 Feeling furnk 5 0 Feeling hot 223 0 Feeling of body temperature change 26 0 Sensation of foreign body 3 0 Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0			1 1
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Pyrexia Feelings and sensations NEC			ا ا
Feelings and sensations NEC 115 0 Chills 54 0 Feeling abnormal 54 0 Feeling cold 83 0 Feeling drunk 5 0 Feeling jittery 5 0 Feeling of body temperature change 26 0 Sensation of foreign body 3 0 Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 8 0 Gait disturbances 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 29 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Ill-defined disorder			_
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Feeling drunk 5 0 Feeling hot 223 0 Feeling jittery 5 0 Feeling of body temperature change 26 0 Sensation of foreign body 3 0 Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 8 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 29 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Glassy eyes 2 0 Ill-defined disorder 7 0 Illness 105 0 Induration 4 0 Influenza like illness 10			
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Feeling jittery 5 0 Feeling of body temperature change 26 0 Sensation of foreign body 3 0 Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 5 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Glassy eyes 2 0 Ill-defined disorder 7 0 Illness 105 0 Induration 4 0 Influenza like illness 127 0 Local reaction 32 0 Multiple organ dysfunction syndrome			-
Feeling of body temperature change 26 0 Sensation of foreign body 3 0 Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 5 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Glassy eyes 2 0 Ill-defined disorder 7 0 Illness 105 0 Induration 4 0 Influenza like illness 127 0 Local reaction 32 0 Multiple organ dysfunction syndrome 1 0 Organ failure			
Sensation of foreign body 3 0 Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 5 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Glassy eyes 2 0 Ill-defined disorder 7 0 Illness 105 0 Induration 4 0 Influenza like illness 127 0 Local reaction 32 0 Multiple organ dysfunction syndrome 1 0 Organ failure 1 0 Peripheral swelling 370 <td></td> <td></td> <td></td>			
Temperature intolerance 7 0 Thirst 8 0 Gait disturbances 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC			
Thirst 8 0 Gait disturbances 35 0 Gait inability 29 0 Loss of control of legs 5 0 General signs and symptoms NEC 5 0 Condition aggravated 16 0 Crying 13 0 Disease recurrence 1 0 Exercise tolerance decreased 7 0 Foaming at mouth 4 0 General physical health deterioration 2 0 Glassy eyes 2 0 Ill-defined disorder 7 0 Illness 105 0 Induration 4 0 Influenza like illness 127 0 Local reaction 32 0 Multiple organ dysfunction syndrome 1 0 Organ failure 1 0 Peripheral swelling 370 0			
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Multiple organ dysfunction syndrome10Organ failure10Peripheral swelling3700			
Organ failure 1 0 Peripheral swelling 370 0			
Peripheral swelling 370 0			
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	Screaming		
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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 27.0	Total	Cotal
Reaction Name General disorders General disorders cont'd	Total	Fatal
Corroral alcoration	0.5	
Swelling face	95	0
Healing abnormal NEC	0	0
Impaired healing	2	0
Hernias NEC	0	_
Hernia	2	0
Inflammations	0.4	_
Inflammation	24	0
Serositis	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		_
Infusion site hypoaesthesia	1	0
Injection site reactions	_	
Injected limb mobility decreased	5	0
Injection site bruising	29	0
Injection site coldness	4	0
Injection site discharge	3	0
Injection site discolouration	6	0
Injection site discomfort	3	0
Injection site erythema	127	0
Injection site granuloma	1	0
Injection site haemorrhage	5	0
Injection site hypoaesthesia	16	0
Injection site induration	11	0
Injection site inflammation	28	0
Injection site injury	1	0
Injection site irritation	6	0
Injection site joint movement impairment	1	0
Injection site joint pain	3	0
Injection site mass	68	0
Injection site movement impairment	3	0
Injection site nerve damage	1	0
Injection site nodule	8	0
Injection site oedema	1 1	0
Injection site pain	151	0
Injection site papule	1	0
Injection site paraesthesia	2	0
Injection site pruritus	29	0
Injection site rash	52	0
Injection site reaction	36	0
Injection site scab	2	0
Injection site scar	1	0
Injection site swelling	176	0
Injection site urticaria	6	0
Injection site vesicles	5	0
Injection site warmth	28	0
Interactions		
Drug interaction	1	0
Mass conditions NEC		
Cyst	1	0
Mass	5	0
Nodule	2	0
Mucosal findings abnormal		
Mucosal ulceration	1	0

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Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 27.0	
Reaction Name	Total	<u>Fatal</u>
General disorders General disorders cont'd		
Oedema NEC		
Face oedema	5	0
Localised oedema	1	0
Oedema peripheral	12	2 0
Pain and discomfort NEC		
Axillary pain	5	0
Chest discomfort	73	
Chest pain	120	
Discomfort	28	
Facial pain	4	0
Non-cardiac chest pain	3	
Pain ·	292	2 0
Tenderness	21	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	25	
Adverse event	1	0
Adverse reaction	3	
Drug ineffective	3	
Drug ineffective for unapproved indication	1	0
Drug resistance	1	0
Immediate post-injection reaction	1	0
Therapeutic product effective for unapprov	red indication 1	0
Therapeutic response unexpected	1	0
Vaccination failure	3	s o
Trophic disorders		
Atrophy	1	0
Hyperplasia	1	0
Precancerous condition	1	0
Ulcers NEC		
Ulcer	3	s ol
Vaccination site reactions		
Extensive swelling of vaccinated limb	3	s ol
Vaccination site atrophy	1	0
Vaccination site bruising	6	
Vaccination site coldness	1	ا ا
Vaccination site discolouration	2	
Vaccination site discomfort	2	2 0
Vaccination site erythema	13	s o
Vaccination site haemorrhage	2	1
Vaccination site hypersensitivity	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	1	0
Vaccination site inflammation	3	
Vaccination site irritation	1	0
Vaccination site joint movement impairment	nt 1	0
Vaccination site joint pain	1	0
Vaccination site mass	11	
Vaccination site movement impairment	3	
Vaccination site nerve damage		0
Vaccination site nodule	1	0
Vaccination site pain	41	-
Vaccination site paraesthesia	1	
Vaccination site pruritus	5	

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site rash	3	0
Vaccination site swelling	23	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	5681	1

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Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	5	0
Hepatic and hepatobiliary disorders NEC		
Hepatic cyst	1	0
Liver disorder	3	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	2	0
Hepatobiliary signs and symptoms		
Hepatic pain	1	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	2	0
Hepatitis	3	0
Hepatitis acute	1	0
Obstructive bile duct disorders (excl neoplasms)		
Sphincter of Oddi dysfunction	1	0
Hepatic disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergic oedema	1	0
Allergy to animal	3	0
Hypersensitivity	89	0
Multiple allergies	6	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	3	0
Type IV hypersensitivity reaction	2	0
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	2	0
Food allergy	6	0
Oral allergy syndrome	1	0
Reaction to excipient	3	0
Reaction to preservatives	1	0
Reaction to sweetener	1	0
Rubber sensitivity	2	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	105	0
Anaphylactic shock	7	0
Anaphylactoid reaction	3	0
Atopic disorders		
Seasonal allergy	1	0
Autoimmune disorders NEC		
Autoimmune disorder	13	0
Overlap syndrome	1	0
Immune and associated conditions NEC		
Decreased immune responsiveness	1	0
Immune system disorder	11	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	265	0

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	MedDRA Version: MedDRA 27.0		
Reaction Name	Tota		atal
Infections		+	
Abdominal and gastrointestinal infections		4	0
Abdominal abscess		1	0
Appendicitis		3	0
Appendicitis perforated		1	0
Gastroenteritis		1	0
Gastrointestinal infection Peritonitis		1	0
Bacterial infections NEC		1	0
		1	0
Cellulitis		4	0
Folliculitis			0
Gastrointestinal bacterial overgrowth		2	0
Injection site cellulitis		4	U
Bone and joint infections		4	0
Osteomyelitis Breast infections		1	0
Mastitis Mastitis		4	0
		1	0
Candida infections			0
Candida infection		2	0
Vulvovaginal candidiasis			0
Central nervous system and spinal infections			0
Encephalitis		8	0
Encephalitis lethargica Subdural abscess		1	0
Coronavirus infections		-	U
COVID-19		7	0
Severe acute respiratory syndrome		1	0
Dental and oral soft tissue infections		1	U
Gingivitis		1	0
Ear infections		1	U
Ear infection		2	0
Labyrinthitis		2	0
Otitis media		1	0
Otitis media chronic		1	0
Ectoparasitic infestations			U
Acarodermatitis		1	0
Enteroviral infections NEC			Ŭ
Hand-foot-and-mouth disease		1	0
Epstein-Barr viral infections			Ŭ
Epstein-Barr virus infection		1	0
Infectious mononucleosis	1	1	0
Eye and eyelid infections			Ū
Conjunctivitis		3	0
Hordeolum		5	0
Female reproductive tract infections		Ĭ	Ŭ
Amniotic cavity infection		1	0
Pelvic inflammatory disease		1	0
Vaginal infection		1	0
Vulvovaginitis		1	0
Haemophilus infections			J
Haemophilus infection		1	0
Herpes viral infections		1	0
Genital herpes		1	0
Herpes simplex		1	0

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Infections Infections cont'd		
Herpes virus infection	1	0
Herpes zoster	21	0
Oral herpes	3	
Varicella	1	0
Infections NEC		
Infection	9	0
Infection susceptibility increased	7	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	1	0
Mucosal infection	1	0
Purulent discharge	1	0
Respiratory tract infection	2	0
Infectious transmissions		
Suspected transmission of an infectious agent via product	1	0
Influenza viral infections		
Influenza	7	0
Lower respiratory tract and lung infections		
Bronchitis	3	0
Lower respiratory tract infection	16	
Pneumonia	2	0
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	0
Papilloma viral infections		
Papilloma viral infection	8	0
Vulvovaginal human papilloma virus infection	1	0
Respiratory syncytial viral infections		
Respiratory syncytial virus infection	1	0
Retroviral infections		
Acquired immunodeficiency syndrome	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	1	0
Sepsis	3	0
Septic rash	1	0
Viraemia	1	0
Skin structures and soft tissue infections		
Application site pustules	1	0
Impetigo	1	0
Pustule	2	0
Skin infection	2	0
Staphylococcal infections		
Furuncle	4	0
Staphylococcal infection	2	0
Streptococcal infections		
Beta haemolytic streptococcal infection	2	0
Streptococcal sepsis	1	1
Upper respiratory tract infections		
Epiglottitis	1	0
Laryngitis	1	0
Nasopharyngitis	45	
Pharyngitis	8	
Sinusitis		
Tonsillitis	9	ő

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Upper respiratory tract infection	3	0
Urinary tract infections		
Kidney infection	1	0
Urinary tract infection	5	0
Viral infections NEC		
Gastroenteritis viral	3	0
Hepatitis viral	1	0
Meningitis viral	1	0
Pneumonia viral	1	0
Viral infection	20	0
Viral pharyngitis	1	0
Infections SOC TOTAL	293	1

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Injuries Abdominal and gastrointestinal injuries NEC Mouth injury 1 Bone and joint injuries NEC Joint injury 1 Chemical injuries Chemical burn 1 Exposures associated with pregnancy, delivery and lactation	0 0
Abdominal and gastrointestinal injuries NEC Mouth injury Bone and joint injuries NEC Joint injury Chemical injuries Chemical burn Exposures associated with pregnancy, delivery and lactation	0
Mouth injury Bone and joint injuries NEC Joint injury Chemical injuries Chemical burn Exposures associated with pregnancy, delivery and lactation	0
Bone and joint injuries NEC Joint injury 1 Chemical injuries Chemical burn 1 Exposures associated with pregnancy, delivery and lactation	0
Joint injury 1 Chemical injuries 1 Chemical burn 1 Exposures associated with pregnancy, delivery and lactation	0
Chemical injuries Chemical burn 1 Exposures associated with pregnancy, delivery and lactation	0
Chemical burn 1 Exposures associated with pregnancy, delivery and lactation	
Exposures associated with pregnancy, delivery and lactation	
Exposure during pregnancy 25	0
Foetal exposure during pregnancy 10	0
Maternal exposure before pregnancy 2	0
Maternal exposure during pregnancy 1	0
Maternal exposure timing unspecified 11	0
Fractures and dislocations NEC	
Joint dislocation 4	0
Medication errors, product use errors and issues NEC	
Circumstance or information capable of leading to medication error	0
Medication error 22	0
Wrong technique in product usage process 3	0
Muscle, tendon and ligament injuries	
Muscle injury 2	0
Nerve injuries NEC	
Nerve injury 4	0
Neurological and psychiatric procedural complications	
Procedural dizziness 2	0
Non-site specific injuries NEC	
Fall 20	0
Injury 3	0
Wound 1	0
Wound haemorrhage 1	0
Off label uses	
Off label use	0
Overdoses NEC	Ĭ
Intentional overdose	0
Overdose 1	0
Peripheral nerve injuries	
Axillary nerve injury 1	0
Peripheral nerve injury	0
Poisoning and toxicity	Ĭ
Metal poisoning 1	0
Poisoning 1	0
Product administration errors and issues	_
Expired product administered 6	0
Extra dose administered 5	0
Inappropriate schedule of product administration 17	0
Incorrect route of product administration 1	
Product administered at inappropriate site 4	0
Product administered to patient of inappropriate age 3	0
Wrong product administered 1	0
Reproductive tract and breast procedural complications	0
Failed in vitro fertilisation	0
Site specific injuries NEC	0
Face injury 1	0
Head injury 1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Skin injuries NEC		
Contusion	57	0
Dermatitis artefacta	1	0
Scar	3	0
Skin abrasion	1	0
Thermal burns		
Thermal burn	1	0
Vaccination related complications		
Immunisation reaction	9	0
Vaccination complication	1	0
Injuries SOC TOTAL	236	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 27.0		
Reaction Name	<u>Total</u>	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	1	0
Autoimmunity analyses		
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Blood counts NEC		
Full blood count abnormal	1	0
Blood gas and acid base analyses		
Blood pH increased	1	0
Oxygen saturation decreased	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	3	0
Blood glucose increased	7	0
Cardiac auscultatory investigations		ŭ
Cardiac murmur	1	0
Heart sounds abnormal	1	0
Cell marker analyses	1	Ŭ
Cell marker increased	1	0
Central nervous system imaging procedures		J
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		J
CSF cell count increased	1	0
Chemistry analyses NEC	1	J
Histamine level increased	2	0
ECG investigations		J
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	1	0
Endocrine analyses and imaging NEC		J
Hormone level abnormal	4	0
Foetal and neonatal diagnostic procedures		J
Foetal heart rate abnormal	1	0
Heart rate and pulse investigations		J
Heart rate abnormal	7	0
Heart rate decreased	10	0
Heart rate increased	61	0
Heart rate irregular	16	0
Pulse abnormal	9	0
Pulse absent	3	0
Pulse pressure decreased	1	0
Hepatobiliary function diagnostic procedures		J
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	1	0
Liver function test abnormal	1	0
Imaging procedures NEC		U
Positron emission tomogram abnormal	1	0
<u> </u>		U
Immunoglobulin analyses Blood immunoglobulin A increased	1	0
_		U
Immunology analyses NEC Immunology test	4	0
		U
Investigations NEC		

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 27.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Investigations Investigations cont'd		
Precancerous cells present	1	0
Quality of life decreased	3	0
Mineral and electrolyte analyses		
Blood iron decreased	6	0
Blood magnesium decreased	1	0
Blood selenium decreased	1	0
Blood sodium abnormal	1	0
Blood zinc decreased	1	0
Serum ferritin decreased	3	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Physical examination procedures and organ system status		
Body temperature	3	0
Body temperature abnormal	4	
Body temperature decreased	8	0
Body temperature fluctuation	8	0
Body temperature increased	108	Ô
Breath sounds abnormal	1	o o
Grip strength decreased	3	0
Respiratory rate decreased	1	o o
Respiratory rate increased	13	0
Weight decreased	30	l
Weight increased	5	0
Pituitary analyses anterior		Ĭ
Blood growth hormone abnormal	1	0
Blood thyroid stimulating hormone abnormal	1	0
Platelet analyses		J
Platelet count decreased	3	0
Protein analyses NEC	J	J
Blood albumin abnormal	1	0
C-reactive protein increased	2	0
Protein total abnormal	1	0
Reproductive hormone analyses		J
Anti-Muellerian hormone level decreased	1	0
Oestradiol decreased	1	0
Progesterone increased	1	0
Reproductive organ and breast histopathology procedures		J
Smear cervix	1	0
Smear cervix abnormal	1	0
Respiratory and pulmonary function diagnostic procedures	'	J
Peak expiratory flow rate decreased	1	0
Tissue enzyme analyses NEC	'	J
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses	'	
Blood chromium decreased	1	0
	'	
Urinalysis NEC	2	0
Blood urine present	2	0
Urinary tract function analyses NEC	4	_
Urine output decreased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure degreesed	12	0
Blood pressure decreased	12	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood pressure immeasurable	1	0
Blood pressure increased	8	0
Blood pressure systolic decreased	1	0
Virus identification and serology		
HIV test positive	1	0
Human papilloma virus test positive	1	0
Vitamin analyses		
Vitamin B12 decreased	1	0
Vitamin B12 increased	1	0
Vitamin D decreased	5	0
White blood cell analyses		
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
Investigations SOC TOTAL	405	0

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Reaction Name	_ Total_	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Appetite disorder	4	0
Decreased appetite	89	0
Hypophagia	3	0
Increased appetite	1	0
Salt craving	2	0
Calcium metabolism disorders		
Tetany	2	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus inadequate control	2	0
Type 1 diabetes mellitus	12	0
Diabetic complications NEC		
Diabetic ketoacidosis	3	0
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	12	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	2	0
Food intolerance	9	0
Gluten sensitivity	5	0
Histamine intolerance	2	0
General nutritional disorders NEC		
Abnormal loss of weight	31	0
Abnormal weight gain	1	0
Cachexia	1	0
Feeding disorder	7	0
Malnutrition	1	0
Underweight	1	0
Weight fluctuation	1	0
Weight gain poor	1	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	4	0
Insulin resistance	1	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	5	0
Iron deficiencies		
Iron deficiency	3	0
Metabolic acidoses (excl diabetic acidoses)		
Lactic acidosis	1	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mineral related disorders NEC		
Mineral deficiency	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	3	0
Total fluid volume decreased		
Dehydration	5	0
Vitamin deficiencies NEC		
Multi-vitamin deficiency	2	0
Water soluble vitamin deficiencies		
Vitamin B12 deficiency	8	0
Vitamin C deficiency	1	n
Metabolic disorders SOC TOTAL	227	Ö

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Reaction Name	Total	<u>Fatal</u>
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	7	0
Arthropathy	7	0
Palindromic rheumatism	1	0
Seronegative arthritis	1	0
Bone disorders NEC		Ĭ
Osteitis	1	0
Bone related signs and symptoms		Ĭ
Bone pain	11	0
Coccydynia	1	
Pain in jaw	6	
Spinal pain	7	
Bursal disorders	1	
Bursitis	1	0
		0
Cartilage disorders		
Costochondritis	2	1
Osteochondrosis	1	0
Connective tissue disorders NEC		
Mixed connective tissue disease		
Morphoea	1	
Reynold's syndrome	1	0
Sjogren's syndrome	1	0
Extremity deformities		
Finger deformity	1	_
Foot deformity	1	0
Hand deformity	1	0
Joint related disorders NEC		
Joint contracture	1	0
Joint lock	1	0
Periarthritis	3	0
Joint related signs and symptoms		
Arthralgia	270	0
Joint effusion	1	0
Joint noise	5	
Joint range of motion decreased	1	l 0
Joint stiffness	15	0
Joint swelling	37	
Ligament disorders		
Ligament pain	1	0
Lupus erythematosus (incl subtypes)		Ĭ
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	
Metabolic bone disorders		
Osteoporosis	1	0
Muscle infections and inflammations	· ·	
Myositis	2	. 0
Muscle pains	2	
Fibromyalgia	18	0
, -	193	1
Myalgia interceptal	193	0
Myalgia intercostal		
Muscle related signs and symptoms NEC		_
Facial myokymia	1	1
Muscle atrophy	2	<u> </u>

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Reaction Name		_Total_	<u>Fatal</u>
Muscle & tissue disorders e & tissue disorde	rs cont'd		
Muscle discomfort		2	0
Muscle fatigue		13	0
Muscle spasms		50	0
Muscle swelling		1	0
Muscle tightness		6	0
Muscle twitching		51	0
Trigger points		1	0
Muscle tone abnormalities			
Muscle rigidity		36	0
Trismus		2	0
Muscle weakness conditions			
Muscular weakness		130	0
Musculoskeletal and connective tissue of	onditions NEC		
Back disorder		2	0
Growth retardation		2 3	0
Mastication disorder		1	0
Mobility decreased		21	0
Muscle contracture		2	0
Musculoskeletal disorder		1	0
Musculoskeletal stiffness		107	0
Posture abnormal		1	0
Weight bearing difficulty		8	0
Musculoskeletal and connective tissue p	ain and discomfort	J	Ĭ
Back pain		98	0
Flank pain		2	0
Growing pains		2	0
Limb discomfort		185	0
Musculoskeletal chest pain		11	0
Musculoskeletal discomfort		4	0
Musculoskeletal pain		5	0
Neck pain		80	0
Pain in extremity		1138	0
Myopathies		1100	Ŭ
Myopathy		1	0
Psoriatic arthropathies			Ŭ
Psoriatic arthropathy		1	0
Rheumatoid arthropathies		· i	Ŭ
Juvenile idiopathic arthritis		4	0
Rheumatoid arthritis		5	0
Soft tissue disorders NEC		Ĭ	
Axillary mass		2	0
Groin pain		5	0
Neck mass		1	0
Soft tissue disorder		1	0
Spine and neck deformities			Ŭ
Scoliosis		3	0
Spondyloarthropathies		J	U
Arthritis reactive		4	0
Synovial disorders		4	U
Synovitis		1	0
Tendon disorders		l I	U
		1	0
Tendon pain		1	0
Tendonitis		1	C

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Reaction Name	Total	Fatal
Muscle & tissue disorders ent'd		
Muscle & tissue disorders SOC TOTAL	2603	0

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Neoplasms		
Bladder neoplasms malignant		
Bladder cancer	1	0
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	0
Cervix neoplasms malignant		
Cervix carcinoma	1	0
Cervix carcinoma stage 0	1	0
Endocrine neoplasms malignant and unspecified NEC		
Pituitary tumour	1	0
Glial tumours malignant		
Medulloblastoma	1	0
Hepatobiliary neoplasms benign		
Focal nodular hyperplasia	1	0
Islet cell neoplasms and APUDoma NEC		
Pancreatic neuroendocrine tumour metastatic	1	0
Kaposi's sarcomas		
Kaposi's sarcoma	1	0
Leukaemias acute NEC		
Acute leukaemia	1	0
Leukaemias acute lymphocytic		
Acute lymphocytic leukaemia	1	0
T-cell type acute leukaemia	1	1
Leukaemias acute myeloid		_
Acute myeloid leukaemia	1	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Metastases to specified sites		
Metastases to liver	1	0
Neoplasms malignant site unspecified NEC	·	
Neoplasm malignant	1	1
Neoplasms unspecified malignancy and site unspecified NEC	·	•
Neoplasm	1	0
Non-Hodgkin's lymphomas NEC	·	
Non-Hodgkin's lymphoma	1	1
Pharyngeal and laryngeal neoplasms benign	·	
Laryngeal papilloma	1	0
Reproductive neoplasms female benign NEC	·	
Benign hydatidiform mole	1	0
Reproductive neoplasms male benign NEC	·	
Penile wart	1	0
Respiratory tract and pleural neoplasms benign NEC		
Respiratory papilloma	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified		
NEC		
Throat cancer	1	0
Salivary gland neoplasms malignant		
Salivary gland cancer stage I	1	0
Skin neoplasms benign		
Anogenital warts	5	0
Melanocytic naevus	1	0
Skin papilloma	7	0
Uterine neoplasms benign	,	J
Uterine leiomyoma	1	0
Oterine leiomyoma		U

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Reaction Nar	ne	Total	Fatal
Neoplasms	Neoplasms cont'd		
Neoplasms SO	CTOTAL	38	3

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Reaction Name	_ Total_	Fatal
Nervous system disorders		
Abnormal reflexes		
Areflexia	6	0
Abnormal sleep-related events		
Sleep paralysis	1	0
Absence seizures		
Petit mal epilepsy	8	0
Acute polyneuropathies		
Guillain-Barre syndrome	9	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	12	0
Autonomic neuropathy	2	0
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia stroke	1	0
Brain stem stroke	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	4	0
Lacunar infarction	1	0
Central nervous system vascular disorders NEC		
Central nervous system vasculitis	1	0
Cerebrovascular disorder	1	0
Choreiform movements		
Chorea	1	0
Chronic polyneuropathies		_
Demyelinating polyneuropathy	1	0
Coordination and balance disturbances		_
Ataxia	5	0
Balance disorder	25	0
Cerebellar ataxia	1	0
Coordination abnormal	9	0
Dysstasia	19	0
Nystagmus	1	0
Cortical dysfunction NEC	·	Ŭ
Agnosia	1	0
Aphasia	11	0
Dyslexia	1	0
Dyspraxia	2	0
Demyelinating disorders NEC	_	J
Acute disseminated encephalomyelitis	1	0
Demyelination		0
Disturbances in consciousness NEC	· ·	J
Altered state of consciousness	4	0
Consciousness fluctuating	5	0
Depressed level of consciousness	8	0
Lethargy	220	0
Loss of consciousness	118	0
Sedation	110	0
Somnolence	176	0
Syncope	934	0
Disturbances in sleep phase rhythm	334	U
Circadian rhythm sleep disorder	1	0
Irregular sleep wake rhythm disorder	4	0
Dyskinesias and movement disorders NEC	4	U
Clumsiness	2	0
Ciumanicaa		U

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Reaction Name		<u>Total</u>	Fatal
Nervous system disorders us system disorders of	cont'd		
Dyskinesia		64	0
Fine motor skill dysfunction		1	0
Hypokinesia		16	0
Motor dysfunction		4	0
Movement disorder		9	0
Psychomotor hyperactivity		4	0
Dystonias			
Dystonia		3 2	0
Opisthotonus		2	0
Encephalitis NEC			
Encephalitis autoimmune		6	1
Noninfective encephalitis		2	0
Encephalopathies NEC			
Encephalopathy		1	0
Hashimoto's encephalopathy		1	0
Eye movement disorders			
lVth nerve paralysis		1	0
VIth nerve paralysis		1	0
Facial cranial nerve disorders			
Bell's palsy		12	0
Facial paralysis		8	0
Facial paresis		1	0
Facial spasm		2	0
Generalised tonic-clonic seizures			
Generalised tonic-clonic seizure		23	0
Headaches NEC			
Cluster headache		7	0
Headache		1887	0
Primary stabbing headache		1	0
Sinus headache		1	0
Tension headache		5	0
Increased intracranial pressure disorders			
Idiopathic intracranial hypertension		1	0
Intracranial pressure increased		2	0
Intellectual disabilities			
Intellectual disability		1	0
Memory loss (excl dementia)			
Amnesia		24	0
Memory impairment		32	0
Mental impairment (excl dementia and men	nory loss)		
Cognitive disorder		22	0
Disturbance in attention		66	0
Mental impairment		4	0
Migraine headaches			
Basilar migraine		1	0
Hemiplegic migraine		1	0
Migraine		90	0
Migraine with aura		5	0
Migraine without aura		3	0
Typical aura without headache		1	0
Mononeuropathies			
Carpal tunnel syndrome		2	0
Peroneal nerve palsy		2 2	0

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Reaction Name		Total	Fatal
Nervous system disorders con system disorders con the system disorders contain the system disorder con the system disorders contain the system disorders contai	ont'd		
Multiple sclerosis acute and progressive			
Multiple sclerosis		2	0
Muscle tone abnormal			
Hypertonia		1	0
Hypotonia		14	0
Myelitis (incl infective)			
Myelitis transverse		4	0
Narcolepsy and hypersomnia			
Cataplexy		6	0
Hypersomnia		29	0
Narcolepsy		10	0
Nervous system cysts and polyps			
Colloid brain cyst		1	0
Pineal gland cyst		1	0
Nervous system disorders NEC			
Cerebral disorder		1	0
Nervous system disorder		8	0
Neurologic visual problems NEC			
Tunnel vision		1	0
Neurological signs and symptoms NEC			
Brain fog		44	0
Clonus		1	0
Dizziness		2383	0
Dizziness exertional		1	0
Dizziness postural		48	0
Drooling		2	0
Head discomfort		15	0
Hyporesponsive to stimuli		1	0
Meningism		2	0
Myoclonus		2 3	0
Neurological symptom		1	0
Patient elopement		1	0
Presyncope		72	0
Slow response to stimuli		6	0
Unresponsive to stimuli		56	0
Neuromuscular disorders NEC			
Muscle contractions involuntary		3	0
Neuromuscular junction dysfunction			
Myasthenia gravis		1	0
Olfactory nerve disorders			
Anosmia		1	0
Parosmia		3	0
Optic nerve disorders NEC			
Optic neuritis		3	0
Paraesthesias and dysaesthesias			
Burning sensation		12	0
Dysaesthesia		1	0
Formication		1	0
Hyperaesthesia		11	0
Hypoaesthesia		390	0
Paraesthesia		295	0
Paralysis and paresis (excl cranial nerve)			
Diplegia		5	0

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Reaction Name		Total	Fatal
Nervous system disorders us system disorders of	ont'd		
Hemiparesis		11	0
Hemiplegia		2	0
Monoparesis		2	0
Monoplegia		15	0
Paralysis		24	0
Paraplegia		2	0
Peripheral paralysis		1	0
Quadriparesis		1	0
Quadriplegia		1	0
Parkinson's disease and parkinsonism			U
Reduced facial expression		1	0
Peripheral neuropathies NEC		'	U
Autoimmune neuropathy		1	0
Brachial plexopathy		1	
		1	0
Lumbosacral plexus lesion Neuritis		1	
		1	0
Neuropathy peripheral		1	
Peripheral sensory neuropathy		2	0
Seizures and seizure disorders NEC			0
Change in seizure presentation		1	0
Clonic convulsion		1	0
Epilepsy		27	0
Febrile convulsion		1	0
Myoclonic epilepsy		1	0
Partial seizures		6	0
Psychogenic seizure		3	0
Seizure		180	0
Seizure anoxic		5	0
Seizure like phenomena		6	0
Status epilepticus		1	0
Tonic clonic movements		7	0
Tonic convulsion		3	0
Sensory abnormalities NEC			
Ageusia		2	0
Allodynia		2	0
Complex regional pain syndrome		24	0
Dysgeusia		10	0
Electric shock sensation		1	0
Neuralgia		8	0
Post herpetic neuralgia		1	0
Restless legs syndrome		1	0
Sensory disturbance		22	0
Sensory loss		35	0
Taste disorder		6	0
Sleep disturbances NEC			
Sudden onset of sleep		3	0
Speech and language abnormalities		Ŭ	Ŭ
Dysarthria		23	0
Incoherent		4	0
Slow speech		1	0
Speech disorder		14	0
		14	U
Spinal cord and nerve root disorders NEC		4	^
Radiculitis brachial		1	0

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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Radiculopathy	1	0
Spinal cord disorder	1	0
Spinal cord oedema	1	0
Structural brain disorders NEC		
Brain injury	1	0
Cerebellar atrophy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	214	0
Nervous system disorders SOC TOTAL	8050	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions not specified as induced or spontaneous		
Abortion	1	0
Abortions spontaneous		
Abortion spontaneous	16	0
Abortion threatened	1	0
Foetal complications NEC		
Foetal distress syndrome	1	0
Foetal growth complications		
Foetal growth restriction	2	0
Gestational age and weight conditions		
Premature baby	6	1
Hypertension associated disorders of pregnancy		
Pre-eclampsia	2	0
Labour onset and length abnormalities		
Premature labour	2	0
Maternal complications of labour NEC		
Labour complication	1	0
Maternal complications of pregnancy NEC		
Cervical incompetence	1	0
Normal pregnancy, labour and delivery		
Live birth	5	0
Unintended pregnancies		
Pregnancy with injectable contraceptive	1	0
Pregnancy conditions SOC TOTAL	39	1

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Reaction Name	<u>Total</u>	Fatal
Product label issues		
Product lot number issue	2	0
Product quality issues NEC		
Product origin unknown	11	0
Product quality issue	1	0
Product substitution issue	1	0
null SOC TOTAL	15	0

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Reaction Name	Total	<u>Fatal</u>
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	12	0
Behaviour disorder	1	0
Staring	1	0
Adjustment disorders		
Adjustment disorder with mixed anxiety and depressed mood	2	0
Affect alterations NEC		
Affect lability	1	0
Inappropriate affect	1	0
Anxiety disorders NEC		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Anxiety symptoms		
Agitation	8	0
Anxiety	91	0
Nervousness	19	0
Stress	4	0
Behaviour and socialisation disturbances		
Aggression	9	0
Disinhibition	2	0
Disturbance in social behaviour	1	0
Impatience	1	0
Indifference	1	0
Paranoia	5	0
Personality change	11	0
Self-destructive behaviour	1	0
Social avoidant behaviour	4	0
Bipolar disorders		
Bipolar I disorder	1	0
Bipolar disorder	3	0
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	2	0
Confusion and disorientation		
Confusional state	53	0
Disorientation	31	0
Deliria		
Delirium	3	0
Delusional symptoms		
Delusion	2	0
Depressive disorders		
Depression	45	0
Depression suicidal	4	0
Dissociative states		
Dissociation	3	0
Disturbances in initiating and maintaining sleep		
Insomnia	62	0
Middle insomnia	1	0
Dyssomnias		
Poor quality sleep	5	0
Eating disorders NEC		
Anorexia nervosa	1	0
Eating disorder	4	0
Merycism	1	0

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Reaction Name	<u>To</u>	<u>tal</u>	<u>Fatal</u>
Psychiatric disorders Psychiatric disorders cont'd			
Emotional and mood disturbances NEC			
Anger		3	0
Emotional disorder		15	0
Emotional distress		14	0
Emotional poverty		1	0
Euphoric mood		1	0
Irritability		7	0
Mood altered		6	0
Fear symptoms and phobic disorders (incl s	ocial phobia)		
Autophobia		1	0
Claustrophobia		1	0
Fear		3	0
Fear of crowded places		1	0
Fear of death		1	0
Phobia		1	0
Social anxiety disorder		6	0
Fluctuating mood symptoms			
Mood swings		7	0
Hallucinations (excl sleep-related)			
Hallucination		18	0
Hallucination, auditory		6	0
Hallucination, visual		3	0
Hallucinations, mixed		1	0
Impulse control disorders			
Impulse-control disorder		1	0
Impulsive behaviour		1	0
Increased physical activity levels			
Restlessness		6	0
Learning disorders			
Reading disorder		1	0
Mental disorders NEC			
Mental disorder		6	0
Mental status changes		1	0
Mood alterations with depressive symptoms			
Decreased interest		4	0
Depressed mood		16	0
Depressive symptom		2	0
Feeling guilty		1	0
Feeling of despair		1	0
Negative thoughts		1	0
Tearfulness		30	0
Mood alterations with manic symptoms			
Hypomania		1	0
Mood disorders NEC			
Affective disorder		1	0
Apathy		3	0
Listless		5	0
Narcolepsy and associated conditions			
Sleep attacks		1	0
Obsessive-compulsive disorders and sympt	oms		
Obsessive thoughts		1	0
Obsessive-compulsive disorder		2	0
Trichotillomania		2 1	0

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Reaction Name	Total	Fatal
Psychiatric disordersPsychiatric disorders cont'd		
Panic attacks and disorders		
Panic attack	31	0
Panic reaction	8	0
Parasomnias		
Abnormal dreams	1	0
Abnormal sleep-related event	1	0
Sleep terror	3	0
Perception disturbances NEC		
Deja vu	1	0
Derealisation	1	0
Illusion	1	0
Near death experience	1	0
Personality disorders NEC		
Self esteem decreased	3	0
Personality disorders with anxious behaviour (C	luster C)	
Dependent personality disorder		0
Pervasive developmental disorders NEC		
Autism spectrum disorder	4	. 0
Psychiatric symptoms NEC		
Psychiatric symptom	3	0
Psychotic disorder NEC		
Acute psychosis	1 1	0
Psychotic disorder	4	. 0
Sexual desire disorders		
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	30	0
Somatic symptom disorders		
Conversion disorder	5	0
Somatic symptom disorder	2	
Speech and language usage disturbances		
Disorganised speech	1	0
Logorrhoea	1	0
Speech articulation and rhythm disturbances		
Dysphemia	3	0
Stereotypies and automatisms		
Bruxism	1	0
Head banging	2	
Stress disorders		
Burnout syndrome	1	0
Post-traumatic stress disorder	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	5	0
Self-injurious ideation	1	
Suicidal ideation	7	0
Suicide attempt	2	
Thinking disturbances		
Bradyphrenia	2	. 0
Intrusive thoughts	2	0
Thinking abnormal	2 2 3	0
Thought blocking	2	
Tic disorders		
Tic	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Psychiatric disorders SOC TOTAL	719	0

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Reaction Name		<u>Total</u>	<u>Fatal</u>
Renal & urinary disorders			
Bladder and urethral symptoms			
Bladder pain		3	0
Bladder spasm		1	0
Dysuria		3	0
Incontinence		4	0
Micturition urgency		4	0
Pollakiuria		10	0
Stress urinary incontinence		1	0
Urinary incontinence		22	0
Urinary retention		4	0
Bladder disorders NEC			
Bladder disorder		4	0
Bladder fibrosis		1	0
Bladder mass		1	0
Bladder infections and inflammations			
Cystitis noninfective		1	0
Genital and urinary tract disorders NEC			
Urinary tract disorder		3	0
Genitourinary tract infections and inflammation	s NFC	J	·
Urinary tract inflammation	37.25	1	0
Glomerulonephritis and nephrotic syndrome			·
Focal segmental glomerulosclerosis		1	0
Henoch-Schonlein purpura nephritis		1	0
IgA nephropathy		1	0
Nephrotic syndrome		1	0
Myoneurogenic bladder disorders		· i	Ŭ
Bladder dysfunction		1	0
Contracted bladder		1	0
Hypertonic bladder		1	0
Loss of bladder sensation		1	0
Neurogenic bladder		1	0
Renal disorders NEC		'	J
Renal disorder		2	0
Renal failure and impairment			J
Renal failure		1	0
Renal lithiasis		'	0
Nephrolithiasis		1	0
Renal vascular and ischaemic conditions		'	U
Renal vasculitis		1	0
Urinary abnormalities		'	U
Proteinuria		2	0
		2	0
Urinary tract signs and symptoms NEC		,	^
Haemorrhage urinary tract		1	0
Polyuria		1	0
Renal pain		1	0
Renal & urinary disorders SOC TOTAL		82	0

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Reaction Name	Total	<u>Fatal</u>
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst		1 0
Breast disorders NEC		
Breast enlargement		1 0
Gynaecomastia		1 0
Nipple disorder		1 0
Breast signs and symptoms		
Breast discharge		1 0
Breast pain		4 0
Breast swelling		1 0
Breast tenderness		2 0
Nipple pain		1 0
Cervix disorders NEC		
Cervical dysplasia		4 0
Uterine cervix atrophy		1 0
Cervix infections and inflammations		
Cervix inflammation		1 0
Menopausal effects NEC		
Premature menopause		7 0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	24	4 0
Intermenstrual bleeding		в о
Menstrual discomfort		1 0
Menstrual disorder	2	
Menstruation irregular	4	o lo
Premenstrual pain		1 0
Premenstrual syndrome		1 0
Menstruation with decreased bleeding		
Amenorrhoea	3	o le
Menstruation delayed	33	
Oligomenorrhoea		3 0
Menstruation with increased bleeding		
Heavy menstrual bleeding	3:	2 0
Polymenorrhoea		2 0
Ovarian and fallopian tube cysts and neoplasi		
Ovarian cyst		4 0
Polycystic ovaries		6 O
Ovarian and fallopian tube disorders NEC		
Ovarian disorder		2 0
Ovarian failure		2 0 7 0
Ovulation disorder		1 0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain		1 0
Reproductive tract disorders NEC (excl neopla	asms)	
Genital haemorrhage		3 0
Reproductive tract signs and symptoms NEC		
Genital erythema		1 0
Genital pain		2 0
Genital rash		1 0
Genital swelling		2 0
Pelvic pain		6 0
Sexual function and fertility disorders NEC		
Dyspareunia		1 0

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Reaction Name	Total	Fatal
Reproductive & breastedisordeins & breast disorders cont'd		
Infertility	3	0
Uterine disorders NEC		
Endometriosis	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	12	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval ulceration	3	0
Vulvar dysplasia	1	0
Vulvovaginal disorder	1	0
Vulvovaginal signs and symptoms		
Coital bleeding	1	0
Vaginal discharge	6	0
Vaginal lesion	1	0
Vulval oedema	2	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	306	0

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Reaction Name	Total	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	213	0
Grunting	3	0
Hyperventilation	53	0
Hypopnoea	15	0
Respiration abnormal	4	0
Respiratory arrest	6	0
Respiratory distress	1	0
Tachypnoea	4	0
Bronchospasm and obstruction		
Asthma	27	0
Bronchospasm	7	0
Obstructive airways disorder	2	0
Wheezing	25	0
Coughing and associated symptoms	20	U
Allergic cough	1	0
Cough	58	0
Haemoptysis	2	0
Productive cough	4	0
	4	U
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Vocal cord disorder	1	0
Laryngeal spasm, oedema and obstruction		J
Laryngeal oedema	5	0
Laryngospasm	1	0
Stridor	1	0
Lower respiratory tract signs and symptoms	1	J
Increased bronchial secretion	1	0
Pleuritic pain	2	0
·		U
Nasal congestion and inflammations	10	0
Nasal congestion	10	U
Nasal disorders NEC	2.4	0
Epistaxis Nasal oedema	34	0
	1	0
Paranasal sinus disorders (excl infections and neoplasms)	4	0
Sinonasal obstruction	1	0
Pharyngeal disorders (excl infections and neoplasms)		0
Pharyngeal erythema	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	20	0
Pharyngeal ulceration	1	0
Tonsillar disorder	2	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	2	0
Pneumothorax and pleural effusions NEC		_
Pneumothorax	2	0
Pulmonary oedemas		
Pulmonary oedema	1	0
Respiratory failures (excl neonatal)		
Acute respiratory failure	1	0
Respiratory signs and symptoms NEC		
Painful respiration	1	0

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Reaction Name	Tot	al	Fatal
Respiratory disorders espiratory disorders cont'd			
Respiratory tract disorders NEC			
Allergic respiratory disease		1	0
Respiratory disorder		3	1
Respiratory tract inflammation		1	0
Upper respiratory tract signs and symptoms			
Aphonia		7	0
Choking		2	0
Choking sensation		2	0
Dry throat		6	0
Dysphonia		3	0
Nasal obstruction		1	0
Oropharyngeal discomfort		2	0
Oropharyngeal pain		146	0
Rhinorrhoea		11	0
Sinus pain		2	0
Sneezing		6	0
Throat irritation		28	0
Throat lesion		1	0
Throat tightness		44	0
Vascular pulmonary disorders NEC			
Pulmonary arteriopathy		2	0
Respiratory disorders SOC TOTAL	•	785	1

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Reaction Name	,	Total	<u>Fatal</u>
Skin disorders			
Acnes			
Acne		9	0
Acne cystic		1	0
Alopecias			
Alopecia		43	0
Alopecia areata		12	0
Alopecia totalis			0
Diffuse alopecia		2	0
Madarosis		1	0
Angioedemas			
Angioedema		18	0
Circumoral oedema		1	0
Apocrine and eccrine gland disorders			
Cold sweat		107	0
Hyperhidrosis		111	0
Miliaria		6	0
Night sweats		3	0
Bullous conditions			_
Blister		23	0
Dermatitis bullous		1	0
Erythema multiforme		12	0
Stevens-Johnson syndrome		1	0
Dermal and epidermal conditions NEC			_
Dry skin		13	0
Pain of skin		11	0
Papule		5	0
Scab		2	0
Sensitive skin		2 6	0
Skin burning sensation		7	0
Skin discolouration		109	0
Skin disorder		8	0
Skin fissures		1	0
Skin induration		1	0
Skin lesion		5	0
Skin reaction		14	0
Skin sensitisation		2	0
Skin texture abnormal		1	0
Skin tightness		3	0
Skin warm		30	0
Yellow skin		4	0
Dermatitis and eczema		· i	J
Dermatitis Dermatitis		1	0
Dermatitis allergic		37	0
Dermatitis contact		4	0
Dyshidrotic eczema		1	0
Eczema		15	0
Eczema nummular		1	0
Eczema vesicular		1	0
Seborrhoeic dermatitis		2	0
Skin irritation		10	0
Dermatitis ascribed to specific agent			
Drug eruption		2	0
Erythemas		_	

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Reaction Name	Total	<u>Fatal</u>
Skin disorders Skin disorders cont'd		
Erythema	242	0
Palmar erythema	1	0
Exfoliative conditions		
Skin exfoliation	7	0
Hyperkeratoses		
Hyperkeratosis	1	0
Hyperpigmentation disorders		
Melanoderma	1	0
Hypopigmentation disorders		
Skin depigmentation	1	0
Vitiligo	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	2	0
Panniculitides		
Erythema nodosum	6	0
Panniculitis	1	0
Papulosquamous conditions		
Lichen planus	1	0
Parapsoriasis	1	0
Pityriasis lichenoides et varioliformis acuta	1	0
Pityriasis rosea	3	0
Pityriasis rubra pilaris	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	19	0
Pigmentation changes NEC		
Pigmentation disorder	2	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Piloerection	1	0
Trichorrhexis	1	0
Pruritus NEC		
Pruritus	209	0
Psoriatic conditions		
Guttate psoriasis	1	0
Psoriasis	6	0
Purpura and related conditions		
Henoch-Schonlein purpura	10	0
Petechiae	11	0
Purpura	8	0
Pustular conditions		
Rash follicular	1	0
Rashes, eruptions and exanthems NEC		
Rash	498	0
Rash erythematous	52	0
Rash macular	87	0
Rash maculo-papular	6	0
Rash papular	11	0
Rash pruritic	75	0
Rash vesicular	3	0
Systemic lupus erythematosus rash	1	0
Skin and subcutaneous conditions NEC		
Skin mass	3	0
Umbilical discharge	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin haemorrhages		
Skin haemorrhage	1	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin striae	4	0
Skin preneoplastic conditions NEC		
Precancerous skin lesion	1	0
Skin vasculitides		
Vasculitic rash	1	0
Skin vasomotor conditions		
Livedo reticularis	44	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	2	0
Urticaria	279	0
Urticaria chronic	3	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	2266	l o

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Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Puberty	1	0
Disability issues		
Bedridden	4	. 0
Disability	2	. 0
Immobile	3	0
Impaired work ability	1	0
Loss of personal independence in daily activities	14	. 0
Physical disability		0
Wheelchair user	1	0
Educational issues		
Educational problem	2	0
Illiteracy	1	0
Social circumstances SOC TOTAL	30	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Gastrointestinal therapeutic procedures NEC		
Prophylaxis of nausea and vomiting	1	0
Hernia repairs		
Inguinal hernia repair	1	0
Induced abortions		
Abortion induced	6	0
Large intestine therapeutic procedures		
Appendicectomy	1	0
Limb therapeutic procedures		
Limb immobilisation	5	0
Obstetric therapeutic procedures		
Vacuum extractor delivery	1	0
Ovarian therapeutic procedures		
Oophorectomy	1	0
Psychiatric therapies		
Antidepressant therapy	1	0
Therapeutic procedures NEC		
Anaphylaxis treatment	1	0
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	19	0

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Vascular disorders		
Blood pressure disorders NEC		
Blood pressure fluctuation	1	0
Circulatory collapse and shock		
Circulatory collapse	8	0
Neurogenic shock	1	0
Peripheral circulatory failure	1	0
Shock	4	0
Haemorrhages NEC		
Haemorrhage	4	0
Venous haemorrhage	1	0
Lymphoedemas		
Lymphoedema	1	0
Non-site specific embolism and thrombosis		
Thrombosis	3	0
Non-site specific necrosis and vascular insufficiency NEC		
Peripheral venous disease	3	0
Vasospasm	1	0
Non-site specific vascular disorders NEC		J
Capillary disorder	3	0
Vascular pain	1	0
Vasodilatation	1	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	0
Superficial vein thrombosis	1	0
Peripheral vascular disorders NEC		U
Cyanosis	36	0
Erythromelalgia	1	0
Flushing	124	
Hot flush		
Peripheral vascular disorder	23	0
!		U
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	0
Ischaemic limb pain	1	0
Peripheral coldness	123	0
Poor peripheral circulation	9	
Raynaud's phenomenon	8	0
Site specific vascular disorders NEC		
Pallor	374	0
Vascular hypertensive disorders NEC		_
Hypertension	10	
Orthostatic hypertension	1	0
Vascular hypotensive disorders		
Hypotension	42	0
Orthostatic hypotension	2	0
Vasculitides NEC		
Behcet's syndrome	1	C
Vasculitis	3	C
Vascular disorders SOC TOTAL	795	
TOTAL REACTIONS FOR DRUG	27782	10
TOTAL REPORTS	10400	
TOTAL FATAL OUTCOME REPORTS		10