Report Run Date: 06-Sep-2023

Data Lock Date: 04-Sep-2023 18:30:03

Earliest Reaction Date: 05-May-2006 MedDRA 26.0 MedDRA Version:

Gardasil Vaccine All UK spontaneous suspected Adverse Drug Reaction

(ADR) reports associated with Gardasil up to and including 04/09/23. Analysis Print:

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Earnest Reaction Bate. 66 May 2000	ModBrat Volcion: ModBrat 20.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Blood disorders			
Anaemia deficiencies			
Iron deficiency anaemia		1	0
Pernicious anaemia		1	0
Anaemias NEC			
Anaemia		5	0
Bleeding tendencies			
Increased tendency to bruise		2	0
Coagulopathies			
Coagulopathy		1	0
Haematological disorders			
Blood disorder		1	0
Lymphatic system disorders NEC			
Lymph node pain		1	0
Lymphadenopathy		22	0
Neutropenias			
Autoimmune neutropenia		2	0
Neutropenia		2	0
Spleen disorders			
Splenomegaly		1	0
Thrombocytopenias			
Immune thrombocytopenia		5	0
Blood disorders SOC TOTAL		44	0

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Reaction Name	<u>Total</u>	Fatal
Cardiac disorders		
Cardiac disorders NEC		
Cardiac disorder	1	0
Cardiac signs and symptoms NEC		
Palpitations	26	0
Ischaemic coronary artery disorders		
Angina pectoris	1	0
Rate and rhythm disorders NEC		
Arrhythmia	1	0
Postural orthostatic tachycardia syndrome	36	0
Tachycardia	13	0
Supraventricular arrhythmias		
Sinus arrhythmia	1	0
Sinus tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	3	2
Pulseless electrical activity	1	0
Cardiac disorders SOC TOTAL	84	2

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Reaction Name	Total	Fatal
Congenital disorders		
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	4	0
Hypermobility syndrome	1	0
Inborn errors of bilirubin metabolism		
Gilbert's syndrome	1	0
Ocular disorders congenital NEC		
Colour blindness	1	0
Congenital disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	6	0
Hearing disorders NEC		
Auditory disorder	1	0
Hearing losses		
Deafness	5	0
Deafness transitory	1	0
Hypoacusis	8	0
Hyperacusia		
Hyperacusis	9	0
Inner ear signs and symptoms		
Motion sickness	1	0
Tinnitus	5	0
Vertigo	4	. 0
Ear disorders SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	3	0
Endocrine abnormalities of gonadal function NEC		
Oestrogen deficiency	1	0
Hypothalamic and pituitary disorders NEC		
Lymphocytic hypophysitis	1	0
Thyroid disorders NEC		
Autoimmune thyroid disorder	1	0
Goitre	1	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	2	0
Hypothyroidism	4	0
Endocrine disorders SOC TOTAL	13	0

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Reaction Name	Total	<u>Fatal</u>
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration	_	
Vitreous floaters	2	0
Eyelid movement disorders		
Blepharospasm	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
Lacrimation disorders		
Lacrimation increased	2	0
Lid, lash and lacrimal infections, irritations and inflammations		_
Eyelid rash	1	0
Swelling of eyelid	7	0
Ocular disorders NEC		_
Dark circles under eyes	1	0
Eye pain	8	0
Eye swelling	6	0
Periorbital pain	1	0
Periorbital swelling	1	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Eye pruritus	3	0
Ocular hyperaemia	4	0
Ocular nerve and muscle disorders	00	0
Eye movement disorder	20	0
Ophthalmoplegia Strabismus	2	0
	1	0
Ocular sensation disorders		^
Abnormal sensation in eye	1	0
Asthenopia	20	0
Photophobia Pupil disorders	20	U
Pupil disorders Miosis	1	0
Mydriasis	5	0
Pupillary disorder	1	0
Visual disorders NEC	'	U
Diplopia Diplopia	7	0
Halo vision	1	0
Photopsia	4	0
Vision blurred	61	0
Visual field disorders		
Visual field defect	1	0
Visual impairment and blindness (excl colour blindness)		ŭ
Blindness	4	0
Blindness transient	9	0
Visual acuity reduced	1	0
Visual impairment	31	0
Eve disorders SOC TOTAL	216	

Reaction Name Total Gastrointestinal disorders Acute and chronic pancreatitis	Fatal
Gastrointestinal disorders	
Acute and chronic pancreatitis	
Pancreatitis	ı o
Anal and rectal disorders NEC	
Anal fissure	ı o
Colitis (excl infective)	
<u> </u>	ı o
Colitis ulcerative	ı o
Crohn's disease	ı o
Diarrhoea (excl infective)	
Diarrhoea 3	7 0
Diarrhoea haemorrhagic	ıl o
Dyspeptic signs and symptoms	
••• • • • •	5 0
Flatulence, bloating and distension	
Abdominal distension	o l
	2 0
Gastric and oesophageal haemorrhages	
	ıl o
Gastritis (excl infective)	
	2 0
	ıl o
Gastrointestinal and abdominal pains (excl oral and throat)	
Abdominal pain 62	2 0
Abdominal pain lower	
Abdominal pain upper 55	5 0
Abdominal rigidity	ıl o
	2 0
Gastrointestinal atonic and hypomotility disorders NEC	
Constipation 10	o o
Gastrointestinal hypomotility	ıl o
l	0
Gastrointestinal disorders NEC	
l <u>-</u>	1 o
Gastrointestinal disorder	1 o
Gastrointestinal dyskinetic disorders	
	ıl o
	2 0
Gastrointestinal inflammatory disorders NEC	
l	2 0
Gastrointestinal mucosal dystrophies and secretion disorders	
l	ı o
Gastrointestinal signs and symptoms NEC	
Abdominal discomfort	1 o
Dysphagia	
Gastrointestinal spastic and hypermotility disorders	
	ıl o
· · · · · · · · · · · · · · · · · · ·	el o
Gingival disorders, signs and symptoms NEC	
	ıl o
Gingival haemorrhages	
•	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	
· · · · · · · · · · · · · · · · · · ·	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0		
Reaction Name		Total	Fatal
Gastrointestinal disordersointestinal disorders	s cont'd		
Inguinal hernias			
Inguinal hernia		2	0
Intestinal haemorrhages			
Rectal haemorrhage		1	0
Malabsorption syndromes			
Bile acid malabsorption		1	0
Coeliac disease		7	0
Malabsorption		1	0
Nausea and vomiting symptoms			
Cyclic vomiting syndrome		1	0
Nausea		446	0
Retching		4	0
Vomiting		195	0
Vomiting projectile		1	0
Non-site specific gastrointestinal haemon	rhages		
Haematemesis		2	0
Haematochezia		1	0
Oral dryness and saliva altered			
Dry mouth		1	0
Lip dry		1	0
Oral soft tissue disorders NEC			
Chapped lips		1	0
Lip blister		1	0
Uvulitis		1	0
Oral soft tissue signs and symptoms			_
Lip erythema		1	0
Oral discomfort		1	0
Oral mucosal blistering		1	0
Oral mucosal eruption		1	0
Oral pain		2	0
Paraesthesia oral		13	0
Oral soft tissue swelling and oedema		40	0
Lip swelling		13	0
Peritoneal and retroperitoneal disorders			0
Intra-abdominal fluid collection		1	Ü
Stomatitis and ulceration		4	0
Lip ulceration		1	0
Mouth ulceration		5	0
Tongue disorders		4	0
Tongue ulceration		1	0
Tongue signs and symptoms			^
Swollen tongue		6	0
Tongue coated		1	0
Gastrointestinal disorders SOC TOTAL		973	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site swelling	1	0
Asthenic conditions		
Asthenia	69	0
Chronic fatigue syndrome	35	0
Fatigue	230	0
Malaise	230	0
Body temperature altered		
Temperature regulation disorder	7	0
Complications associated with device NEC		
Injury associated with device	1	0
Death and sudden death		
Death	1	1
Febrile disorders		
Pyrexia	163	0
Feelings and sensations NEC		
Chills	33	0
Feeling abnormal	21	0
Feeling cold	20	0
Feeling drunk	1	0
Feeling hot	61	0
Feeling jittery	2	2 0
Feeling of body temperature change	5	0
Sensation of foreign body	1	0
Temperature intolerance	6	0
Thirst	3	0
Gait disturbances		
Gait disturbance	12	2 0
Gait inability	11	0
Loss of control of legs	3	0
General signs and symptoms NEC		
Condition aggravated	6	0
Crying	5	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	2 0
General physical health deterioration	1	0
Glassy eyes	1	0
III-defined disorder	4	0
Illness	29	0
Induration	1	0
Influenza like illness	20	0
Local reaction	6	0
Peripheral swelling	100	0
Screaming	1	0
Secretion discharge	1	0
Swelling	19	0
Swelling face	22	2 0
Healing abnormal NEC		
Impaired healing	2	2 0
Hernias NEC		
Hernia	1	0
Inflammations		
Inflammation	7	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0		
Reaction Name		<u>Total</u>	Fatal
General disorders General disorders cont'd			
Serositis		1	0
Injection site reactions			
Injected limb mobility decreased		2	0
Injection site bruising		4	0
Injection site discomfort		1	0
Injection site erythema		11	0
Injection site haemorrhage		2	0
Injection site hypoaesthesia		5 2	0
Injection site induration		2	0
Injection site inflammation		1	0
Injection site joint pain		2	0
Injection site mass		12	0
Injection site movement impairment		1	0
Injection site nerve damage		1	0
Injection site oedema		1	0
Injection site pain		30	0
Injection site paraesthesia		1	0
Injection site pruritus		8	0
Injection site rash		1	0
Injection site reaction		1	0
Injection site swelling		20	0
Injection site warmth		2	0
Mass conditions NEC			
Mass		2	0
Mucosal findings abnormal			
Mucosal ulceration		1	0
Oedema NEC			
Face oedema		1	0
Localised oedema		1	0
Oedema peripheral		5	0
Pain and discomfort NEC			
Axillary pain		2	0
Chest discomfort		22	0
Chest pain		39	0
Discomfort		11	0
Facial pain		1	0
Non-cardiac chest pain		2	0
Pain		76	0
Tenderness		4	0
Therapeutic and nontherapeutic responses			
Adverse drug reaction		3	0
Adverse event		1	0
Adverse reaction		2	0
Drug ineffective			0
Drug ineffective for unapproved indication		2 1	0
Drug resistance		1	0
Immediate post-injection reaction		1	0
Therapeutic response unexpected		1	0
Vaccination failure		1	0
Trophic disorders			
Atrophy		1	0
Hyperplasia			0
Vaccination site reactions		,	J

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0		
Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	10	0
Vaccination site inflammation	2	0
Vaccination site irritation	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	2	0
Vaccination site movement impairment	2	0
Vaccination site nerve damage	1	0
Vaccination site pain	13	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	4	0
Vaccination site rash	3	0
Vaccination site swelling	11	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	1497	1

Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	2	0
Hepatic and hepatobiliary disorders NEC		
Liver disorder	1	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	1	0
Hepatitis	1	0
Hepatitis acute	1	0
Hepatic disorders SOC TOTAL	8	0

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergic oedema	1	0
Hypersensitivity	32	0
Multiple allergies	2	0
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	1	0
Food allergy	2	0
Oral allergy syndrome	1	0
Reaction to excipient	2	0
Rubber sensitivity	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	33	0
Anaphylactic shock	2	0
Autoimmune disorders NEC		
Autoimmune disorder	6	0
Immune and associated conditions NEC		
Decreased immune responsiveness	1	0
Immune system disorder	7	0
Immune system disorders SOC TOTAL	91	0

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Reaction Name	<u> Total</u>	Fatal
Infections		
Abdominal and gastrointestinal infections		
Abdominal abscess	1	0
Appendicitis	1	0
Appendicitis perforated	1	0
Gastroenteritis	1	0
Gastrointestinal infection	1	0
Bacterial infections NEC		
Cellulitis	1	0
Candida infections		Ĭ
Candida infection	1	0
Vulvovaginal candidiasis	1	0
Central nervous system and spinal infections	'	
Encephalitis	4	0
Subdural abscess	1	0
Dental and oral soft tissue infections	'	l o
Gingivitis	1	0
Ear infections	'	l o
Otitis media	1	0
Enteroviral infections NEC	'	l o
Hand-foot-and-mouth disease	1	0
Epstein-Barr viral infections	'	l o
Epstein-Barr virus infection	1	0
Infectious mononucleosis	1	0
Eye and eyelid infections	_ <u>'</u>	
Conjunctivitis	2	0
Female reproductive tract infections		U
	1	0
Amniotic cavity infection Pelvic inflammatory disease	1	0
	1	0
Vaginal infection Vulvovaginitis	1	0
Haemophilus infections	'	l o
Haemophilus infection	1	0
·	'	U
Herpes viral infections Herpes zoster	5	0
	3	
Oral herpes Infections NEC	_ '	0
Infection	2	0
	2	0
Infection susceptibility increased	1	
Injection site infection Localised infection		0
Influenza viral infections	'	U
Influenza	2	0
	2	U
Lower respiratory tract and lung infections Bronchitis	1	0
		0
Lower respiratory tract infection	2	0
Papilloma viral infections		
Papilloma viral infection	3	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	1	0
Sepsis	1	0
Septic rash	1	0
Staphylococcal infections		
Staphylococcal infection	11	0

Reaction Name		Total		Fatal
Infections Infe	ections cont'd			
Streptococcal infection	ns			
Beta haemolytic str	eptococcal infection		1	0
Upper respiratory trace	t infections			
Nasopharyngitis			7	0
Pharyngitis			3	0
Sinusitis			2	0
Tonsillitis			3	0
Urinary tract infection	s			
Urinary tract infection	n		1	0
Viral infections NEC				
Gastroenteritis viral			2	0
Post viral fatigue sy	ndrome		1	0
Viral infection			4	0
Infections SOC TOTAL		8	2	0

Reaction Name	Total	Fatal
Injuries		
Bone and joint injuries NEC		
Joint injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	3	0
Fractures and dislocations NEC		
Joint dislocation	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	1	0
Medication error	3	0
Non-site specific injuries NEC		
Fall	7	0
Injury	1	0
Wound haemorrhage	1	0
Overdoses NEC		
Overdose	1	0
Poisoning and toxicity		
Metal poisoning	1	0
Poisoning	1	0
Product administration errors and issues		
Expired product administered	1	0
Extra dose administered	2	0
Inappropriate schedule of product administration	5	0
Product administered at inappropriate site	3	0
Wrong product administered	1	0
Site specific injuries NEC		
Head injury	1	0
Skin injuries NEC		
Contusion	10	0
Thermal burns		
Thermal burn	1	0
Vaccination related complications		
Immunisation reaction	7	0
Vaccination complication	1	0
Injuries SOC TOTAL	57	1 0

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Reaction Name	<u>Total</u>	Fatal
Investigations		
Blood gas and acid base analyses		
Oxygen saturation decreased	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	2	0
Blood glucose increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Heart sounds abnormal	1	0
ECG investigations		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	1	0
Heart rate and pulse investigations	· ·	
Heart rate abnormal	3	0
Heart rate decreased	5	0
Heart rate increased	20	0
Heart rate irregular	6	0
Pulse abnormal	3	0
Pulse absent	2	0
Pulse pressure decreased	1	0
Hepatobiliary function diagnostic procedures		
Blood bilirubin increased	1	0
Hepatic enzyme increased	1	0
Immunoglobulin analyses		U
Blood immunoglobulin A increased	1	0
Mineral and electrolyte analyses	'	U
Blood iron decreased	3	0
Blood magnesium decreased	1	0
Blood selenium decreased	1	0
Blood zinc decreased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Physical examination procedures and organ system status		
Body temperature	1	0
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature fluctuation	3	0
Body temperature increased	15	0
Respiratory rate increased	5	0
Weight decreased	4	0
Weight increased	1	0
Pituitary analyses anterior	'	U
Blood growth hormone abnormal	1	0
Blood thyroid stimulating hormone abnormal	1	0
Platelet analyses	'	Ŭ
Platelet count decreased	1	0
Protein analyses NEC		U
Blood albumin abnormal	1	0
C-reactive protein increased	2	0
Protein total abnormal	1	0
Reproductive hormone analyses		U
Progesterone increased	1	0
r rogesterone increased		U

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Reproductive organ and breast histopathology procedures		
Smear cervix abnormal	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	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure immeasurable	1	0
Blood pressure increased	2	0
Vitamin analyses		
Vitamin B12 increased	1	0
Vitamin D decreased	3	0
Investigations SOC TOTAL	119	0

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Appetite disorder	3	0
Decreased appetite	29	0
Salt craving	2	0
Calcium metabolism disorders		
Tetany	1	0
Diabetes mellitus (incl subtypes)		
Type 1 diabetes mellitus	6	0
Diabetic complications NEC		
Diabetic ketoacidosis	2	0
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	6	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	1	0
Food intolerance	2	0
Gluten sensitivity	3	0
Histamine intolerance	1	0
General nutritional disorders NEC		
Abnormal loss of weight	10	0
Abnormal weight gain	1	0
Feeding disorder	3	0
Weight gain poor	1	0
Hyperglycaemic conditions NEC		
Insulin resistance	1	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	1	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	2	0
Total fluid volume decreased		
Dehydration	1	0
Vitamin deficiencies NEC		
Multi-vitamin deficiency	2	0
Water soluble vitamin deficiencies		
Vitamin B12 deficiency	4	0
Metabolic disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	0
Arthropathy	3	0
Seronegative arthritis	1	0
Bone related signs and symptoms		
Bone pain	5	0
Coccydynia	1	
Pain in jaw	4	
Spinal pain	2	2 0
Cartilage disorders		
Osteochondrosis	1	0
Extremity deformities		
Finger deformity	1	
Foot deformity	1	0
Joint related disorders NEC		
Joint lock	1	0
Periarthritis	2	0
Joint related signs and symptoms		
Arthralgia	101	
Joint noise	2	2 0
Joint range of motion decreased	1	
Joint stiffness	7	
Joint swelling	14	0
Ligament disorders		
Ligament pain	1	0
Muscle infections and inflammations		
Myositis	1	0
Muscle pains		
Fibromyalgia	3	
Myalgia	51	0
Muscle related signs and symptoms NEC		
Muscle atrophy	1	0
Muscle fatigue	5	
Muscle spasms	27	0
Muscle tightness	2	
Muscle twitching	22	
Trigger points		0
Muscle tone abnormalities		
Muscle rigidity	18	
Trismus		0
Muscle weakness conditions		
Muscular weakness	57	0
Musculoskeletal and connective tissue cond	itions NEC	
Back disorder	1	_
Growth retardation	1	
Mobility decreased	7	' 0
Muscle contracture		0
Musculoskeletal stiffness	31	1
Posture abnormal	1	
Weight bearing difficulty	4	0
Musculoskeletal and connective tissue pain		
Back pain	30	
Growing pains		0

Reaction Name	Total	Fatal
Muscle & tissue disorders e & tissue disorders cont'd		
Limb discomfort	18	0
Musculoskeletal chest pain	5	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	3	0
Neck pain	32	0
Pain in extremity	169	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
Soft tissue disorders NEC		
Axillary mass	1	0
Groin pain	1	0
Spondyloarthropathies		
Arthritis reactive	2	0
Synovial disorders		
Synovitis	1	0
Tendon disorders		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	652	0

Reaction Name	Total	Fatal
Neoplasms		1 (4(4)
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	0
Cervix neoplasms malignant		
Cervix carcinoma	1	0
Cervix carcinoma stage 0	1	0
Islet cell neoplasms and APUDoma NEC		
Pancreatic neuroendocrine tumour metastatic	1	0
Leukaemias acute NEC		
Acute leukaemia	1	0
Leukaemias acute lymphocytic		
T-cell type acute leukaemia	1	1
Metastases to specified sites		
Metastases to liver	1	0
Reproductive neoplasms male benign NEC		
Penile wart	1	0
Respiratory tract and pleural neoplasms benign NEC		
Respiratory papilloma	1	0
Skin neoplasms benign		
Anogenital warts	2	0
Skin papilloma	1	0
Uterine neoplasms benign		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	13	1

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	2	0
Absence seizures		
Petit mal epilepsy	3	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	2	0
Autonomic neuropathy	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Brain stem stroke	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	2	0
Lacunar infarction	1	0
Coordination and balance disturbances		
Ataxia	4	0
Balance disorder	9	0
Coordination abnormal	5	0
Dysstasia	6	0
Nystagmus	1	l о
Cortical dysfunction NEC		
Aphasia	3	l о
Dyslexia	1	О (
Dyspraxia	1	l o
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	1	l o
Disturbances in consciousness NEC		
Altered state of consciousness	1	0
Consciousness fluctuating	2	0
Depressed level of consciousness	6	0
Lethargy	63	
Loss of consciousness	35	
Somnolence	49	
Syncope	288	
Disturbances in sleep phase rhythm		
Irregular sleep wake rhythm disorder	2	0
Dyskinesias and movement disorders NEC		
Dyskinesia	36	0
Fine motor skill dysfunction	1	o
Hypokinesia	4	
Motor dysfunction	4	I
Movement disorder	7	ő
Encephalitis NEC	1	Ĭ
Encephalitis autoimmune	1	0
Noninfective encephalitis	1	ő
Facial cranial nerve disorders		Ĭ
Bell's palsy	3	О
Facial paralysis	4	ő
Facial spasm	1	ő
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizures Generalised tonic-clonic seizure	8	0
Headaches NEC		
Cluster headache	F	^
	480	0 0
Headache Tanaign headache	1	
Tension headache	3	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0		
Reaction Name		Total	<u>Fatal</u>
Nervous system disordersus system disorder	rs cont'd		
Increased intracranial pressure disorders			
Idiopathic intracranial hypertension		1	0
Intracranial pressure increased		1	0
Memory loss (excl dementia)			
Amnesia		12	0
Memory impairment		10	0
Mental impairment (excl dementia and m	emory loss)		
Cognitive disorder	• ,	10	0
Disturbance in attention		22	0
Mental impairment		2	0
Migraine headaches			
Migraine		30	0
Migraine with aura		2	0
Mononeuropathies		_	Ū
Peroneal nerve palsy		1	0
Multiple sclerosis acute and progressive		·	
Multiple sclerosis		1	0
Muscle tone abnormal			·
Hypotonia		10	0
Narcolepsy and hypersomnia		10	J
Cataplexy		1	0
Hypersomnia		10	0
Narcolepsy		3	0
Nervous system cysts and polyps			·
Colloid brain cyst		1	0
Pineal gland cyst		1	0
Nervous system disorders NEC			Ŭ
Cerebral disorder		1	0
Nervous system disorder		5	0
Neurologic visual problems NEC			·
Tunnel vision		1	0
Neurological signs and symptoms NEC			·
Brain fog		18	0
Dizziness		706	0
Dizziness exertional		1	0
Dizziness postural		14	0
Head discomfort		4	0
Hyporesponsive to stimuli		1	0
Myoclonus		1	0
Patient elopement		1	0
Presyncope		21	0
Slow response to stimuli		3	0
Unresponsive to stimuli		25	0
Olfactory nerve disorders		23	U
Anosmia		1	0
Paraesthesias and dysaesthesias			U
Burning sensation		7	0
Hyperaesthesia		6	0
Hypoaesthesia		87	0
Paraesthesia		101	0
		101	U
Paralysis and paresis (excl cranial nerve)		0	^
Diplegia		2 6	0
Hemiparesis		1 6	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0	
Reaction Name	Total	<u> Fatal</u>
Nervous system disordersus system disorde	rs cont'd	
Hemiplegia		1 (
Monoplegia	1	10 (
Paralysis	1	∣1 (
Paraplegia		1 (
Peripheral paralysis		1 (
Quadriplegia		1 (
Peripheral neuropathies NEC		
Peripheral sensory neuropathy		1 (
Seizures and seizure disorders NEC		
Change in seizure presentation		1 (
Epilepsy		9 (
Febrile convulsion		1 (
Partial seizures		1 (
Psychogenic seizure		1 (
Seizure	6	61 (
Seizure anoxic		1 (
Seizure like phenomena		4 (
Tonic clonic movements		5 (
Tonic convulsion		1 (
Sensory abnormalities NEC		
Ageusia		1 (
Allodynia		1 (
Complex regional pain syndrome		8 (
Dysgeusia		2 (
Neuralgia		4 (
Sensory disturbance		7 (
Sensory loss	1	0 (
Taste disorder		2 (
Speech and language abnormalities		
Dysarthria		7 (
Incoherent		1 (
Slow speech		4 (
Speech disorder		4 (
Spinal cord and nerve root disorders NE	C	
Spinal cord oedema		1 (
Structural brain disorders NEC		
Brain injury		1 (
Tremor (excl congenital)		
Tremor	6	67 (
Nervous system disorders SOC TOTAL	240	

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions not specified as induced or spontaneous		
Abortion	1	0
Abortions spontaneous		
Abortion spontaneous	1	0
Abortion threatened	1	0
Gestational age and weight conditions		
Premature baby	1	1
Hypertension associated disorders of pregnancy		
Pre-eclampsia	2	0
Labour onset and length abnormalities		
Premature labour	1	0
Maternal complications of pregnancy NEC		
Cervical incompetence	1	0
Pregnancy conditions SOC TOTAL	8	1

Reaction Name	Total	Fatal
Product label issues		
Product lot number issue	2	0
Product quality issues NEC		
Product origin unknown	5	0
Product quality issue	1	0
Product substitution issue	1	0
null SOC TOTAL	9	0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Psychiatric disorders			
Abnormal behaviour NEC			
Abnormal behaviour		7	0
Staring		1	0
Affect alterations NEC			
Inappropriate affect		1	0
Anxiety disorders NEC			
Generalised anxiety disorder		1	0
Anxiety symptoms			
Agitation		2	0
Anxiety		33	0
Nervousness		2	0
Stress		2	0
Behaviour and socialisation disturbances			
Aggression		2	0
Disinhibition		1	0
Paranoia		2	0
Personality change		7	0
Social avoidant behaviour		1	0
Bipolar disorders			
Bipolar disorder		1	0
Cognitive and attention disorders and distu	rbances NEC		
Mental fatigue		2	0
Confusion and disorientation			
Confusional state		22	0
Disorientation		14	0
Deliria			
Delirium		2	0
Delusional symptoms			
Delusion		1	0
Depressive disorders			
Depression		14	0
Depression suicidal		4	0
Disturbances in initiating and maintaining s	leep		
Insomnia		17	0
Dyssomnias			
Poor quality sleep		1	0
Eating disorders NEC			
Anorexia nervosa		1	0
Eating disorder		1	0
Emotional and mood disturbances NEC			
Anger		2	0
Emotional disorder		2	0
Emotional distress		6	0
Mood altered		2	0
Fear symptoms and phobic disorders (incl s	social phobia)		
Claustrophobia	. ,	1	0
Phobia		1	0
Social anxiety disorder		3	0
Fluctuating mood symptoms			
Mood swings		3	0
Hallucinations (excl sleep-related)			
Hallucination		3	0
Hallucination, auditory		3	0

Earliest Reaction Date: 05-May-2006 MedDRA Version		
Reaction Name	<u>Total</u>	Fatal
Psychiatric disorders ^{Psychiatric} disorders cont'd		
Hallucination, visual	1	0
Increased physical activity levels		
Restlessness	1	0
Learning disorders		
Reading disorder	1	0
Mental disorders NEC		
Mental disorder	4	. 0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Decreased interest	1	0
Depressed mood	4	. 0
Tearfulness	12	el o
Mood disorders NEC		
Apathy	3	0
Listless	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive disorder	1	0
Panic attacks and disorders		
Panic attack	5	0
Panic reaction	3	
Parasomnias		
Sleep terror	1	0
Perception disturbances NEC		
Deja vu	1	0
Near death experience	1	0
Personality disorders NEC		
Self esteem decreased	1	0
Personality disorders with anxious behaviour (Cluster C)		
Dependent personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	1	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychotic disorder NEC		
Psychotic disorder	1	0
Sleep disorders NEC		
Sleep disorder	12	. 0
Somatic symptom disorders		
Conversion disorder	4	. 0
Somatic symptom disorder	1	0
Speech and language usage disturbances		
Logorrhoea	1	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	3	0
Suicidal ideation	4	
Suicide attempt	1	Ö
Thinking disturbances		
Thought blocking	1	0
Tic disorders		
Tic	3	0
Psychiatric disorders SOC TOTAL	246	1
i syonialite disorders soot TOTAL		<u>'</u>

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder pain	2	0
Dysuria	1	0
Incontinence	1	0
Urinary incontinence	11	0
Urinary retention	2	0
Bladder disorders NEC		
Bladder disorder	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		
Nephrotic syndrome	1	0
Renal disorders NEC		
Renal disorder	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
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	30	0

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Reaction Name	Total	<u> Fatal</u>
Reproductive & breast disorders		
Breast disorders NEC		
Gynaecomastia	1	0
Nipple disorder	1	0
Breast signs and symptoms		
Breast pain	1	0
Nipple pain	1	0
Cervix disorders NEC		
Cervical dysplasia		3 0
Menopausal effects NEC		
Premature menopause	2	2 0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	3	3 0
Menstrual disorder	7	_
Menstruation irregular	12	2 0
Premenstrual pain	1	0
Premenstrual syndrome	1	0
Menstruation with decreased bleeding		
Amenorrhoea	12	2 0
Menstruation delayed	3	3 0
Oligomenorrhoea	2	2 0
Menstruation with increased bleeding		
Heavy menstrual bleeding	14	∤ 0
Polymenorrhoea	1	0
Ovarian and fallopian tube cysts and neoplas	ms	
Polycystic ovaries	2	2 0
Ovarian and fallopian tube disorders NEC		
Ovarian disorder	1	0
Ovarian failure		3 0
Reproductive tract signs and symptoms NEC		
Pelvic pain		3 0
Sexual function and fertility disorders NEC		
Dyspareunia	1	0
Infertility	1	0
Uterine disorders NEC		
Endometriosis	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	2	2 0
Vulval ulceration	1	0
Vulvovaginal signs and symptoms		
Coital bleeding	1	0
Reproductive & breast disorders SOC TOTAL	86	sl o

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26		
Reaction Name	Total_	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	68	0
Grunting	1	0
Hyperventilation	16	0
Hypopnoea	9	0
Respiration abnormal	2	0
Respiratory arrest	4	0
Tachypnoea	2	0
Bronchospasm and obstruction		
Asthma	9	0
Bronchospasm	5	0
Obstructive airways disorder	2	0
Wheezing	5	0
Coughing and associated symptoms		
Allergic cough	1	0
Cough	14	0
Productive cough	2	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		ŭ
Vocal cord disorder	1	0
Laryngeal spasm, oedema and obstruction		
Laryngospasm	1	0
Lower respiratory tract signs and symptoms		
Pleuritic pain	1	0
Nasal congestion and inflammations	i i	Ŭ
Nasal congestion	4	0
Nasal disorders NEC	i i	Ŭ
Epistaxis	12	0
Pharyngeal disorders (excl infections and neoplasms)	'-	Ŭ
Pharyngeal erythema	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	4	0
Pneumothorax and pleural effusions NEC		J
Pneumothorax and prediat endsions NEO	1	0
Pulmonary oedemas		U
Pulmonary oedema	1	0
Respiratory tract disorders NEC	· ·	J
Allergic respiratory disease	1	0
Respiratory disease Respiratory disorder	1	1
Respiratory tract inflammation	1	0
Upper respiratory tract signs and symptoms	- I	U
Choking sensation	1	0
Dry throat	1	0
		0
Dysphonia Oropharyngeal discomfort	1	0
	32	0
Oropharyngeal pain		0
Rhinorrhoea	3	0
Sinus pain	2	0
Throat irritation	9	0
Throat tightness	8	0
Respiratory disorders SOC TOTAL	229	1

·	edDRA Version: MedDRA 26.0	
Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	4	0
Acne cystic	1	0
Alopecias		
Alopecia	13	0
Alopecia areata	2	2 0
Diffuse alopecia	1	0
Madarosis	1	0
Angioedemas		
Angioedema	5	0
Apocrine and eccrine gland disorders		
Cold sweat	43	0
Hyperhidrosis	35	0
Miliaria	2	2 0
Night sweats	1	0
Bullous conditions		
Blister	3	0
Erythema multiforme	3	0
Dermal and epidermal conditions NEC		
Dry skin	6	0
Pain of skin	4	1
Papule	4	1
Scab	1	1
Skin burning sensation	2	
Skin discolouration	27	
Skin reaction		
Skin tightness	3	0
Skin warm	15	
Yellow skin	1	0
Dermatitis and eczema		
Dermatitis allergic	14	0
Dermatitis contact	1	1
Eczema	6	1
Eczema nummular	1	
Skin irritation	4	
Dermatitis ascribed to specific agent		
Drug eruption	2	2 0
Erythemas		
Érythema	54	0
Palmar erythema	1	0
Exfoliative conditions		
Skin exfoliation	3	0
Hyperpigmentation disorders		
Melanoderma	1	0
Nail and nail bed conditions (excl infections and	l infestations)	
Nail discolouration	1 1	0
Panniculitides		
Erythema nodosum	3	0
Papulosquamous conditions		
Pityriasis rosea	2	2 0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction		0
Pigmentation changes NEC		
<u></u>		

Reaction Name	MedDRA Version: MedDRA 26.0	Fotal	Fatal
Skin disorders Skin disorders cont'd		l Otal	<u>i atai</u>
Pigmentation disorder		1	0
Pruritus NEC			U
Pruritus		59	0
Psoriatic conditions			
Psoriasis		1	0
Purpura and related conditions			
Henoch-Schonlein purpura		5	0
Petechiae		4	0
Purpura		3	0
Rashes, eruptions and exanthems NEC			
Rash		110	0
Rash erythematous		24	0
Rash macular		19	0
Rash maculo-papular		2	0
Rash papular		4	0
Rash pruritic		15	0
Rash vesicular		2	0
Skin and subcutaneous conditions NEC			
Skin mass		1	0
Umbilical discharge		1	0
Skin hyperplasias and hypertrophies			
Skin hypertrophy		1	0
Skin hypoplasias and atrophies			
Skin striae		2	0
Skin preneoplastic conditions NEC			
Precancerous skin lesion		1	0
Skin vasculitides			
Vasculitic rash		1	0
Skin vasomotor conditions		_	
Livedo reticularis		20	0
Urticarias			
Urticaria		91	0
Skin disorders SOC TOTAL		646	0

Reaction Name	Total	Fatal
Social circumstances		
Disability issues		
Bedridden	2	2 0
Loss of personal independence in daily activities	(6 0
Physical disability	1	0
Educational issues		
Educational problem	1	0
Social circumstances SOC TOTAL	10	ol o

Reaction Name	Total	Fatal
Surgical & medical procedures		
Gastrointestinal therapeutic procedures NEC		
Prophylaxis of nausea and vomiting	1	0
Hernia repairs		
Inguinal hernia repair	1	0
Obstetric therapeutic procedures		
Vacuum extractor delivery	1	0
Ovarian therapeutic procedures		
Oophorectomy	1	0
Psychiatric therapies		
Antidepressant therapy	1	0
Surgical & medical procedures SOC TOTAL	5	l o

Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Vascular disorders		
Blood pressure disorders NEC		
Blood pressure fluctuation	1	0
Circulatory collapse and shock		
Circulatory collapse	1	0
Shock	2	0
Haemorrhages NEC		
Venous haemorrhage	1	0
Non-site specific embolism and thrombosis		
Thrombosis	1	0
Non-site specific vascular disorders NEC		
Vascular pain	1	0
Vasodilatation	1	0
Peripheral vascular disorders NEC		
Cyanosis	11	0
Flushing	27	0
Hot flush	6	0
Peripheral vascular disorder	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	31	0
Poor peripheral circulation	3	0
Raynaud's phenomenon	1	0
Site specific vascular disorders NEC		
Pallor	127	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Orthostatic hypertension	1	0
Vascular hypotensive disorders		
Hypotension	13	0
Orthostatic hypotension	1	0
Vasculitides NEC		
Vasculitis	1	0
Vascular disorders SOC TOTAL	232	0
TOTAL REACTIONS FOR DRUG	7891	6
TOTAL REPORTS	2581	
TOTAL FATAL OUTCOME REPORTS		6