Report Run Date: 11-Feb-2021

Data Lock Date: 03-Feb-2021 19:00:04

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1

Human Papilloma UK Spontaneous ADR reports for Human Papilloma

Virus (HPV): Virus until 31/01/2021

Report Run Date: 11-Feb-2021, Page 1

Reaction Name	Total	Fatal
Blood disorders	lotai	i alai
Anaemia deficiencies		
Anaemia vitamin B12 deficiency	2	0
Iron deficiency anaemia	1	o o
Pernicious anaemia	1	o o
Anaemias NEC		
Anaemia	10	0
Anaemias haemolytic mechanical factor		
Haemolytic uraemic syndrome	1	0
Bleeding tendencies		
Increased tendency to bruise	4	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	59	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Pancytopenia	1	0
Neutropenias		
Autoimmune neutropenia	2	
Neutropenia	3	0
Spleen disorders		
Splenomegaly	2	0
Thrombocytopenias		
Immune thrombocytopenia	9	0
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	112	l o

Report Run Date: 11-Feb-2021 Data Lock Date: 03-Feb-2021 19:00:04 Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1

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	56	0
Ischaemic coronary artery disorders		
Angina pectoris	3	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Pulmonary valvular disorders		
Pulmonary valve stenosis	2	2 0
Rate and rhythm disorders NEC		
Arrhythmia	2	2 0
Bradycardia	6	0
Postural orthostatic tachycardia syndrome	81	0
Tachycardia	48	0
Supraventricular arrhythmias		
Sinus arrhythmia		0
Sinus tachycardia	7	' o
Supraventricular tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	3	1
Pulseless electrical activity	1	0
Cardiac disorders SOC TOTAL	217	1 1

Report Run Date: 11-Feb-2021, Page 3

Report Run Date: 11-Feb-2021 Data Lock Date: 03-Feb-2021 19:00:04 Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
Reaction Name	_ Total_	<u>Fatal</u>
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	

Report Run Date: 11-Feb-2021, Page 4

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		0
Tinnitus	16	0
Vertigo	15	0
Ear disorders SOC TOTAL	125	o l

Report Run Date: 11-Feb-2021 Data Lock Date: 03-Feb-2021 19:00:04 Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1

Lariest Reaction Date. 05-May-2000 MedDRA Version. MedDRA		
Reaction Name	Total	<u>Fatal</u>
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	1	0
Hypothyroidism	10	0
Endocrine disorders SOC TOTAL	28	l o

Report Run Date: 11-Feb-2021, Page 6

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
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	2	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	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	0
Periorbital pain	1	0
Periorbital swelling	2	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	7	0
Ocular nerve and muscle disorders	· l	·
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		U
	1	0
Asthonomia	1	0
Asthenopia	3	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23	3.1	
Reaction Name	<u>Total</u>	<u>Fatal</u>
Eye disorders Eye disorders cont'd		
Foreign body sensation in eyes	1	0
Photophobia	62	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	21	0
Pupil fixed	3	0
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	0
Vision blurred	161	0
Visual impairment and blindness (excl colour blindness)		
Blindness	14	
Blindness transient	22	0
Blindness unilateral	1	0
Visual acuity reduced	1	0
Visual impairment	75	C
Eve disorders SOC TOTAL	584	l o

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
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	2 0
Colitis ulcerative	4	· 0
Crohn's disease	1	0
Dental disorders NEC		
Tooth erosion	1	0
Diaphragmatic hernias		
Hiatus hernia	1	0
Diarrhoea (excl infective)		
Diarrhoea	131	0
Diarrhoea haemorrhagic	2	0
Dyspeptic signs and symptoms		
Dyspepsia	10	) o
Eructation	2	0
Faecal abnormalities NEC		
Abnormal faeces	1	0
Flatulence, bloating and distension		
Abdominal distension	16	0 ا
Flatulence	2	2 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	, o
Reflux gastritis	1	0
Gastrointestinal and abdominal pains (excl o	ral and throat)	
Abdominal migraine	1	0
Abdominal pain	209	o o
Abdominal pain lower	16	
Abdominal pain upper	193	
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	2	
Gastrointestinal atonic and hypomotility disor	rders NEC	
Constipation	17	0
Gastric dilatation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	14	0
Impaired gastric emptying	5	1
Gastrointestinal disorders NEC		
Functional gastrointestinal disorder	1	0
Gastric disorder	7	, 0
Gastrointestinal disorder	17	
Gastrointestinal dyskinetic disorders	,	
Bowel movement irregularity	1	0
Dyschezia	1	

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Gastrointestinal disorders con		
Gastrointestinal motility disorder	2	. 0
Gastrointestinal inflammatory disorders NEC		
Duodenitis	1	0
Gastrointestinal inflammation	3	0
Gastrointestinal mucosal dystrophies and sec	retion disorders	
Oesophageal mucosal hyperplasia	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	55	0
Dysphagia	27	0
Oesophageal discomfort	1	0
Gastrointestinal spastic and hypermotility disc	orders	
Defaecation urgency	1	
Frequent bowel movements	3	
Irritable bowel syndrome	22	0
Gastrointestinal ulcers and perforation, site ur	nspecified	
Gastrointestinal ulcer	1	0
Gingival disorders, signs and symptoms NEC		
Gingival disorder	1	
Gingival pain	2	. 0
Gingival swelling	1	_
Gingival ulceration	1	0
Gingival haemorrhages		
Gingival bleeding	1	0
Haemorrhoids and gastrointestinal varices (ex	(cl oesophageal)	
Haemorrhoids	1	0
Inguinal hernias		
Inguinal hernia	2	. 0
Intestinal haemorrhages		
Rectal haemorrhage	2	2 0
Malabsorption syndromes		
Bile acid malabsorption	1	_
Coeliac disease	8	
Malabsorption	2	. 0
Nausea and vomiting symptoms		
Cyclic vomiting syndrome	1	0
Nausea	1685	
Regurgitation	1	0
Retching	7	0
Vomiting	723	
Vomiting projectile	1	0
Non-site specific gastrointestinal haemorrhage		
Gastrointestinal haemorrhage	1	
Haematemesis	6	
Haematochezia	1	0
Oesophagitis (excl infective)		_
Eosinophilic oesophagitis	1	0
Oral dryness and saliva altered		_
Dry mouth	5	
Lip dry	1	0
Saliva altered		
Salivary hypersecretion	3	0
Oral soft tissue disorders NEC		
Chapped lips		0

Reaction Name	Total	Fatal
Gastrointestinal disorders ointestinal disorders cont'd		
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
Odynophagia	2	0
Oral discomfort	3	0
Oral mucosal blistering	2	0
Oral mucosal eruption	1	0
Oral pain	5	0
Oral pruritus	2	0
Paraesthesia oral	38	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	0
Tongue coated	2	0
Tongue discomfort	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	3446	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site pain	1	0
Administration site swelling	1	0
Puncture site reaction	1	0
Asthenic conditions		
Asthenia	187	0
Chronic fatigue syndrome	103	
Decreased activity	100	
Fatigue	776	_
Malaise	775	
	113	
Body temperature altered	1.5	
Temperature regulation disorder	15	0
Death and sudden death		
Death 5 to 1 to 2	1	1
Febrile disorders		
Hyperpyrexia	1	0
Pyrexia	550	
Feelings and sensations NEC		
Chills	105	
Feeling abnormal	90	
Feeling cold	79	
Feeling drunk	4	1 1
Feeling hot	216	0
Feeling jittery	5	0
Feeling of body temperature change	24	0
Sensation of foreign body	3	0
Temperature intolerance	7	' 0
Thirst	8	0
Gait disturbances		
Gait disturbance	33	0
Gait inability	29	0
Loss of control of legs	5	0
General signs and symptoms NEC		
Condition aggravated	15	0
Crying	13	0
Disease recurrence	1	0
Exercise tolerance decreased	7	'l ol
Foaming at mouth	4	l o
General physical health deterioration	2	. 0
Glassy eyes	2	
III-defined disorder	2	
Illness	89	
Induration		o
Influenza like illness	123	_
Local reaction	31	
Organ failure		0
Peripheral swelling	351	-
Screaming	331	
Screaming Secretion discharge	1	
	80	
Swelling Swelling face	93	
Swelling face	93	9 0
Healing abnormal NEC		
Impaired healing		2 0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1		
Reaction Name	To	al	Fatal
General disorders General disorders cont'd			
Hernias NEC			
Hernia		2	0
Inflammations			
Inflammation		21	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		2	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		170	0
Injection site swelling		176	0
Injection site urticaria		5 5	0
Injection site vesicles			0
Injection site warmth  Mass conditions NEC		28	0
		1	0
Cyst Mass		5	0
		2	
Nodule  Mucosal findings abnormal			0
Mucosal findings abnormal  Mucosal ulceration		1	0
Oedema NEC			0
Face oedema		_	0
Localised oedema		5	0
		12	0
Oedema peripheral		12	U
Pain and discomfort NEC			

	A Version: MedDRA 23.1	
Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Axillary pain	5	0
Chest discomfort	67	0
Chest pain	108	0
Discomfort	28	0
Facial pain	4	0
Non-cardiac chest pain	2	0
Pain	265	
Tenderness	20	
Therapeutic and nontherapeutic responses		
Adverse drug reaction	4	0
Adverse event	1	l o
Adverse reaction	1	Ö
Drug ineffective	3	_
Drug resistance	1	o o
Immediate post-injection reaction	1	Ö
Therapeutic response unexpected	1	0
Trophic disorders		
Atrophy	1	0
Hyperplasia	1	
Ulcers NEC	,	
Ulcer	3	0
Vaccination site reactions	3	
Extensive swelling of vaccinated limb	2	
_	3	0
Vaccination site atrophy		
Vaccination site bruising Vaccination site coldness	5	
Vaccination site discolouration		0
	2	0
Vaccination site discomfort	1	0
Vaccination site erythema	12	
Vaccination site haemorrhage	2	
Vaccination site hypersensitivity	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	1	0
Vaccination site inflammation	3	ا ا
Vaccination site irritation	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	9	
Vaccination site movement impairment	3	
Vaccination site nerve damage	1	0
Vaccination site nodule	1	0
Vaccination site pain	26	
Vaccination site paraesthesia	1	0
Vaccination site pruritus	5	0
Vaccination site rash	3	
Vaccination site swelling	22	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	5334	1

Reaction Name	Total	<u>Fatal</u>
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	3	0
Hepatic and hepatobiliary disorders NEC		
Hepatic cyst	1	0
Liver disorder	2	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	1	0
Hepatobiliary signs and symptoms		
Hepatic pain	1	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	2	0
Hepatitis acute	1	0
Obstructive bile duct disorders (excl neoplasms)		
Sphincter of Oddi dysfunction	1	0
Hepatic disorders SOC TOTAL	12	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
Reaction Name	<u>Total</u>	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergic oedema		1 0
Allergy to animal		2 0
Hypersensitivity	86	6 0
Multiple allergies		6 0
Type I hypersensitivity		2 0
Type III immune complex mediated reaction		3 0 2 0
Type IV hypersensitivity reaction		2 0
Allergies to foods, food additives, drugs and d	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	99	
Anaphylactic shock		7 0
Anaphylactoid reaction		3 0
Atopic disorders		
Seasonal allergy	•	1 0
Autoimmune disorders NEC		
Autoimmune disorder	1	
Overlap syndrome	•	1 0
Immune and associated conditions NEC		
Decreased immune responsiveness		1 0
Immune system disorder	1·	
Immunisation reaction		2 0
Immunodeficiency disorders NEC		
Immunodeficiency		1 0
Immune system disorders SOC TOTAL	25	1l 0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA		
Reaction Name	<u>Total</u>	Fatal
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
Gastrointestinal bacterial overgrowth	1	
Injection site cellulitis	2	
Bone and joint infections	_	
Osteomyelitis	1	0
Breast infections	·	Ĭ
Mastitis	1	0
Candida infections		
Candida infection	2	0
Vulvovaginal candidiasis	1	
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	1	0
Labyrinthitis	3	
Otitis media	3 2	O
Ectoparasitic infestations		
Acarodermatitis	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	11	
Eye and eyelid infections		
Conjunctivitis	3	О
Hordeolum	5	o
Female reproductive tract infections		
Amniotic cavity infection	1	0
Pelvic inflammatory disease		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	
Varicella	1	0
Infections NEC		
IIIIGUIUIIS NEU		

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Infections Infections cont'd			
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		_	J
Suspected transmission of an infe	ections agent via product	1	0
Influenza viral infections	olious agent via product		0
Influenza		4	0
Lower respiratory tract and lung infe	ections		U
Bronchitis	50tiO113	3	0
Lower respiratory tract infection		16	
Pneumonia		2	0
	·		U
Molluscum contagiosum viral infect	ions		0
Molluscum contagiosum		1	0
Papilloma viral infections		4	_
Papilloma viral infection		4	0
Vulvovaginal human papilloma vir		1	0
Respiratory syncytial viral infections			
Respiratory syncytial virus infection	on	1	0
Retroviral infections			
Acquired immunodeficiency syndi		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 infec	tions		
Application site pustules		1	0
Folliculitis		1	0
Impetigo		1	0
Pustule		1	0
Skin infection		2	0
Staphylococcal infections			
Furuncle		3	0
Staphylococcal infection		2	0
Streptococcal infections			_
Beta haemolytic streptococcal infe	ection	2	0
Streptococcal sepsis		1	1
Upper respiratory tract infections		·	
Epiglottitis		1	0
Laryngitis		1	0
Nasopharyngitis		39	0
Pharyngitis			0
Sinusitis		8 2	0
Tonsillitis		8	
		3	0
Upper respiratory tract infection		3	U
Urinary tract infections		4	^
Kidney infection		1 1	0
Urinary tract infection		5	0
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	54	0
Viral infection	20	0
Viral pharyngitis	1	0
Infections SOC TOTAL	314	1

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Injuries		
Abdominal and gastrointestinal injuries NEC		
Mouth injury	1	0
Bone and joint injuries NEC		
Joint injury	1	0
Chemical injuries		
Chemical burn	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	25	0
Foetal exposure during pregnancy	9	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		
Wrong technique in product usage process	2	0
Muscle, tendon and ligament injuries		
Muscle injury	2	0
Nerve injuries NEC		
Nerve injury	3	0
Neurological and psychiatric procedural complications		
Procedural dizziness	2	0
Non-site specific injuries NEC		
Fall	18	0
Injury	3	0
Wound	1	0
Wound haemorrhage	1	0
Off label uses		
Off label use	1	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	1	0
Peripheral nerve injuries		
Axillary nerve injury	1	0
Peripheral nerve injury	1	0
Poisoning and toxicity		
Metal poisoning	1	0
Poisoning	1	0
Product administration errors and issues		
Expired product administered	2	0
Extra dose administered	4	0
Inappropriate schedule of product administration	8	0
Product administered at inappropriate site	4	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	1	0
Site specific injuries NEC		
Face injury	1	0
Head injury	1	0
Skin injuries NEC		
Contusion	54	0
Dermatitis artefacta	1	0
Scar	2	0
Skin abrasion	1	0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Thermal burns		
Thermal burn	1	0
Vaccination related complications		
Vaccination complication	8	0
Vaccination failure	3	0
Injuries SOC TOTAL	186	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
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		
Blood count abnormal	1	0
Blood gas and acid base analyses	·	Ŭ
Blood pH increased	1	0
Oxygen saturation decreased	2	0
Carbohydrate tolerance analyses (incl diabetes)		0
Blood glucose decreased	3	0
Blood glucose decreased	6	0
Cardiac auscultatory investigations	J	U
Cardiac auscultatory investigations Cardiac murmur	- 1	0
Heart sounds abnormal	1	0
		U
Cell marker analyses		0
Cell marker increased	1	0
Central nervous system imaging procedures		0
Magnetic resonance imaging brain 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	5	0
Heart rate decreased	10	0
Heart rate increased	53	0
Heart rate irregular	16	0
Pulse abnormal	9	0
Pulse absent	3	0
Pulse pressure decreased	. 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
Hepatic enzyme increased	1	0
Liver function test abnormal	1	0
Liver function test abnormal	1	0
Mineral and electrolyte analyses	1	J
Blood iron decreased	_	^
	5 1	0
Blood magnesium decreased	1	0
Blood selenium decreased	1	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	<u>Fatal</u>
Investigations Investigations cont'd			
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 s	system status		
Body temperature abnormal		4	0
Body temperature decreased		7	0
Body temperature fluctuation		8	0
Body temperature increased		102	0
Breath sounds abnormal		1	0
Grip strength decreased		3	0
Respiratory rate decreased		1	0
Respiratory rate increased		13	0
Weight decreased		24	0
Weight increased		5	0
Pituitary analyses anterior			
Blood growth hormone abnormal		1	0
Blood thyroid stimulating hormone abnorma	I	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 histopatholog	y procedures		
Smear cervix abnormal	•	1	0
Respiratory and pulmonary function diagnosti	c procedures		
Peak expiratory flow rate decreased	•	1	0
Tissue enzyme analyses NEC			
Blood lactate dehydrogenase 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		12	0
Blood pressure immeasurable		1	0
Blood pressure increased		8	0
Blood pressure systolic decreased		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

<b>Reaction Nam</b>	e	Total	Fatal
Investigations	Investigations cont'd		
White blood of	cell count decreased	1	0
Investigations SC	OC TOTAL	369	o o

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
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	Ĭ	Ŭ
Vitamin D deficiency	12	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	2	0
Food intolerance	8	0
Gluten sensitivity	5	0
Histamine intolerance	1	0
General nutritional disorders NEC	'	J
Abnormal loss of weight	30	0
Abnormal weight gain	1	0
Cachexia	1	0
	5	0
Feeding disorder Malnutrition	5	0
	1	-
Underweight Weight fluctuation	1	0
Weight fluctuation	1	0
Weight gain poor	1	0
Hyperglycaemic conditions NEC	2	0
Hyperglycaemia	3	0
Insulin resistance	1	0
Hypoglycaemic conditions NEC	_	0
Hypoglycaemia	3	0
Iron deficiencies	۰	0
Iron deficiency	3	0
Metabolic acidoses (excl diabetic acidoses)		0
Lactic acidosis	1	0
Metabolic disorders NEC		0
Metabolic disorder	1	0
Mineral related disorders NEC	4	
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	0
Metabolic disorders SOC TOTAL	212	0

	MedDRA Version: MedDRA 23.1	
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		
Osteitis		1 0
Bone related signs and symptoms		
Bone pain	1	1 0
Coccydynia		1 0
Pain in jaw		6 0
Spinal pain		7 0
Cartilage disorders		
Costochondritis		2 0
Osteochondrosis		1 0
Connective tissue disorders NEC		
Mixed connective tissue disease		1 0
Reynold's syndrome		1 0
Sjogren's syndrome		1 0
Extremity deformities		
Finger deformity		1 0
Foot deformity		1 0
Hand deformity		1 0
Joint related disorders NEC		
Hypermobility syndrome	!	9 0
Joint contracture		1 0
Joint lock		1 0
Periarthritis		2 0
Joint related signs and symptoms		
Arthralgia	24	8 0
Joint effusion		1 0
Joint noise		3 0
Joint range of motion decreased		1 0
Joint stiffness	1.	4 0
Joint swelling	3	4 0
Ligament disorders		
Ligament pain		1 0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome		1 0
Systemic lupus erythematosus		3 0
Metabolic bone disorders		
Osteoporosis		1 0
Muscle infections and inflammations		
Myositis		1 0
Muscle pains		
Fibromyalgia	1	7 0
Myalgia	17	
Myalgia intercostal		1 0
Muscle related signs and symptoms NEC		
Muscle atrophy		2 0
Muscle discomfort		2l 0
Muscle fatigue	1	2 0
Muscle spasms	4	

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Muscle & tissue disordersle & tissue disord	ders cont'd		
Muscle swelling		1	0
Muscle tightness		6	0
Muscle twitching		49	0
Muscle tone abnormalities			
Muscle rigidity		35	0
Trismus		1	0
Muscle weakness conditions			
Muscular weakness		123	0
Musculoskeletal and connective tissue	conditions 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 stiffness		105	0
Posture abnormal		1	0
Weight bearing difficulty		8	0
Musculoskeletal and connective tissue	pain and discomfort		
Back pain		85	0
Flank pain		2	0
Growing pains		2	0
Limb discomfort		180	0
Musculoskeletal chest pain		11	0
Musculoskeletal discomfort		4	0
Musculoskeletal pain		5	0
Neck pain		74	0
Pain in extremity		1092	0
Rheumatoid arthropathies			
Juvenile idiopathic arthritis		3	0
Rheumatoid arthritis		4	0
Soft tissue disorders NEC			
Axillary mass		2	0
Groin pain		5	0
Neck mass		1	0
Soft tissue disorder		1	0
Spine and neck deformities			
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		2464	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
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
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		
Neoplasm malignant	1	1
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	1	1
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
Salivary gland neoplasms malignant		
Salivary gland cancer stage I	1	0
Skin neoplasms benign		
Anogenital warts	5	0
Melanocytic naevus	1	0
Skin papilloma	4	0
Uterine neoplasms benign		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	31	4

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	Fatal
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	217	0
Loss of consciousness	109	0
Sedation	1	0
Somnolence	166	0
Syncope	864	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	0
Irregular sleep wake rhythm disorder	4	0
Dyskinesias and movement disorders NEC		
Clumsiness	2	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Nervous system disorders us system disorders co	ont'd	
Dyskinesia	62	0
Fine motor skill dysfunction	1	0
Hypokinesia	14	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		
Facial paralysis	16	0
Facial paresis	1	0
Facial spasm	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	23	0
Headaches NEC		
Cluster headache	5	0
Headache	1794	0
Tension headache	3	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	21	0
Memory impairment	31	0
Mental impairment (excl dementia and memo	ory loss)	
Cognitive disorder	20	
Disturbance in attention	65	0
Mental impairment	3	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	1	0
Migraine	82	0
Migraine with aura	4	_
Migraine without aura	3	
Typical aura without headache	1	0
Mononeuropathies		
Carpal tunnel syndrome	2	0
Peroneal nerve palsy	2	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	0
Muscle tone abnormal		

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	Fatal
Nervous system disorders us system disorders of	cont'd		
Hypertonia		1	0
Hypotonia		13	0
Myelitis (incl infective)			
Myelitis transverse		2	0
Narcolepsy and hypersomnia			
Cataplexy		6	0
Hypersomnia		28	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
Visual field defect		8	0
Neurological signs and symptoms NEC			
Clonus		1	0
Dizziness		2304	0
Dizziness exertional		1	0
Dizziness postural		43	0
Drooling		2	0
Head discomfort		14	0
Hyporesponsive to stimuli		1	0
Meningism		2	0
Myoclonus		3	0
Neurological symptom		1	0
Patient elopement		1	0
Presyncope		64	0
Slow response to stimuli		6	0
Unresponsive to stimuli		54	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		14	0
Hypoaesthesia		370	0
Paraesthesia		279	0
Paralysis and paresis (excl cranial nerve)			
Diplegia		4	0
Hemiparesis		11	0
Hemiplegia		2	0
Monoparesis		1	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Nervous system disorders us system disorders of	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		26	0
Febrile convulsion		1	0
Myoclonic epilepsy		1	0
Partial seizures		5	0
Psychogenic seizure		3	0
Seizure		164	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		9	0
Neuralgia		8	0
Post herpetic neuralgia		1	0
Restless legs syndrome		1	0
Sensory disturbance		22	0
Sensory loss		33	0
Taste disorder		5	U
Sleep disturbances NEC		4	0
Poor quality sleep		4	0
Sudden onset of sleep		3	0
Speech and language abnormalities		22	^
Dysarthria Incoherent		22	0
Slow speech		4	0
Slow speech Speech disorder		13	0
Spinal cord and nerve root disorders NEC		13	U
Radiculitis brachial		1	0
Spinal cord oedema		1	0
Structural brain disorders NEC			U
Brain injury		1	0
Transient cerebrovascular events		I I	U
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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	198	0
Nervous system disorders SOC TOTAL	7604	0

Desetion Name		Catal
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 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 quality issues NEC		
Product origin unknown	7	0
Product substitution issue	1	0
null SOC TOTAL	8	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA		
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	81	0
Nervousness	19	0
Stress	4	0
Behaviour and socialisation disturbances		
Aggression	9	
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		
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	44	0
Disorientation	30	0
Deliria		
Delirium	3	0
Delusional symptoms		
Delusion	2	0
Depressive disorders		
Depression	42	0
Depression suicidal	4	0
Dissociative states		
Dissociation	3	0
Disturbances in initiating and maintaining sleep		
Insomnia	57	0
Middle insomnia	1	0
Eating disorders NEC		
Anorexia nervosa	1	0
Eating disorder	3	I
Merycism		Ö
Emotional and mood disturbances NEC		
Anger	3	0
Emotional disorder	13	

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Emotional distress	1:	3 0
Emotional poverty		1 0
Euphoric mood		1 o
Irritability		zl ol
Mood altered		5l ol
Fear symptoms and phobic disorders (incl s	ocial phobia)	
Autophobia	, , , , , , , , , , , , , , , , , , ,	1 0
Claustrophobia		ا ا
Fear		3 0
Fear of crowded places		
Fear of death		1 0
Phobia		1 0
		6 0
Social anxiety disorder		
Fluctuating mood symptoms		7
Mood swings		7 0
Hallucinations (excl sleep-related)		
Hallucination	11	1
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		4 0
Mental disorders NEC		
Mental disorder		6 0
Mental status changes		1 0
Mood alterations with depressive symptoms		
Decreased interest		4 o
Depressed mood	10	sl ol
Depressive symptom		2 0
Feeling guilty		1 0
Feeling of despair		1 0
Negative thoughts		1 0
Tearfulness	31	
Mood alterations with manic symptoms	0	<u> </u>
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	UIIIS	
Obsessive thoughts		1 0
Obsessive-compulsive disorder		1 0
Trichotillomania		1 0
Panic attacks and disorders		
Panic attack	2	
Panic reaction		0
Parasomnias		
Abnormal dreams		1 0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1		
Reaction Name	Т	otal	<u>Fatal</u>
Psychiatric disorders Psychiatric disorders cont'd			
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		3	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	;		
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		668	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder pain	2	0
Bladder spasm	1	0
Dysuria	2	0
Incontinence	2	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	73	Ő

Resorductive & breast disorders         Total         Fatal           Benign and malignant breast neoplasms         1         0           Breast cyst         1         0           Breast disorders NEC         1         0           Breast enlargement         1         0           Nipple disorder         1         0           Breast signs and symptoms         1         0           Breast swelling         1         0           Cervix indisorderss NEC         1         0           Cervix inflammations         1         0           Cervix inflammations         1         0           Cervix inflammation         1         0           Menoraturion and inflammations         2         0           Cervix inflammation         1         0           Menstruation and uterine bleeding NEC         0         0           Dysmenorrh	Earliest Reaction Date: 05-May-2006 Med	dDRA Version: MedDRA 23.1	
Benign and malignant breast neoplasms   1	Reaction Name	Total	Fatal
Breast clyst   Breast clisorders NEC   Breast disorders NEC   Breast sellargement   1   0   0   0	Reproductive & breast disorders		
Breast disorders NEC	Benign and malignant breast neoplasms		
Breast enlargement   1	Breast cyst		1 0
Nipple disorder   Breast signs and symptoms   1	Breast disorders NEC		
Breast signs and symptoms   1	Breast enlargement		1 0
Breast pain	Nipple disorder		1 0
Breast pain	Breast signs and symptoms		
Breast swelling	Breast discharge		1 0
Breast tenderness	Breast pain	4	4 0
Nipple pain	Breast swelling	,	1 0
Cervix disorders NEC         3         0           Cervix infections and inflammations         1         0           Cervix inflammation         1         0           Cervix inflammation         1         0           Cervix inflammation         1         0           Menostrual diffects NEC         Premature menopause         5         0           Menstruation and uterine bleeding NEC         20         0         0           Dysmenorrhoea         20         0         0           Menstrual discomfort         1         0         0           Menstrual discomfort         19         0         0         0           Menstrual discomfort         19         0	Breast tenderness		2 0
Cervical dysplasia   3   0   Uterine cervix atrophy   1   0   0	Nipple pain	,	1 0
Uterine cervix atrophy	Cervix disorders NEC		
Uterine cervix atrophy	Cervical dysplasia		3 0
Cervix infections and inflammations         1         0           Cervix inflammation         1         0           Menopausal effects NEC         5         0           Premature menopause         5         0           Menstruation and uterine bleeding NEC         20         0           Dysmenorrhoea         20         0           Menstrual discomfort         1         0           Menstrual discorder         19         0           Menstruation irregular         34         0           Menstruation irregular         3         0           Menstrual pain         1         0           Premenstrual syndrome         1         0           Menstruation with decreased bleeding         38         0           Menstruation with decreased bleeding         38         0           Menstruation delayed         25         0           Oligomenorrhoea         3         0           Menstruation with increased bleeding         28         0           Menorrhagia         28         0           Polymenorrhoea         2         0           Ovarian and fallopian tube cysts and neoplasms         0           Ovarian and fallopian tube disorders NEC <t< td=""><td></td><td></td><td></td></t<>			
Menopausal effects NEC         5         0           Premature menopause         5         0           Menstruation and uterine bleeding NEC         20         0           Dysmenorrhoea         20         0           Menstrual discomfort         1         0           Menstrual disorder         19         0           Menstruation irregular         34         0           Metrorrhagia         3         0           Premenstrual pain         1         0           Premenstrual syndrome         1         0           Menstruation with decreased bleeding         38         0           Menstruation with decreased bleeding         38         0           Menstruation delayed         25         0           Oligomenorrhoea         3         0           Menstruation with increased bleeding         28         0           Menstruation with increased bleeding         28         0           Oligomenorrhoea         2         0           Ovarian of selayed         25         0           Oligomenorrhoea         2         0           Ovarian and fallopian tube cysts and neoplasms         0           Ovarian and fallopian tube disorders NEC			
Premature menopause   5	Cervix inflammation		1 0
Menstruation and uterine bleeding NEC         20         0           Dysmenorrhoea         20         0           Menstrual discomfort         1         0           Menstruation irregular         34         0           Metrorrhagia         3         0           Premenstrual pain         1         0           Premenstrual syndrome         1         0           Menstruation with decreased bleeding         38         0           Amenorrhoea         38         0           Menstruation delayed         25         0           Oligomenorrhoea         3         0           Menstruation with increased bleeding         28         0           Menorrhagia         28         0           Polymenorrhoea         2         0           Ovarian and fallopian tube cysts and neoplasms         2         0           Ovarian ocyst         4         0           Polycystic ovaries         1         0           Ovarian disorder         2         0           Ovarian failure         6         0           Ovarian failure         6         0           Ovarian broad ligament disorders NEC         2         0	Menopausal effects NEC		
Dysmenorrhoea   20   0	Premature menopause		5 0
Dysmenorrhoea   20   0			
Menstrual discomfort         1         0           Menstrual disorder         19         0           Menstruation irregular         34         0           Metrorrhagia         3         0           Premenstrual pain         1         0           Premenstrual syndrome         1         0           Menstruation with decreased bleeding         38         0           Amenorrhoea         38         0           Menstruation delayed         25         0           Oligomenorrhoea         3         0           Menstruation with increased bleeding         28         0           Menorrhagia         28         0           Polymenorrhoea         2         0           Ovarian and fallopian tube cysts and neoplasms         2           Ovarian cyst         4         0           Polycystic ovaries         10         0           Ovarian and fallopian tube disorders NEC         2         0           Ovarian failure         6         0           Ovarian failure         6         0           Ovulation disorder         1         0           Pelvis and broad ligament disorders NEC         1         0           Adn	_	20	ol o
Menstruation irregular       34       0         Metrorrhagia       3       0         Premenstrual pain       1       0         Premenstrual syndrome       1       0         Menstruation with decreased bleeding       38       0         Amenorrhoea       38       0         Menstruation delayed       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       2       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian disorder       2       0         Ovarian fallure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       1       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         <			1
Menstruation irregular       34       0         Metrorrhagia       3       0         Premenstrual pain       1       0         Premenstrual syndrome       1       0         Menstruation with decreased bleeding       38       0         Amenorrhoea       38       0         Menstruation delayed       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       2       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian disorder       2       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       1       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         <	Menstrual disorder	19	el ol
Metrorrhagia       3       0         Premenstrual pain       1       0         Premenstrual syndrome       1       0         Menstruation with decreased bleeding       38       0         Amenorrhoea       38       0         Menstruation delayed       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       2       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian failure       6       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       1       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         Genital pain       2       0			
Premenstrual pain       1       0         Premenstrual syndrome       1       0         Menstruation with decreased bleeding       38       0         Amenorrhoea       38       0         Menstruation delayed       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       2       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       2       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         Genital pain       2       0			
Premenstrual syndrome       1       0         Menstruation with decreased bleeding       38       0         Amenorrhoea       38       0         Menstruation delayed       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       2       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian failure       6       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       1       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         Genital pain       2       0			
Menstruation with decreased bleeding       38       0         Amenorrhoea       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       2       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian failure       6       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       2       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       0       0         Genital erythema       1       0         Genital pain       2       0		•	
Amenorrhoea       38       0         Menstruation delayed       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian disorder       2       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       1       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         Genital pain       2       0			
Menstruation delayed       25       0         Oligomenorrhoea       3       0         Menstruation with increased bleeding       28       0         Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       0         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian disorder       2       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       1       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         Genital pain       2       0		38	3 0
Oligomenorrhoea  Menstruation with increased bleeding  Menorrhagia Polymenorrhoea  Ovarian and fallopian tube cysts and neoplasms Ovarian cyst Polycystic ovaries Ovarian and fallopian tube disorders NEC Ovarian disorder Ovarian failure Ovulation disorder Pelvis and broad ligament disorders NEC Adnexa uteri pain Reproductive tract signs and symptoms NEC Genital erythema Genital pain  Ouder 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Menstruation delayed		
Menstruation with increased bleeding28Menorrhagia280Polymenorrhoea20Ovarian and fallopian tube cysts and neoplasmsOvarian cyst40Polycystic ovaries100Ovarian and fallopian tube disorders NEC20Ovarian disorder20Ovarian failure60Ovulation disorder10Pelvis and broad ligament disorders NEC10Adnexa uteri pain10Reproductive tract signs and symptoms NEC10Genital erythema10Genital pain20			
Menorrhagia       28       0         Polymenorrhoea       2       0         Ovarian and fallopian tube cysts and neoplasms       2         Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian disorder       2       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       2       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         Genital pain       2       0			
Polymenorrhoea 2 0  Ovarian and fallopian tube cysts and neoplasms Ovarian cyst 4 0  Polycystic ovaries 10 0  Ovarian and fallopian tube disorders NEC Ovarian disorder 2 0  Ovarian failure 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		28	3 0
Ovarian and fallopian tube cysts and neoplasmsOvarian cyst40Polycystic ovaries100Ovarian and fallopian tube disorders NEC20Ovarian disorder20Ovarian failure60Ovulation disorder10Pelvis and broad ligament disorders NEC10Adnexa uteri pain10Reproductive tract signs and symptoms NEC10Genital erythema10Genital pain20			
Ovarian cyst       4       0         Polycystic ovaries       10       0         Ovarian and fallopian tube disorders NEC       2       0         Ovarian disorder       2       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC       1       0         Adnexa uteri pain       1       0         Reproductive tract signs and symptoms NEC       1       0         Genital erythema       1       0         Genital pain       2       0			
Polycystic ovaries			4 o
Ovarian and fallopian tube disorders NEC           Ovarian disorder         2         0           Ovarian failure         6         0           Ovulation disorder         1         0           Pelvis and broad ligament disorders NEC			
Ovarian disorder       2       0         Ovarian failure       6       0         Ovulation disorder       1       0         Pelvis and broad ligament disorders NEC			
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			2 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	Ovarian failure		6 0
Adnexa uteri pain 1 0  Reproductive tract signs and symptoms NEC  Genital erythema 1 0  Genital pain 2 0	Ovulation disorder		
Adnexa uteri pain 1 0  Reproductive tract signs and symptoms NEC  Genital erythema 1 0  Genital pain 2 0	Pelvis and broad ligament disorders NEC		
Reproductive tract signs and symptoms NECGenital erythema10Genital pain20			ı  o
Genital erythema 1 0 Genital pain 2 0			
Genital pain 2 0			ı  o
·	1 · · · · · · · · · · · · · · · · · · ·		
	Genital swelling		2 0
Pelvic pain 3 0	I = = = = = = = = = = = = = = = = = = =		
Sexual function and fertility disorders NEC			
Dyspareunia 1 0	•		0
Infertility 2 0			_
Uterine disorders NEC			
Endometriosis 1 0			1 0
Vulvovaginal disorders NEC			

Reaction Name	Total	Fatal
Reproductive & breast disorders cont'd		
Vaginal haemorrhage	10	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	265	0

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 23.1		
Reaction Name	Total	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	197	0
Grunting	3	0
Hyperventilation	53	0
Hypopnoea	14	0
Respiration abnormal	3	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	24	0
Coughing and associated symptoms	27	U
Allergic cough	1	0
	51	
Cough		0
Haemoptysis	2	
Productive cough	4	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Vocal cord disorder	1	0
	I	0
Laryngeal spasm, oedema and obstruction	_	0
Laryngeal oedema	5	0
Laryngospasm	1	0
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	29	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)	'	0
Acute respiratory failure	1	0
Respiratory signs and symptoms NEC		U
Painful respiration	1	0
raiiiui lespiialiuii		0

Reaction Name	Total	Fatal
Respiratory disorders espiratory disorders cont'd	Total	i alai
Respiratory tract disorders NEC		4
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	134	0
Rhinorrhoea	7	0
Sinus pain	2	0
Sneezing	4	0
Throat irritation	26	0
Throat lesion	1	0
Throat tightness	41	0
Vascular pulmonary disorders NEC		
Pulmonary arteriopathy	2	0
Respiratory disorders SOC TOTAL	725	1

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	9	) o
Acne cystic	1	0
Alopecias		
Alopecia	42	0
Alopecia areata	11	0
Alopecia totalis		0
Diffuse alopecia	3	3 O
Madarosis	1	0
Angioedemas		
Angioedema	15	0
Circumoral oedema		ı <b>l</b> 0
Apocrine and eccrine gland disorders		
Cold sweat	105	5 O
Hyperhidrosis	101	ıl o
Miliaria		ıl o
Night sweats		3 o
Bullous conditions		
Blister	20	) o
Dermatitis bullous		ı <b>l</b> 0
Erythema multiforme	11	ı <b>l</b> 0
Stevens-Johnson syndrome		ı <b>l</b> 0
Dermal and epidermal conditions NEC		
Dry skin	13	3 o
Pain of skin	3	1
Papule	5	5 O
Scab		1
Sensitive skin		0
Skin burning sensation	4	ıl o
Skin discolouration	103	3 O
Skin disorder	3	3 O
Skin fissures		0
Skin induration	1	0
Skin lesion	4	ıl o
Skin reaction	14	· o
Skin sensitisation		
Skin texture abnormal	1	0
Skin tightness	3	3 O
Skin warm	29	) o
Yellow skin		
Dermatitis and eczema		
Dermatitis		ı <b>l</b> 0
Dermatitis allergic	34	ıl o
Dermatitis contact		
Dyshidrotic eczema		ı <b>l</b> 0
Eczema	15	0
Eczema nummular		0
Eczema vesicular	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	10	
Erythemas		
Erythema	232	0
Palmar erythema		ō

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	<u>Fatal</u>
Skin disorders Skin disorders cont'd		
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 infection	ns and infestations)	
Nail discolouration	,	2 0
Panniculitides		
Erythema nodosum		6 0
Panniculitis		1 0
Papulosquamous conditions		
Lichen planus		1 0
Pityriasis lichenoides et varioliformis ac	uta	1 0
Pityriasis rosea		1 0
Photosensitivity and photodermatosis co	nditions	
Photosensitivity reaction		8 0
Pigmentation changes NEC		
Pigmentation disorder		1 0
Pilar disorders NEC		
Hair growth abnormal		1 0
Piloerection		1 0
Trichorrhexis		1 0
Pruritus NEC		
Pruritus	19	0   0
Psoriatic conditions		
Guttate psoriasis		1 0
Psoriasis		5 0
Purpura and related conditions		
Henoch-Schonlein purpura	1	ol o
Petechiae	1	1 0
Purpura		8 0
Pustular conditions		
Rash follicular		1 0
Rashes, eruptions and exanthems NEC		
Rash	46	2 0
Rash erythematous	4	.o o
Rash macular	8	0 0
Rash maculo-papular		6 0
Rash papular		9 0
Rash pruritic	6	8 0
Rash vesicular		2 0
Systemic lupus erythematosus rash		1 0
Skin and subcutaneous conditions NEC		
Skin mass		3 0
Umbilical discharge		1 0
Skin haemorrhages		
Skin haemorrhage		1 0
Skin hyperplasias and hypertrophies		
Skin hypertrophy		2 0

Reaction Name	Total	Fatal
	IUlai	гацаі
Skin disorders Skin disorders cont'd		
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	237	0
Urticaria chronic	3	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	2080	0

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

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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 MedDR	A Version: MedDRA 23.1	
Reaction Name	Total	Fatal
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	3	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		Ĭ
Peripheral venous disease	3	0
Vasospasm	1	
Non-site specific vascular disorders NEC		
Capillary disorder	3	0
Vascular pain	1	Ö
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	О
Thrombophlebitis superficial	1	0
Peripheral vascular disorders NEC		
Cyanosis	35	0
Erythromelalgia	33	0
Flushing	122	
Hot flush	19	
	2	
Peripheral vascular disorder		
Peripheral vasoconstriction, necrosis and vascular i		
Peripheral coldness	119	
Poor peripheral circulation	7	0
Raynaud's phenomenon	/	0
Site specific vascular disorders NEC	200	
Pallor	366	0
Vascular hypertensive disorders NEC		
Hypertension	9	
Orthostatic hypertension	1	0
Vascular hypotensive disorders	40	
Hypotension	40	
Orthostatic hypotension		0
Vasculitides NEC	4	_
Behcet's syndrome	1	0
Vasculitis	3	0
Vascular disorders SOC TOTAL	764	
TOTAL REACTIONS FOR DRUG	26004	9
TOTAL REPORTS	9695	
TOTAL FATAL OUTCOME REPORTS		9