Case Series Drug Analysis Print Name: Human Papilloma Virus Vaccine Drug Analysis Print

Report Run Date: 05-Nov-2021

Data Lock Date: 17-Oct-2021 22:57:05

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0

Human Papilloma

Virus Vaccine Drug Analysis Print: Spontaneous UK cases received up to 30/09/2021.

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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	10	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	64	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Pancytopenia	1	0
Neutropenias		
Autoimmune neutropenia	2	
Neutropenia	3	0
Spleen disorders		
Splenomegaly	3	0
Thrombocytopenias		
Immune thrombocytopenia	9	0
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	119	l o

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac conduction disorders		
Atrioventricular block	1	0
Cardiac disorders NEC		
Cardiac disorder	4	. 0
Cardiac signs and symptoms NEC		
Palpitations	57	0
Ischaemic coronary artery disorders		
Angina pectoris	3	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Pulmonary valvular disorders		
Pulmonary valve stenosis	2	. 0
Rate and rhythm disorders NEC		
Arrhythmia	2	. 0
Bradycardia	6	0
Postural orthostatic tachycardia syndrome	82	. 0
Tachycardia	49	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	3	1
Pulseless electrical activity		0
Cardiac disorders SOC TOTAL	222	1

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Congenital disorders		
Anorectal disorders congenital		
Preternatural anus	2	0
Cardiac septal defects congenital		
Atrioventricular septal defect	2	0
Cerebral disorders congenital		
Cerebral palsy	1	0
Congenital disorders NEC		
Congenital anomaly	1	0
VACTERL syndrome	2	0
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	12	0
Great vessel disorders congenital		
Double outlet right ventricle	2	0
Inborn errors of bilirubin metabolism		
Gilbert's syndrome	1	0
Male reproductive tract disorders congenital		
Hypospadias	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Limb hypoplasia congenital	2	0
Limb reduction defect	2	0
Talipes	1	0
Musculoskeletal and connective tissue disorders of spine congenital		
Spine malformation	2	0
Non-site specific bone disorders congenital		
Osteopetrosis	1	0
Palate disorders congenital		
Cleft palate	1	0
High arched palate	1	0
Pulmonary and bronchial disorders congenital		
Pulmonary aplasia	2	0
Pulmonary hypoplasia	2	0
Renal disorders congenital		
Congenital cystic kidney disease	2	0
Skin and subcutaneous tissue disorders congenital NEC		
Birth mark	1	0
Congenital skin dimples	2	0
Ichthyosis	1	0
Sebaceous naevus	1	0
Tongue disorders congenital		
Ankyloglossia congenital	2	0
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	48	0

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	3	0
Ear pain	19	0
Hearing disorders NEC		
Auditory disorder	1	0
Hearing losses		
Deafness	17	0
Deafness bilateral	1	0
Deafness transitory	4	0
Hypoacusis	19	0
Hyperacusia		
Hyperacusis	26	0
Inner ear disorders NEC		
Inner ear disorder	1	0
Vestibular disorder	1	0
Inner ear signs and symptoms		
Motion sickness	2	0
Tinnitus	17	0
Vertigo	15	0
Ear disorders SOC TOTAL	126	0

Name: Human Papilloma Virus Vaccine Drug Analysis Print
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Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	5	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
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 hypofunction disorders		
Autoimmune hypothyroidism	2	0
Hypothyroidism	10	0
Endocrine disorders SOC TOTAL	29	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0	Total	Fotal
Reaction Name	Total	<u>Fatal</u>
Eye disorders Charaid and vitrous structural shange deposit and degeneration		
Choroid and vitreous structural change, deposit and degeneration	4	0
Vitreous floaters	4	0
Colour blindness (incl acquired)	0	0
Dyschromatopsia	2	0
Conjunctival infections, irritations and inflammations	0	0
Conjunctival hyperaemia	2	0
Eyelid movement disorders	0	0
Blepharospasm	2 2 3	0
Excessive eye blinking	2	0
Eyelid ptosis	3	0
Glaucomas (excl congenital)	4	0
Glaucoma	1	0
Iris and ciliary body structural change, deposit and degeneration	4	0
Iris adhesions	1	0
Iris and uveal tract infections, irritations and inflammations	4	0
Iritis	1	0
Uveitis	1	0
Lacrimation disorders		0
Dry eye	2 3	0
Lacrimation increased	3	0
Lid, lash and lacrimal infections, irritations and inflammations	4	•
Eyelid oedema	1	0
Eyelid rash	1	0
Swelling of eyelid	20	0
Ocular disorders NEC		•
Dark circles under eyes	4	0
Eye disorder	5	0
Eye pain	22	0
Eye swelling	36	0
Eyelid disorder	1	0
Eyelids pruritus	1	0
Ocular discomfort	1	0
Periorbital oedema	2 1	0
Periorbital pain	1 3	0
Periorbital swelling	3	0
Ocular infections, inflammations and associated manifestations	4	•
Eye allergy	1	0
Eye discharge	2	0
Eye inflammation	1	0
Eye irritation	2 7	0
Eye pruritus	-	0
Ocular hyperaemia	10	0
Ocular nerve and muscle disorders		•
Extraocular muscle paresis	2	0
Eye movement disorder	38	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Oculogyric crisis	1	0
Ophthalmoplegia	1	0
Strabismus	1	0
Ocular sensation disorders		
Abnormal sensation in eye	1	0
Asthenopia	3	0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Foreign body sensation in eyes	1	0
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	3	
Pupillary disorder	1	0
Pupillary reflex impaired	1	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	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	13	
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	5	1
Vision blurred	162	0
Visual field disorders		
Visual field defect	8	0
Visual impairment and blindness (excl colour blindness)		
Blindness	15	
Blindness transient	22	
Blindness unilateral	1	0
Visual acuity reduced	1	0
Visual impairment	76	
Eve disorders SOC TOTAL	601	l o

Earliest Reaction Date: 05-May-2006 MedDRA	Version: MedDRA 24.0	
Reaction Name	Total	<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	<u>2</u> 0
Colitis ulcerative	4	l o
Crohn's disease	2	<u> </u> 0
Dental disorders NEC		
Tooth erosion	1	0
Diaphragmatic hernias		
Hiatus hernia	1	0
Diarrhoea (excl infective)		
Diarrhoea	137	'l 0
Diarrhoea haemorrhagic	2	<u> </u>
Dyspeptic signs and symptoms		
Dyspepsia	12	2 0
Eructation	2	2 0
Faecal abnormalities NEC		
Abnormal faeces	1	0
Flatulence, bloating and distension		
Abdominal distension	16	6 0
Flatulence	3	3 o
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 the	hroat)	
Abdominal migraine	1	0
Abdominal pain	215	
Abdominal pain lower	18	3 O
Abdominal pain upper	195	
Abdominal rigidity	1	-
Abdominal tenderness	3	
Gastrointestinal pain	2	2 0
Gastrointestinal atonic and hypomotility disorders NE		
Constipation	17	' 0
Gastric dilatation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	15	
Impaired gastric emptying	5	5 O
Gastrointestinal disorders NEC		
Functional gastrointestinal disorder	1	0
Gastric disorder		' 0
Gastrointestinal disorder	17	' 0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	1	_
Dyschezia	1	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Gastrointestinal disorders contestinal disorder contestinal disorders contestinal disorders contestinal disord	ont'd		
Gastrointestinal motility disorder		2	0
Gastrointestinal inflammatory disorders NEC			
Duodenitis		1	0
Gastrointestinal inflammation		3	0
Gastrointestinal mucosal dystrophies and se	ecretion disorders		
Oesophageal mucosal hyperplasia		1	0
Gastrointestinal signs and symptoms NEC			
Abdominal discomfort		55	0
Dysphagia		27	0
Odynophagia		2	0
Oesophageal discomfort		1	0
Gastrointestinal spastic and hypermotility di	sorders		
Defaecation urgency		1	0
Frequent bowel movements		3	0
Irritable bowel syndrome		22	0
Gastrointestinal ulcers and perforation, site	unspecified		
Gastrointestinal ulcer	•	1	0
Gingival disorders, signs and symptoms NE	C		
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	0
Inguinal hernias			
Inguinal hernia		2	0
Intestinal haemorrhages			
Rectal haemorrhage		2	0
Malabsorption syndromes			
Bile acid malabsorption		1	0
Coeliac disease		10	0
Malabsorption		2	0
Nausea and vomiting symptoms			
Cyclic vomiting syndrome		1	0
Nausea		1707	0
Regurgitation		1	0
Retching		7	0
Vomiting		737	0
Vomiting projectile		1	0
Non-site specific gastrointestinal haemorrha	ges		
Gastrointestinal haemorrhage		1	0
Haematemesis		6	0
Haematochezia		1	0
Oesophagitis (excl infective)			
Eosinophilic oesophagitis		1	0
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			

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 2	0
Oral mucosal blistering	2	0
Oral mucosal eruption	1	0
Oral pain	5	0
Oral pruritus	2	0
Paraesthesia oral	39	0
Oral soft tissue swelling and oedema		
Lip swelling	61	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	30	
Tongue coated	2	0
Tongue discomfort	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	3508	0

	edDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site pain	•	0
Administration site swelling	•	0
Puncture site reaction	•	ı 0
Asthenic conditions		
Asthenia	187	7 0
Chronic fatigue syndrome	105	
Decreased activity	2	2 0
Fatigue	786	
Malaise	782	2 0
Body temperature altered		
Temperature regulation disorder	15	0
Death and sudden death		
Death	•	1
Febrile disorders		
Hyperpyrexia	2	2 0
Pyrexia	563	3 0
Feelings and sensations NEC		
Chills	108	3 0
Feeling abnormal	92	2 0
Feeling cold	80	0
Feeling drunk	4	1 0
Feeling hot	219	9 0
Feeling jittery		
Feeling of body temperature change	25	0
Sensation of foreign body		
Temperature intolerance		7 0
Thirst	3	3 0
Gait disturbances		
Gait disturbance	33	3 0
Gait inability	29	0
Loss of control of legs	Ę	0
General signs and symptoms NEC		
Condition aggravated	16	6 0
Crying	13	3 0
Disease recurrence	•	0
Exercise tolerance decreased	7	7 0
Foaming at mouth	4	1 0
General physical health deterioration	2	0 0
Glassy eyes	2	0
III-defined disorder	7	7 0
Illness	94	1 0
Induration	4	1 0
Influenza like illness	124	1 0
Local reaction	3′	
Organ failure	•	1 0
Peripheral swelling	354	
Screaming	2	0
Secretion discharge	•	0
Swelling	8′	0
Swelling face	93	3 0
Healing abnormal NEC		
Impaired healing		2 0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.	.0	
Reaction Name	<u>Total</u>	Fatal
General disorders General disorders cont'd		
Hernias NEC		
Hernia	2	0
Inflammations		
Inflammation	22	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	67	0
Injection site movement impairment	3	0
Injection site nerve damage	1	0
Injection site nodule	8	0
Injection site oedema	1	0
Injection site pain	147	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	5	0
Injection site vesicles	5	0
Injection site warmth	28	0
Mass conditions NEC		
Cyst	1	0
Mass	5	0
Nodule	2	0
Mucosal findings abnormal		
Mucosal ulceration	1	0
Oedema NEC		
Face oedema	5	0
Localised oedema	1	0
Oedema peripheral	12	0
Pain and discomfort NEC		

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Reaction Name	Total	<u>Fatal</u>
General disorders General disorders cont'd		
Axillary pain	5	
Chest discomfort	70	1
Chest pain	111	
Discomfort	28	0
Facial pain	4	
Non-cardiac chest pain	3	0
Pain	271	0
Tenderness	20	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	33	0
Adverse event	1	0
Adverse reaction	2	2 0
Drug ineffective	3	
Drug resistance	1	
Immediate post-injection reaction	1	0
Therapeutic response unexpected	1	
Vaccination failure	3	1
Trophic disorders		
Atrophy	1	0
Hyperplasia	1	
Ulcers NEC		
Ulcer	3	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	3	0
Vaccination site atrophy	1	ő
Vaccination site bruising	5	
Vaccination site coldness	1	ő
Vaccination site discolouration	2	
Vaccination site disconfort	2	
Vaccination site erythema	13	
Vaccination site crymenta Vaccination site haemorrhage	2	1
Vaccination site hypersensitivity	1	
Vaccination site hypoaesthesia	1	0
Vaccination site hypoaestriesia Vaccination site induration		0
Vaccination site induration Vaccination site inflammation	3	
Vaccination site irritation	1	
Vaccination site joint movement impairment		0
Vaccination site joint pain Vaccination site mass	10	
	10	
Vaccination site movement impairment	3	1
Vaccination site nerve damage		0
Vaccination site nodule		0
Vaccination site pain	29	
Vaccination site paraesthesia		0
Vaccination site pruritus	5	
Vaccination site rash	3	
Vaccination site swelling	22	
Vaccination site warmth	3	
General disorders SOC TOTAL	5448	1

Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	4	0
Hepatic and hepatobiliary disorders NEC		
Hepatic cyst	1	0
Liver disorder	2	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	1	0
Hepatitis acute	1	0
Obstructive bile duct disorders (excl neoplasms)		
Sphincter of Oddi dysfunction	1	0
Hepatic disorders SOC TOTAL	15	0

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergic oedema	1	0
Allergy to animal	3	0
Hypersensitivity	87	0
Multiple allergies	6	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	3	
Type IV hypersensitivity reaction	2	0
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	2	0
Food allergy	6	0
Reaction to excipient	3	0
Reaction to food additive	1	0
Reaction to preservatives	1	0
Rubber sensitivity	2	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	97	0
Anaphylactic shock	7	
Anaphylactoid reaction	3	0
Atopic disorders		
Seasonal allergy	1	0
Autoimmune disorders NEC		
Autoimmune disorder	12	
Overlap syndrome	1	0
Immune and associated conditions NEC		
Decreased immune responsiveness	1	0
Immune system disorder	11	0
Immunisation reaction	2	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	255	l o

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Infections		
Abdominal and gastrointestinal infections		
Abdominal abscess	1	0
Appendicitis	3	0
Appendicitis perforated	1	0
Gastroenteritis	1	0
Gastrointestinal infection	1	0
Peritonitis	1	0
Bacterial infections NEC		
Cellulitis	3	0
Folliculitis	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Bone and joint infections		
Osteomyelitis	1	0
Breast infections		
Mastitis	1	0
Candida infections		
Candida infection	2	0
Vulvovaginal candidiasis	1	0
Central nervous system and spinal infections		
Encephalitis	8	0
Encephalitis lethargica	1	0
Subdural abscess	1	0
Coronavirus infections		
Severe acute respiratory syndrome	1	0
Coxsackie viral infections		
Hand-foot-and-mouth disease	1	0
Dental and oral soft tissue infections		
Gingivitis	1	0
Ear infections		
Ear infection	2	0
Labyrinthitis	3	0
Otitis media	2	0
Ectoparasitic infestations		
Acarodermatitis	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	11	0
Eye and eyelid infections		
Conjunctivitis	3	0
Hordeolum	5	0
Female reproductive tract infections		
Amniotic cavity infection	1	0
Pelvic inflammatory disease	1	0
Vulvovaginitis	1	0
Haemophilus infections		
Haemophilus infection	1	0
Herpes viral infections		
Genital herpes	1	0
Herpes virus infection	1	0
Herpes zoster	17	0
Oral herpes	3	0
Varicella	1	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Infections Infections cont'd			
Infections NEC			
Infection		8	0
Infection susceptibility increased		7	0
Injection site abscess		1	0
Injection site infection		5	0
Localised 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	ů '		
Influenza		5	0
Lower respiratory tract and lung infections	3		
Bronchitis		3	0
Lower respiratory tract infection		16	0
Pneumonia		2	0
Molluscum contagiosum viral infections			
Molluscum contagiosum		1	0
Papilloma viral infections			
Papilloma viral infection		4	0
Vulvovaginal human papilloma virus info	ection	1	0
Respiratory syncytial viral infections		·	
Respiratory syncytial virus infection		1	0
Retroviral infections			
Acquired immunodeficiency syndrome		1	0
Sepsis, bacteraemia, viraemia and funga	emia NEC	·	
Neutropenic sepsis		1	0
Sepsis		3	0
Septic rash		1	0
Viraemia		1	0
Skin structures and soft tissue infections			ŭ
Application site pustules		1	0
Impetigo		1	0
Pustule		1	0
Skin infection		2	0
Staphylococcal infections		_	Ū
Furuncle		3	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		40	0
Pharyngitis			0
Sinusitis		8 2	0
Tonsillitis		8	0
Upper respiratory tract infection		3	0
Urinary tract infections			0
Kidney infection		1	0
Urinary tract infection		5	0
		5	U
Viral infections NEC			

Reaction Name	Total	Fatal
Infections Infections cont'd		
Gastroenteritis viral	3	0
Hepatitis viral	1	0
Meningitis viral	1	0
Pneumonia viral	1	0
Post viral fatigue syndrome	56	0
Viral infection	20	0
Viral pharyngitis	1	0
Infections SOC TOTAL	319	1

Abdominal and gastrointestinal injuries NEC	Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0	Total	Fatal
Abdominal and gastrointestinal injuries NEC Mouth injury 1 0 Bone and joint injuries NEC Joint injuries Chemical injuries Chemical injuries Chemical injuries Chemical burn Exposure during pregnancy, delivery and lactation Exposure during pregnancy Foetal exposure during pregnancy Foetal exposure during pregnancy Maternal exposure turing pregnancy Maternal exposure turing pregnancy Maternal exposure timing unspecified Fractures and dislocations NEC Joint dislocation Medication errors, product use errors and issues NEC Circumstance or information capable of leading to medication error Medication error Wrong technique in product usage process Muscle injury Nerve injuries NEC Nerve injuries Muscle injury Nerve injuries NEC Fall Injury Non-site specific injuries NEC Fall Injury Nound haemorrhage Off label uses Overdoses NEC Intentional overdose Overdose Projeoning and toxicity Metal poisoning Poisoning Product administration errors and issues Expired product administered Extra dose injuries NEC Face injury Folsoning and toxicity Metal poisoning Poisoning Product administered to patient of inappropriate age Wrong product administered Site specific injuries NEC Face injury Face injury Face injury Face injuries NEC Face injury F	Reaction Name	Total	Гаіаі
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Face injury 1 0 Head injury 1 0		· ·	J
Head injury 1 0		1	0
		·	
			J
Contusion 55 0		55	0
Dermatitis artefacta 1 0			

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Scar	2	0
Skin abrasion	1	0
Thermal burns		
Thermal burn	1	0
Vaccination related complications		
Vaccination complication	8	0
Injuries SOC TOTAL	192	0

<u> </u>	: MedDRA 24.0	
Reaction Name	Total_	<u>Fatal</u>
Investigations		
Adrenal cortex tests		
Cortisol decreased	1	0
Autoimmunity analyses		
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Blood counts NEC		
Blood count abnormal	1	0
Blood gas and acid base analyses		
Blood pH increased		0
Oxygen saturation decreased	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	3	0
Blood glucose increased	6	0
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Heart sounds abnormal	1	0
Cell marker analyses		
Cell marker increased	1	0
Central nervous system imaging procedures		
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF cell count increased	1	0
Chemistry analyses NEC		
Histamine level increased	2	0
ECG investigations		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	4	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	1	0
Heart rate and pulse investigations		
Heart rate abnormal	6	0
Heart rate decreased	10	0
Heart rate increased	57	0
Heart rate irregular	16	0
Pulse abnormal	9	0
Pulse absent	3	0
Pulse pressure decreased	1	0
Imaging procedures NEC		
Positron emission tomogram abnormal	1	0
Immunoglobulin analyses		
Blood immunoglobulin A increased	1	0
Investigations NEC		
Quality of life decreased	3	0
Liver function analyses		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	1	0
Liver function test increased	1	0
Mineral and electrolyte analyses		- J

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Investigations Investigations cont'd		
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 orgain	n system status	
Body temperature abnormal	4	4 0
Body temperature decreased	-	7 0
Body temperature fluctuation	3	3 0
Body temperature increased	104	4 0
Breath sounds abnormal		1 0
Grip strength decreased	;	3 0
Respiratory rate decreased		1 0
Respiratory rate increased	1;	3 0
Weight decreased	25	5 0
Weight increased		5 0
Pituitary analyses anterior		
Blood growth hormone abnormal		1 0
Blood thyroid stimulating hormone abnorr	nal ·	1 0
Platelet analyses		
Platelet count decreased		3 0
Protein analyses NEC		
Blood albumin abnormal		1 0
C-reactive protein increased		2 0
Protein total abnormal		1 0
Reproductive hormone analyses		
Anti-Muellerian hormone level decreased		1 0
Oestradiol decreased		1 0
Progesterone increased		1 0
Reproductive organ and breast histopathology	ogy procedures	
Smear cervix abnormal	,	1 0
Respiratory and pulmonary function diagno	stic procedures	
Peak expiratory flow rate decreased		1 0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased		1 0
Enzyme level increased		1 0
Toxicology laboratory analyses		
Blood chromium decreased		1 0
Urinalysis NEC		
Blood urine present		2 0
Urinary tract function analyses NEC		
Urine output decreased		1 0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal		2 0
Blood pressure decreased	1:	2 0
Blood pressure immeasurable		1 0
Blood pressure increased		3 0
Blood pressure systolic decreased		1 0
Vitamin analyses		
Vitamin B12 decreased		1 0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	381	0

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Appetite disorder	4	0
Decreased appetite	85	0
Hypophagia	2	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	10	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	1	0
General nutritional disorders NEC		
Abnormal loss of weight	30	0
Abnormal weight gain	1	0
Cachexia	1	0
Feeding disorder	5	0
Malnutrition	1	0
Underweight	1	0
Weight fluctuation	1	0
Weight gain poor	1	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	3	0
Insulin resistance	1	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	3	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	o o
Metabolic disorders SOC TOTAL	213	

	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	7	7 0
Arthropathy	7	7 0
Palindromic rheumatism	1	0
Seronegative arthritis	1	0
Bone disorders NEC		
Osteitis	1	0
Bone related signs and symptoms		
Bone pain	11	0
Coccydynia	1	0
Pain in jaw		0
Spinal pain	7	7 0
Cartilage disorders		
Costochondritis	2	0
Osteochondrosis	1	0
Connective tissue disorders NEC		
Mixed connective tissue disease	1	0
Morphoea	1	0
Reynold's syndrome	1	0
Sjogren's syndrome	1	ı l 0
Extremity deformities		
Finger deformity	1	0
Foot deformity	1	0
Hand deformity	1	0 ا
Joint related disorders NEC		
Hypermobility syndrome	10	o l
Joint contracture	1	0
Joint lock	1	ı l 0
Periarthritis	3	0
Joint related signs and symptoms		
Arthralgia	255	5 O
Joint effusion	1	ı l 0
Joint noise	3	3 O
Joint range of motion decreased	1	
Joint stiffness	15	0
Joint swelling	34	
Ligament disorders		
Ligament pain	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus		3 O
Metabolic bone disorders		
Osteoporosis	1	ı l 0
Muscle infections and inflammations		
Myositis	1	0
Muscle pains		
Fibromyalgia	17	0
Myalgia	178	
Myalgia intercostal		
Muscle related signs and symptoms NEC		
Muscle atrophy		0
Muscle discomfort		ŏ
Muscle fatique	12	o o

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Muscle & tissue disorders e & tissue disorde	rs cont'd		
Muscle spasms		47	0
Muscle swelling		1	0
Muscle tightness		6	0
Muscle twitching		50	0
Muscle tone abnormalities			
Muscle rigidity		35	0
Trismus		1	0
Muscle weakness conditions			
Muscular weakness		124	0
Musculoskeletal and connective tissue c	onditions NEC		
Back disorder		2	0
Growth retardation		3	0
Mastication disorder		1	0
Mobility decreased		16	0
Muscle contracture		2	0
Musculoskeletal disorder		1	0
Musculoskeletal disorder Musculoskeletal stiffness		106	0
Posture abnormal		100	0
Weight bearing difficulty		8	0
Musculoskeletal and connective tissue p	ain and discomfort	O	U
Back pain	alli allu discomion	88	0
Flank pain		2	0
Growing pains		2	0
Limb discomfort		183	0
Musculoskeletal chest pain		11	0
Musculoskeletal discomfort			0
		4 5	0
Musculoskeletal pain		75	0
Neck pain Pain in extremity		1100	0
		1100	U
Rheumatoid arthropathies		2	0
Juvenile idiopathic arthritis Rheumatoid arthritis		3 5	0
		5	0
Soft tissue disorders NEC		_	^
Axillary mass		2	0
Groin pain		5	U
Neck mass		1	0
Soft tissue disorder		1	0
Spine and neck deformities		0	0
Scoliosis		3	0
Spondyloarthropathies			
Arthritis reactive		4	0
Synovial disorders			
Synovitis		1	0
Tendon disorders			
Tendon pain		1	0
Tendonitis		1	0
Muscle & tissue disorders SOC TOTAL		2496	0

Reaction Name	Total	Fatal
		<u>ı alaı</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
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 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		4
Neoplasm malignant	1	1
Non-Hodgkin's lymphomas NEC	1	1
Non-Hodgkin's lymphoma	1	1
Pharyngeal and laryngeal neoplasms benign Laryngeal papilloma	1	0
Reproductive neoplasms female benign NEC	1	0
Benign hydatidiform mole	1	0
Reproductive neoplasms male benign NEC	'	U
Penile wart	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	5	0
Uterine neoplasms benign		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	31	3

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	5	0
Abnormal sleep-related events		
Sleep paralysis	1	0
Absence seizures		
Petit mal epilepsy	8	0
Acute polyneuropathies		
Guillain-Barre syndrome	7	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	11	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	3	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	24	0
Cerebellar ataxia	1	0
Coordination abnormal	9	0
Dysstasia	19	0
Nystagmus	1	0
Cortical dysfunction NEC		
Agnosia	1	0
Aphasia	11	0
Dyslexia	1	0
Dyspraxia	2	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	1	0
Demyelination	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	4	0
Consciousness fluctuating	5	0
Depressed level of consciousness	8	0
Lethargy	218	0
Loss of consciousness	112	0
Sedation	1	0
Somnolence	167	0
Syncope	873	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	0
Irregular sleep wake rhythm disorder	4	0
Dyskinesias and movement disorders NEC		Ŭ
Clumsiness	2	0

Reaction Name Nervous system disorders us system disorders cont'd Dyskinesia Fine mater skill dysfunction	Total 63	<u>Fatal</u>
Dyskinesia	63	
Dyskinesia	63	
Fine motor skill dyafunation		0
Fine motor skill dysfunction	1	0
Hypokinesia	15	0
Motor dysfunction	4	0
Movement disorder	8	0
Psychomotor hyperactivity	4	0
Dystonias		
Dystonia	1	0
Opisthotonus	2	0
Encephalitis NEC		
Encephalitis autoimmune	5	0
Noninfective encephalitis	1	0
Encephalopathies NEC		
Encephalopathy	1	0
Hashimoto's encephalopathy	1	0
Eye movement disorders		
IVth nerve paralysis	1	0
VIth nerve paralysis	1	0
Facial cranial nerve disorders		
Bell's palsy	11	0
Facial paralysis	7	0
Facial paresis	1	0
Facial spasm	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	23	0
Headaches NEC		_
Cluster headache	7	0
Headache	1817	0
Tension headache	4	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	23	0
Memory impairment	32	
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	21	0
Disturbance in attention	66	
Mental impairment	4	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	1	0
Migraine	85	0
Migraine with aura	4	0
Migraine without aura	3	0
Typical aura without headache	1	0
Mononeuropathies		
Carpal tunnel syndrome	2	0
Peroneal nerve palsy	2	0
Multiple sclerosis acute and progressive		
Multiple sclerosis acute and progressive Multiple sclerosis	2	0

<u>, , , , , , , , , , , , , , , , , , , </u>	A Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Nervous system disorders us system disorders cont'd		
Muscle tone abnormal		
Hypertonia		-
Hypotonia	13	0
Myelitis (incl infective)		
Myelitis transverse	2	0
Narcolepsy and hypersomnia		
Cataplexy	6	
Hypersomnia	29	
Narcolepsy	10	0
Nervous system cysts and polyps		
Colloid brain cyst		_
Pineal gland cyst	1	0
Nervous system disorders NEC		
Cerebral disorder		-
Nervous system disorder		0
Neurologic visual problems NEC		
Tunnel vision	1	0
Neurological signs and symptoms NEC		_
Clonus	1	_
Dizziness	2319	
Dizziness exertional	1	·
Dizziness postural	45	
Drooling	2	
Head discomfort	14	
Hyporesponsive to stimuli	1	
Meningism	2	0
Myoclonus	3	3 0
Neurological symptom		-
Patient elopement	1	
Presyncope	66	
Slow response to stimuli	6	
Unresponsive to stimuli	55	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	1	-
Parosmia	3	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias	4.6	
Burning sensation	12	
Dysaesthesia	1	-
Formication	1	0
Hyperaesthesia	15	1
Hypoaesthesia	376	
Paraesthesia	285	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	5	
Hemiparesis	11	
Hemiplegia	2	
Monoparesis		<u> 0</u>

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Nervous system disorders co	ont'd		
Monoplegia		15	0
Paralysis		22	0
Paraplegia		2	0
Peripheral paralysis		1	0
Quadriparesis		1	0
Quadriplegia		1	0
Parkinson's disease and parkinsonism			
Reduced facial expression		1	0
Peripheral neuropathies NEC			
Autoimmune neuropathy		1	0
Brachial plexopathy		1	0
Lumbosacral plexus lesion		1	0
Neuritis		1	0
Peripheral sensory neuropathy		2	0
Seizures and seizure disorders NEC			
Change in seizure presentation		1	0
Clonic convulsion		1	0
Epilepsy		27	0
Febrile convulsion		1	0
Myoclonic epilepsy		1	0
Partial seizures		5	0
Psychogenic seizure		3	0
Seizure		170	0
Seizure anoxic		5	0
Seizure like phenomena		6	0
Status epilepticus		1	0
Tonic clonic movements		6	0
Tonic convulsion		2	0
Sensory abnormalities NEC			
Ageusia		2	0
Allodynia		1	0
Complex regional pain syndrome		23	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		34	0
Taste disorder		5	0
Sleep disturbances NEC			
Sudden onset of sleep		3	0
Speech and language abnormalities			
Dysarthria		22	0
Incoherent		4	0
Slow speech		4	0
Speech disorder		13	0
Spinal cord and nerve root disorders NEC			
Radiculitis brachial		1	0
Spinal cord oedema		1	0
Structural brain disorders NEC			
Brain injury		1	0
Transient cerebrovascular events			

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	201	0
Nervous system disorders SOC TOTAL	7693	l o

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

Reaction Name	Total	Fatal
Product label issues		
Product lot number issue	1	0
Product quality issues NEC		
Product origin unknown	8	0
Product substitution issue	1	0
null SOC TOTAL	10	0

Psychiatric disorders	Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 2	4.0	
Abnormal behaviour NEC	Reaction Name	Total_	Fatal
Abnormal behaviour 12 0 0			
Behaviour disorder 1	Abnormal behaviour NEC		
Staring Adjustment disorders Adjustment disorder with mixed anxiety and depressed mood 2 Oxaffect alterations NEC Affect lability 1 1 1 1 1 1 1 1 1	Abnormal behaviour	12	0
Adjustment disorders Adjustment disorder with mixed anxiety and depressed mood 2 Affect lability 1 0 Affect lability 1 0 Anxiety disorder 1 0 Anxiety disorder 1 0 Anxiety disorder 1 0 Anxiety symptoms 8 0 Agitation 8 0 Anxiety 82 0 Nervousness 19 0 Stress 4 0 Behaviour and socialisation disturbances 4 0 Aggression 9 0 Disturbance in social behaviour 1 0 Impatience 1 0 Indifference 1 0 Personality change 5 0 Social avoidant behaviour 4 0 Bipolar disorder 1 0 Bipolar disorder 1 0 Bipolar disorder 1 0 Bipolar disorder 3	Behaviour disorder	1	0
Afjustment disorder with mixed anxiety and depressed mood 2 Affect alterations NEC 1 Affect lability 1 Inappropriate affect 1 Anxiety disorder SNEC 1 Anxiety disorder 1 Generalised anxiety disorder 1 Anxiety symptoms 8 Agitation 8 Anxiety 82 Nervousness 19 Stress 4 Behaviour and socialisation disturbances Aggression 9 Disinhibition 2 Disinhibition 2 Disinhibition 2 Disinhibition 2 1 0 Impatience 1 1 0 Personality change 5 Social avoidant behaviour 4 Bipolar disorders Bipolar disorders Bipolar disorder 1 Bipolar disorder 1 Confusion and disorders and disturbances NEC Mental fatigue 2<	Staring	1	0
Affect albitity 1 Affect labitity 1 Inappropriate affect 1 Anxiety disorder SNEC Anxiety disorder 1 Generalised anxiety disorder 1 Anxiety symptoms 8 Agitation 8 Anxiety 82 Nervousness 19 Stress 4 Behaviour and socialisation disturbances Aggression 9 Disturbance in social behaviour 1 Impatence 1 Indifference 1 Paranoia 5 Personality change 11 Social avoidant behaviour 4 Bipolar disorders 1 Bipolar I disorder 1 Bipolar I disorder 1 Bipolar I disorder 1 Bipolar I disorder 1 Confusional state 4 Disorientation 2 Confusional state 45 Disorientation 2 Depression disorders<	Adjustment disorders		
Affect lability Inappropriate affect Anxiety disorders NEC Anxiety disorder Generalised anxiety disorder Anxiety symptoms Agitation Anxiety Agitation Anxiety Agitation Anxiety Agitation Anxiety Agression Disinhibition Disturbance in social behaviour Impatience Indifference Paranoia Social avoidant behaviour Bipolar disorders Bipolar I disorder Bipolar disorder Bipolar disorder Cognitive and attention disorders and disturbances NEC Mental fatigue Confusional state Disorientation Deliria Delirium Deliria Delirium Delirian Delirium Delirian Delirium Delirian Delirium Delpression suicidal Dissociative states Dissociation Dissociation Dissociation Dissociation Disposaria disorders Disposaria disorders Depression and disorders Depression Depression suicidal Dissociative states Dissociative states Dissociative states Dissociation Dissociative states Dissociation Disturbances in initiating and maintaining sleep Insomnia Dyssomnias Poor quality sleep Eating disorders NEC Anorexia nervosa 1 0 0	Adjustment disorder with mixed anxiety and depressed mood	2	0
Inappropriate affect	Affect alterations NEC		
Anxiety disorder 1	Affect lability	1	0
Anxiety disorder Generalised anxiety disorder Anxiety symptoms Agitation Anxiety Nervousness Stress Behaviour and socialisation disturbances Aggression Disinhibition Disturbance in social behaviour Impatience Paranoia Personality change Social avoidant behaviour Bipolar disorders Bipolar I disorder Bipolar disorder Cognitive and attention disorders and disturbances NEC Mental fatigue Confusion and disorientation Confusional state Disorientation Deliria Delusion Delpressive disorders Depression suicidal Dissociative states Dissociative states Dissociative states Dissociative sleep Insomnia Dyssomnias Poor quality sleep Eating disorder NEC Anorexia nervosa 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Inappropriate affect	1	0
Generalised anxiety disorder 1	Anxiety disorders NEC		
Anxiety symptoms 8 0 Anxiety 82 0 Nervousness 19 0 Stress 4 0 Behaviour and socialisation disturbances 4 0 Aggression 9 0 Distinbibition 2 0 Disturbance in social behaviour 1 0 Impatience 1 0 Indifference 1 0 Paranoia 5 0 Personality change 11 0 Social avoidant behaviour 4 0 Bipolar disorders 1 0 Bipolar disorders 1 0 Bipolar disorder 1 0 Bipolar disorder 1 0 Bipolar disorder 1 0 Confusion and disorientation 2 0 Confusional state 45 0 Disorientation 31 0 Delirium 3 0 Delirium 3 0 Delusional symptoms 2 0	Anxiety disorder	1	0
Agitation Anxiety Rervousness Stress Aggression Disinhibition Disturbance in social behaviour Impatience Indifference Paranoia Personality change Social avoidant behaviour Bipolar disorder Bipolar disorder Bipolar disorder Bipolar disorder Cognitive and attention disorders and disturbances NEC Mental fatigue Confusion and disorientation Confusional state Disorientation Deliria Delirium Delirium Delirium Delirium Delirius disorders Depression Depression uicidal Dissociative states Dissociative states Dissociative states Dissomia Individual step Insomnia Middle insomnia Por Quality sleep Eating disorders NEC Anorexia nervosa I 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Generalised anxiety disorder	1	0
Anxiety Nervousness 19	Anxiety symptoms		
Nervousness 19	Agitation	8	0
Stress	Anxiety	82	0
Behaviour and socialisation disturbances	Nervousness	19	0
Aggression 9 0 Disinhibition 2 0 Disturbance in social behaviour 1 0 Impatience 1 0 Indifference 1 0 Paranoia 5 0 Personality change 5 0 Social avoidant behaviour 4 0 Bipolar disorders 1 0 Bipolar disorder 1 0 Bipolar disorder 1 0 Bipolar disorder 1 0 Bipolar disorder 1 0 Cognitive and attention disorders and disturbances NEC 0 Mental fatigue 2 0 Confusion and disorientation 3 0 Confusional state 45 0 Deliria 31 0 Deliria 3 0 Delusional symptoms 2 0 Delusion 2 0 Depressive disorders 0 0 Depressi	Stress	4	0
Disinhibition 2 0 Disturbance in social behaviour 1 0 Impatience 1 0 Indifference 1 0 Paranoia 5 0 Personality change 11 0 Social avoidant behaviour 4 0 Bipolar disorders 3 0 Bipolar I disorder 1 0 Bipolar disorder 3 0 Bipolar disorder 3 0 Cognitive and attention disorders and disturbances NEC 0 Mental fatigue 2 0 Confusion and disorientation 3 0 Confusional state 45 0 Disorientation 31 0 Deliria 3 0 Deliria 3 0 Delusional symptoms 2 0 Depressive disorders 2 0 Depression suicidal 4 0 Dissociative states 3 0	Behaviour and socialisation disturbances		
Disturbance in social behaviour 1	Aggression		0
Impatience	Disinhibition	2	0
Indifference	Disturbance in social behaviour	1	0
Paranoia 5 0 Personality change 11 0 Social avoidant behaviour 4 0 Bipolar disorders 8 1 0 Bipolar I disorder 3 0 Cognitive and attention disorders and disturbances NEC 0 Mental fatigue 2 0 Confusion and disorientation 2 0 Confusional state 45 0 Disorientation 31 0 Deliria 3 0 Deliria 3 0 Delusional symptoms 2 0 Delusion 2 0 Depressive disorders 2 0 Depressive disorders 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociative states 3 0 Dissociation 3 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 7 0 Poor quality sleep	Impatience	1	0
Personality change		1	0
Social avoidant behaviour Bipolar disorders 1	Paranoia	5	0
Bipolar disorders 1 0 Bipolar disorder 3 0 Cognitive and attention disorders and disturbances NEC 2 0 Mental fatigue 2 0 Confusion and disorientation 45 0 Confusional state 45 0 Disorientation 31 0 Deliria 3 0 Deliria 3 0 Delusional symptoms 2 0 Delusion 2 2 0 Depressive disorders 2 0 Depression suicidal 4 0 Dissociative states 0 0 Dissociative states 5 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 9 4 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0 <td>Personality change</td> <td>11</td> <td>0</td>	Personality change	11	0
Bipolar I disorder 1	Social avoidant behaviour	4	0
Bipolar disorder 3 0 0 0 0 0 0 0 0 0	Bipolar disorders		
Cognitive and attention disorders and disturbances NEC 2 0 Mental fatigue 2 0 Confusion and disorientation 31 0 Confusional state 45 0 Disorientation 31 0 Deliria 3 0 Delirium 3 0 Delusional symptoms 2 0 Depressive disorders 2 0 Depressive disorders 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociative states 3 0 Dissociation 3 0 Middle insomnia 59 0 Middle insomnia 1 0 Dyssomnias 2 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Bipolar I disorder	1	0
Mental fatigue 2 0 Confusion and disorientation 45 0 Confusional state 45 0 Disorientation 31 0 Deliria 3 0 Delusional symptoms 2 0 Delusion 2 0 Depressive disorders 2 0 Depressive disorders 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 3 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 2 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Bipolar disorder	3	0
Confusion and disorientation 45 0 Confusional state 45 0 Disorientation 31 0 Deliria 3 0 Delirium 3 0 Delusional symptoms 2 0 Delusion 2 0 Depressive disorders 2 0 Depressive disorders 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 2 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Cognitive and attention disorders and disturbances NEC		
Confusional state 45 0 Disorientation 31 0 Deliria 3 0 Delirium 3 0 Delusional symptoms 2 0 Delusion 2 0 Depressive disorders 2 0 Depressive disorders 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 9 4 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Mental fatigue	2	0
Disorientation 31 0 Deliria 3 0 Delusional symptoms 2 0 Depressive disorders 2 0 Depression 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 3 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 2 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0			
Deliria 3 0 Delusional symptoms 2 0 Depressive disorders 2 0 Depression 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 3 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 2 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Confusional state	45	0
Delirium 3 0 Delusional symptoms 2 0 Depressive disorders 2 0 Depression 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 1 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Disorientation	31	0
Delusional symptoms2Delusion20Depressive disorders3Depression Suicidal40Dissociative states0Dissociation30Disturbances in initiating and maintaining sleep590Insomnia590Middle insomnia10Dyssomnias10Poor quality sleep40Eating disorders NEC40Anorexia nervosa10	Deliria		
Delusion 2 0 Depressive disorders 2 0 Depression 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 9 4 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Delirium	3	0
Delusion 2 0 Depressive disorders 2 0 Depression 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 9 4 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Delusional symptoms		
Depression 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 9 4 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0		2	0
Depression 43 0 Depression suicidal 4 0 Dissociative states 3 0 Dissociation 3 0 Disturbances in initiating and maintaining sleep 59 0 Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 9 4 0 Poor quality sleep 4 0 Eating disorders NEC 4 0 Anorexia nervosa 1 0	Depressive disorders		
Dissociative statesDissociation30Disturbances in initiating and maintaining sleepInsomnia590Middle insomnia10DyssomniasPoor quality sleep40Eating disorders NEC40Anorexia nervosa10		43	0
Dissociative statesDissociation30Disturbances in initiating and maintaining sleepInsomnia590Middle insomnia10DyssomniasPoor quality sleep40Eating disorders NEC40Anorexia nervosa10	Depression suicidal	4	0
Disturbances in initiating and maintaining sleepInsomnia59Middle insomnia1Dyssomnias0Poor quality sleep4Eating disorders NEC0Anorexia nervosa1			
Insomnia 59 0 Middle insomnia 1 0 Dyssomnias 0 Poor quality sleep 4 0 Eating disorders NEC 0 Anorexia nervosa 1 0	Dissociation	3	0
Middle insomnia 1 0 Dyssomnias Poor quality sleep 4 0 Eating disorders NEC Anorexia nervosa 1 0	Disturbances in initiating and maintaining sleep		
Middle insomnia 1 0 Dyssomnias Poor quality sleep 4 0 Eating disorders NEC Anorexia nervosa 1 0	_ · · · · · · · · · · · · · · · · · · ·	59	0
Poor quality sleep 4 0 Eating disorders NEC Anorexia nervosa 1 0	Middle insomnia	1	0
Poor quality sleep 4 0 Eating disorders NEC Anorexia nervosa 1 0	Dyssomnias		
Eating disorders NEC Anorexia nervosa 1 0	l v	4	0
Anorexia nervosa 1 0			
		1	0
Eating disorder 3 0		3	0
			0
,	Emotional and mood disturbances NEC		

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0	T-1-1	F-1-1
Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric} disorders cont'd		_
Anger	3	0
Emotional disorder	14	0
Emotional distress	13	0
Emotional poverty	1	0
Euphoric mood	1	0
Irritability	7	0
Mood altered	6	0
Fear symptoms and phobic disorders (incl social 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	17	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		U
Restlessness	5	0
Mental disorders NEC	3	U
Mental disorder Mental disorder	6	0
Mental status changes	1	0
Mood alterations with depressive symptoms		J
Decreased interest	4	0
Depressed mood	16	0
Depressive symptom		0
Feeling guilty	2	0
Feeling of despair	1	0
Negative thoughts	1	0
Tearfulness	30	0
Mood alterations with manic symptoms	30	U
Hypomania	1	0
Mood disorders NEC		U
Affective disorder	1	0
	-	0
Apathy	3	
Listless	5	0
Narcolepsy and associated conditions	4	^
Sleep attacks	1	0
Obsessive-compulsive disorders and symptoms	4	_
Obsessive thoughts	1	0
Obsessive-compulsive disorder	1	0
Trichotillomania	1	0
Panic attacks and disorders		
Panic attack	30	0
Panic reaction	8	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 24.0	Total	Cotol
Reaction Name		Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd			
Parasomnias		4	_
Abnormal dreams		1	0
Abnormal sleep-related event		1	0
Sleep terror		2	0
Perception disturbances NEC			
Deja vu		1	0
Illusion		1	0
Near death experience		1	0
Personality disorders NEC			
Self esteem decreased		3	0
Personality disorders with anxious behaviou	r (Cluster C)		
Dependent personality disorder		1	0
Pervasive developmental disorders NEC			
Autism spectrum disorder		4	0
Psychiatric symptoms NEC			
Psychiatric symptom		3	0
Psychotic disorder NEC			
Acute psychosis		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	0
Speech and language usage disturbances			
Disorganised speech		1	0
Logorrhoea		1	0
Speech articulation and rhythm disturbances	3		
Dysphemia		3	0
Stereotypies and automatisms			
Bruxism		1	0
Head banging		2	0
Stress disorders			
Burnout syndrome		1	0
Post-traumatic stress disorder		1	0
Suicidal and self-injurious behaviour			
Intentional self-injury		6	0
Self-injurious ideation		1	0
Suicidal ideation		7	0
Suicide attempt		2	0
Thinking disturbances			
Bradyphrenia		2	0
Intrusive thoughts		1	0
Thinking abnormal		3	0
Thought blocking		2	0
Tic disorders			
Tic		2	0
Psychiatric disorders SOC TOTAL		684	

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0	- , ,	
Reaction Name	Total	<u>Fatal</u>
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder pain	2	0
Bladder spasm	1	0
Dysuria	3	0
Incontinence	3	0
Micturition urgency	3	0
Pollakiuria	9	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 inflammations NEC		
Urinary tract inflammation	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		
Contracted bladder	1	0
Hypertonic bladder	1	0
Neurogenic bladder	1	0
Renal disorders NEC		
Renal disorder	2	0
Renal failure and impairment		
Renal failure	1	0
Renal lithiasis		
Nephrolithiasis	1	0
Renal vascular and ischaemic conditions		
Renal vasculitis	1	0
Urinary abnormalities		
Proteinuria	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	75	0

	MedDRA Version: MedDRA 24.0		
Reaction Name	Tota	<u>al</u>	<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		5	0
Menstruation and uterine bleeding NEC			
Dysmenorrhoea		21	0
Intermenstrual bleeding		3	0
Menstrual discomfort		1	0
Menstrual disorder		20	0
Menstruation irregular		38	0
Premenstrual pain		1	0
Premenstrual syndrome		1	0
Menstruation with decreased bleeding			
Amenorrhoea		38	0
Menstruation delayed		26	0
Oligomenorrhoea		3	0
Menstruation with increased bleeding			
Heavy menstrual bleeding		30	0
Polymenorrhoea		2	0
Ovarian and fallopian tube cysts and neoplas	ms		
Ovarian cyst		4	0
Polycystic ovaries		11	0
Ovarian and fallopian tube disorders NEC			
Ovarian disorder		2	0
Ovarian failure		2 6	0
Ovulation disorder		1	0
Pelvis and broad ligament disorders NEC			
Adnexa uteri pain		1	0
Reproductive tract signs and symptoms NEC			
Genital erythema		1	0
Genital pain		2	0
Genital swelling		2	0
Pelvic pain		2 2 5	0
Sexual function and fertility disorders NEC			
Dyspareunia		1	0
Infertility		2	0
Uterine disorders NEC			
Endometriosis		1	0

Reaction Name	Total	Fatal
Reproductive & breast disorders cont'd		
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	281	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	203	0
Grunting	3	0
Hyperventilation	53	0
Hypopnoea	14	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	53	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	1	J
	_	0
Laryngeal oedema	5 1	0
Laryngospasm		
Stridor	1	0
Lower respiratory tract signs and symptoms		_
Increased bronchial secretion	1	0
Pleuritic pain	2	0
Nasal congestion and inflammations		
Nasal congestion	9	0
Nasal disorders NEC		
Epistaxis	32	0
Nasal oedema	1	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinonasal obstruction	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	16	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

Reaction Name	Total	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	136	0
Rhinorrhoea	7	0
Sinus pain	2	0
Sneezing	4	0
Throat irritation	27	0
Throat lesion	1	0
Throat tightness	42	0
Vascular pulmonary disorders NEC		
Pulmonary arteriopathy	2	0
Respiratory disorders SOC TOTAL	743	1

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 24.0		
Reaction Name	To	<u>otal</u>	<u>Fatal</u>
Skin disorders			
Acnes			
Acne		9	0
Acne cystic		1	0
Alopecias			
Alopecia		43	0
Alopecia areata		11	0
Alopecia totalis		2	0
Diffuse alopecia		3	0
Madarosis		1	0
Angioedemas			
Angioedema		16	0
Circumoral oedema		1	0
Apocrine and eccrine gland disorders			
Cold sweat		106	0
Hyperhidrosis		103	
Miliaria		4	_
Night sweats		3	0
Bullous conditions			
Blister		20	0
Dermatitis bullous		1	0
Erythema multiforme		11	0
Stevens-Johnson syndrome		1	0
Dermal and epidermal conditions NEC			
Dry skin		13	0
Pain of skin		8	0
Papule		5	0
Scab			0
Sensitive skin		2 2	0
Skin burning sensation		4	0
Skin discolouration		104	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		29	0
Yellow skin		2	0
Dermatitis and eczema			
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		1	0
Erythemas			

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0 Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Erythema	233	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
Pityriasis lichenoides et varioliformis acuta	1	0
Pityriasis rosea	3	0
Photosensitivity and photodermatosis conditions		_
Photosensitivity reaction	18	0
Pigmentation changes NEC		_
Pigmentation disorder	2	0
Pilar disorders NEC		_
Hair growth abnormal	1	0
Piloerection	1	0
Trichorrhexis		0
Pruritus NEC	•	J
Pruritus	197	0
Psoriatic conditions		_
Guttate psoriasis	1	0
Psoriasis	5	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	464	0
Rash erythematous	42	0
Rash macular	81	0
Rash maculo-papular	6	0
Rash papular	9	0
Rash pruritic	71	0
Rash vesicular	2	0
Systemic lupus erythematosus rash	1	O
Skin and subcutaneous conditions NEC	·	
Skin mass	3	0
Umbilical discharge	1	0
Skin haemorrhages		
Skin haemorrhage	1	0

Reaction Name	Total	Fatal
Skin disorders Cont'd		
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	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	42	. 0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	247	0
Urticaria chronic	3	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	2112	el o

Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Puberty	1	0
Disability issues		
Bedridden	5	0
Disability	2	0
Immobile	2	0
Impaired work ability	1	0
Loss of personal independence in daily activities	14	0
Physical disability	1	0
Wheelchair user	1	0
Educational issues		
Educational problem	2	0
Social circumstances SOC TOTAL	29	0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Hernia repairs		
Inguinal hernia repair	1	0
Induced abortions		
Abortion induced	6	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
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	16	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	<u>Fatal</u>
Vascular disorders		
Blood pressure disorders NEC		
Blood pressure fluctuation	1	0
Circulatory collapse and shock		
Circulatory collapse	7	0
Peripheral circulatory failure	1	0
Shock	4	0
Haemorrhages NEC		
Haemorrhage	3	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		
Capillary disorder	3	0
Vascular pain	1	0
Vasodilatation	1	0
Peripheral embolism and thrombosis		_
Deep vein thrombosis	1	0
Thrombophlebitis superficial	1	0
Peripheral vascular disorders NEC	·	Ĭ
Cyanosis	36	0
Erythromelalgia	1	0
Flushing	122	0
Hot flush	21	0
Peripheral vascular disorder	2	o o
Peripheral vasoconstriction, necrosis and vascular insufficiency	_	
Peripheral coldness	121	0
Poor peripheral circulation	9	
Raynaud's phenomenon	7	0
Site specific vascular disorders NEC	'	١
Pallor	368	0
Vascular hypertensive disorders NEC	300	"
Hypertension	10	_
Orthostatic hypertension	10	0
	I	
Vascular hypotensive disorders	41	_
Hypotension Orthostatic hypotension	41	0
Orthostatic hypotension Vasculitides NEC		0
1	4	_
Behcet's syndrome	3	0
Vasculitis		l
Vascular disorders SOC TOTAL	777	8
TOTAL REACTIONS FOR DRUG	26462	٤
TOTAL REPORTS	9870	
TOTAL FATAL OUTCOME REPORTS		8