### Case Series Drug Analysis Print Name: Human Papillomavirus Vaccine Analysis Print

Report Run Date: 14-Oct-2022 Data Lock Date: 05-Oct-2022 Earliest Reaction Date: 05-May-2006 MedDRA 25.0 MedDRA Version:

Human Papillomavirus FOI 22/981 - All UK spontaneous suspected Adverse

Vaccine Analysis Print: Drug Reaction (ADR) reports for Human
Papillomavirus vaccine up to and including 05/10/2022

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Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia vitamin B12 deficiency	2	0
Iron deficiency anaemia	1	0
Pernicious anaemia	1	0
Anaemias NEC		
Anaemia	11	0
Anaemias haemolytic mechanical factor		
Haemolytic uraemic syndrome	1	0
Bleeding tendencies		
Increased tendency to bruise	5	0
Coagulopathies		
Coagulopathy	2	0
Eosinophilic disorders		
Eosinophilia	1	0
Haematological disorders		
Blood disorder	1	0
Mast cell activation syndrome	6	0
Lymphatic system disorders NEC		
Lymph node pain	3	0
Lymphadenitis	1	0
Lymphadenopathy	64	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	0
Pancytopenia	1	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	3	0
Spleen disorders		
Splenomegaly	3	0
Thrombocytopenias		
Immune thrombocytopenia	9	0
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	120	0

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Reaction Name	Tota	aL	Fatal
Cardiac disorders			
Cardiac conduction disorders			
Atrioventricular block		1	0
Cardiac disorders NEC			
Cardiac disorder		4	0
Cardiac signs and symptoms NEC			
Palpitations		59	0
Ischaemic coronary artery disorders			
Angina pectoris		3	0
Pericardial disorders NEC			
Pericardial effusion		1	0
Pulmonary valvular disorders			
Pulmonary valve stenosis		2	0
Rate and rhythm disorders NEC			
Arrhythmia		3	0
Bradycardia		6	0
Postural orthostatic tachycardia syndrome		84	0
Tachycardia		52	0
Supraventricular arrhythmias			
Atrial tachycardia		1	0
Sinus arrhythmia		1	0
Sinus tachycardia		8	0
Supraventricular tachycardia		1	0
Ventricular arrhythmias and cardiac arrest			
Cardiac arrest		4	2
Pulseless electrical activity		1	0
Cardiac disorders SOC TOTAL		231	2

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0	Total	Cotol
Reaction Name	Total	Fatal
Congenital disorders		
Anorectal disorders congenital		0
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 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		
Congenital musculoskeletal disorder of spine	2	0
Non-site specific bone disorders congenital		
Osteopetrosis	1	0
Ocular disorders congenital NEC		
Colour blindness	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	49	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	4	0
Ear pain	19	0
Eustachian tube disorders		
Eustachian tube dysfunction	1	0
Hearing disorders NEC		
Auditory disorder	1	0
Hearing losses		
Deafness	17	0
Deafness bilateral	1	0
Deafness transitory	4	0
Hypoacusis	21	0
Hyperacusia		
Hyperacusis	26	0
Inner ear disorders NEC		
Inner ear disorder	1	0
Vestibular disorder	1	0
Inner ear signs and symptoms		
Motion sickness	2	0
Tinnitus	17	0
Vertigo	15	0
Ear disorders SOC TOTAL	130	0

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Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	6	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 hyperfunction disorders		
Basedow's disease	1	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	2	0
Hypothyroidism	10	0
Endocrine disorders SOC TOTAL	31	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0		
Reaction Name	Total	<u>Fatal</u>
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	4	0
Colour blindness (incl acquired)		
Dyschromatopsia	2	0
Conjunctival infections, irritations and inflammations		
Conjunctival hyperaemia	2	0
Eyelid movement disorders		
Blepharospasm	3	0
Excessive eye blinking	2	0
Eyelid ptosis	3	0
Glaucomas (excl congenital)		
Glaucoma	1	0
Iris and ciliary body structural change, deposit and degeneration		
Iris adhesions	1	0
Iris and uveal tract infections, irritations and inflammations		
Iritis	1	0
Uveitis	1	0
Lacrimation disorders		
Dry eye	2	0
Lacrimation increased	3	0
Lid, lash and lacrimal infections, irritations and inflammations		
Eyelid oedema	1	0
Eyelid rash	1	0
Swelling of eyelid	20	0
Ocular disorders NEC		
Dark circles under eyes	4	0
Eye disorder	6	0
Eye pain	24	0
Eye swelling	37	0
Eyelid disorder	1	0
Eyelids pruritus	1	0
Ocular discomfort	1	0
Periorbital oedema	2	0
Periorbital pain	1	0
Periorbital swelling	3	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	1	0
Eye discharge	2	0
Eye inflammation	1	0
Eye irritation	2	0
Eye pruritus	7	0
Ocular hyperaemia	11	0
Ocular nerve and muscle disorders		
Eye movement disorder	40	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Oculogyric crisis	1	0
Ophthalmoplegia	3	0
Strabismus	1	0
Ocular sensation disorders		
Abnormal sensation in eye	1	0
Asthenopia	3	
Foreign body sensation in eyes	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Photophobia	63	0
Optic disc abnormalities NEC		
Optic disc disorder	1	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	1	0
Pupil disorders		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	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	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	6	0
Vision blurred	165	0
Visual field disorders		
Visual field defect	8	0
Visual impairment and blindness (excl colour blindness)		
Blindness	16	0
Blindness transient	22	0
Blindness unilateral	1	0
Visual acuity reduced	1	0
Visual impairment	79	0
Eve disorders SOC TOTAL	617	0

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,	ledDRA Version: MedDRA 25.0	Fatal
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 0
Colitis ulcerative		4 0
Crohn's disease		2 0
Dental disorders NEC		
Tooth erosion		1 0
Diaphragmatic hernias		
Hiatus hernia		1 0
Diarrhoea (excl infective)		
Diarrhoea	140	1
Diarrhoea haemorrhagic		2 0
Dyspeptic signs and symptoms		
Dyspepsia	1:	
Eructation		2 0
Faecal abnormalities NEC		
Abnormal faeces		1 0
Flatulence, bloating and distension		
Abdominal distension	1	
Flatulence		3 0
Gastric and oesophageal haemorrhages		
Oesophageal haemorrhage		1 0
Gastric ulcers and perforation		
Gastric ulcer		1 0
Gastritis erosive		1 0
Gastritis (excl infective)		
Chronic gastritis		1 0
Gastritis		7 0
Reflux gastritis		1 0
Gastrointestinal and abdominal pains (excl ora	l and throat)	
Abdominal migraine		1 0
Abdominal pain	218	_
Abdominal pain lower	19	1
Abdominal pain upper	204	4 0
Abdominal rigidity		1 0
Abdominal tenderness		3 0
Gastrointestinal pain		2 0
Gastrointestinal atonic and hypomotility disord		
Constipation	1	7 0
Gastric dilatation		1 0
Gastrointestinal hypomotility		1 0
Gastrooesophageal reflux disease	10	
Impaired gastric emptying	!	5 0
Gastrointestinal disorders NEC		
Functional gastrointestinal disorder		2 0
Gastric disorder		7 0
Gastrointestinal disorder	1	7 C
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity		1 C
Dyschezia		<u>1 0</u>

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Reaction Name	<u>  Total</u>	<u>Fatal</u>
Gastrointestinal disorders cont'd		
Gastrointestinal motility disorder	2	0
Gastrointestinal inflammatory disorders NEC	4	0
Duodenitis	1	0
Gastrointestinal inflammation	3	0
Gastrointestinal mucosal dystrophies and secretion disorders		0
Oesophageal mucosal hyperplasia	1	0
Gastrointestinal signs and symptoms NEC		0
Abdominal discomfort	55	0
Dysphagia	27	0
Odynophagia	2	0
Oesophageal discomfort	'	U
Gastrointestinal spastic and hypermotility disorders	1	0
Defaecation urgency Frequent bowel movements	3	0
Irritable bowel syndrome	22	0
Gastrointestinal ulcers and perforation, site unspecified		U
Gastrointestinal ulcer	1	0
Gingival disorders, signs and symptoms NEC	'	U
Gingival disorder  Gingival disorder	1	0
Gingival disorder  Gingival pain	2	0
Gingival swelling	1	0
Gingival swelling Gingival ulceration	1	0
Gingival haemorrhages	'	J
Gingival bleeding	1	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	'	U
Haemorrhoids	1	0
Inguinal hernias	'	Ū
Inguinal hernia	2	0
Intestinal haemorrhages	_	Ŭ
Rectal haemorrhage	2	0
Malabsorption syndromes		
Bile acid malabsorption	1	0
Coeliac disease	10	0
Malabsorption	2	0
Nausea and vomiting symptoms		
Cyclic vomiting syndrome	1	0
Nausea	1736	0
Regurgitation	1	0
Retching	7	0
Vomiting	755	0
Vomiting projectile	1	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	1	0
Haematemesis	6	0
Haematochezia	1	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	0
Oral dryness and saliva altered		
Dry mouth	6	0
Lip dry	1	0
Saliva altered	1	0
Salivary hypersecretion	3	0
Oral soft tissue disorders NEC		

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Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Chapped lips	1	0
Cheilitis	1	0
Lip blister	3	0
Uvulitis	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	9	0
Lip erythema	1	0
Lip pain	1	0
Oral discomfort	3	0
Oral mucosal blistering	3	0
Oral mucosal eruption	1	0
Oral pain	6	0
Oral pruritus	2	0
Paraesthesia oral	39	0
Oral soft tissue swelling and oedema		
Lip swelling	63	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	32	0
Tongue coated	2	0
Tongue discomfort	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	3586	

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Reaction Name		otal	<u>Fatal</u>
General disorders  Administration site reactions NEC			
		1	0
Administration site pain Administration site swelling		1	0
Puncture site reaction		1	0
Asthenic conditions			U
		101	0
Asthenia		191	0
Chronic fatigue syndrome		106	0
Decreased activity		2 802	
Fatigue Malaise		788	0
		700	U
Body temperature altered		15	0
Temperature regulation disorder		15	0
Complications associated with device NEC		1	0
Injury associated with device  Death and sudden death		1	0
		1	4
Death		1	1
Febrile disorders		2	_
Hyperpyrexia		500	0
Pyrexia		582	0
Feelings and sensations NEC		444	^
Chills		111	0
Feeling abnormal		93	0
Feeling cold		82	0
Feeling drunk		5	0
Feeling hot		221	0
Feeling jittery		5	0
Feeling of body temperature change		26	0
Sensation of foreign body		3	0
Temperature intolerance		7	0
Thirst		8	0
Gait disturbances		0.4	0
Gait disturbance		34	0
Gait inability		29	0
Loss of control of legs		5	0
General signs and symptoms NEC		4.0	^
Condition aggravated		16	
Crying		13	0
Disease recurrence		1	0
Exercise tolerance decreased		7	0
Foaming at mouth		4	0
General physical health deterioration		2 2 7	0
Glassy eyes Ill-defined disorder			0
		101	0
Illness		101	0
Induration Influenza like illness		4 127	0
			0
Local reaction		32	0
Organ failure		1	0
Peripheral swelling		359	0
Screaming		2	0
Secretion discharge		1	0
Swelling		86	
Swelling face		95	0

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Reaction Name	MedDRA Version: MedDRA 25.0	Total	Fatal
General disorders General disorders cont'd		Total	ı ataı
Healing abnormal NEC			
Impaired healing		2	0
Hernias NEC		-	
Hernia		2	0
Inflammations		_	Ŭ
Inflammation		23	0
Serositis		1	0
Systemic inflammatory response syndron	ne	1	0
Infusion site reactions	. •		J
Infusion site hypoaesthesia		1	0
Injection site reactions			_
Injected limb mobility decreased		5	0
Injection site bruising		29	0
Injection site coldness		4	0
Injection site discharge		3	0
Injection site discolouration		6	0
Injection site discomfort		3	0
Injection site erythema		127	0
Injection site granuloma		1	0
Injection site haemorrhage		5	0
Injection site hypoaesthesia		16	0
Injection site induration		11	0
Injection site inflammation		28	0
Injection site injury		1	0
Injection site irritation		6	0
Injection site joint movement impairment		1	0
Injection site joint pain		3	0
Injection site mass		67	0
Injection site movement impairment		3	0
Injection site nerve damage		1	0
Injection site nodule		8	0
Injection site oedema		1	0
Injection site pain		150	0
Injection site papule		1	0
Injection site paraesthesia		2	0
Injection site pruritus		29	0
Injection site rash		52	0
Injection site reaction		36	0
Injection site scab		2	0
Injection site scar		1	0
Injection site swelling		176	0
Injection site urticaria		5	0
Injection site vesicles		5	0
Injection site warmth		28	0
Interactions			
Drug interaction		1	0
Mass conditions NEC			
Cyst		1	C
Mass		5	0
Nodule		2	O
Mucosal findings abnormal		_	
Mucosal ulceration		1	0
Oedema NEC		·	

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Reaction Name		<u>Total</u>	Fatal
General disorders General disorders cont'd			
Face oedema		5	0
Localised oedema		1	0
Oedema peripheral		12	0
Pain and discomfort NEC			
Axillary pain		5	0
Chest discomfort		72	0
Chest pain		115	0
Discomfort		28	0
Facial pain		4	0
Non-cardiac chest pain		3	0
Pain		282	0
Tenderness		20	0
Therapeutic and nontherapeutic responses		20	U
Adverse drug reaction		18	0
Adverse event		1	0
Adverse reaction		2	0
Drug ineffective		3	0
, and the second		1	0
Drug ineffective for unapproved indication			
Drug resistance		1	0
Immediate post-injection reaction		1	
Therapeutic product effective for unapprov	ed indication	1	0
Therapeutic response unexpected		1	0
Vaccination failure		3	0
Trophic disorders			_
Atrophy		1	0
Hyperplasia		1	0
Ulcers NEC		_	_
Ulcer		3	0
Vaccination site reactions		_	_
Extensive swelling of vaccinated limb		3	0
Vaccination site atrophy		1	0
Vaccination site bruising		5	0
Vaccination site coldness		1	0
Vaccination site discolouration		2	0
Vaccination site discomfort		2 13	0
Vaccination site erythema			0
Vaccination site haemorrhage		2	0
Vaccination site hypersensitivity		1	0
Vaccination site hypoaesthesia		1	0
Vaccination site induration		1	0
Vaccination site inflammation		3	0
Vaccination site irritation		1	0
Vaccination site joint movement impairmer	nt	1	0
Vaccination site joint pain		1	0
Vaccination site mass		11	0
Vaccination site movement impairment		3	0
Vaccination site nerve damage		1	0
Vaccination site nodule		1	0
Vaccination site pain		33	0
Vaccination site paraesthesia		1	0
Vaccination site pruritus		5	0
Vaccination site rash		3	0
Vaccination site swelling		22	0
vaccination site swelling			

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site warmth	3	0
General disorders SOC TOTAL	5543	1

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Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	4	0
Hepatic and hepatobiliary disorders NEC		
Hepatic cyst	1	0
Liver disorder	2	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	2	0
Hepatobiliary signs and symptoms		
Hepatic pain	1	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	2	0
Hepatitis	1	0
Hepatitis acute	1	0
Obstructive bile duct disorders (excl neoplasms)		
Sphincter of Oddi dysfunction	1	0
Hepatic disorders SOC TOTAL	15	0

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Pagetian Name	Total	Eatal
Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		0
Allergic oedema	1	0
Allergy to animal	3	0
Hypersensitivity	88	
Multiple allergies	6	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	3	0
Type IV hypersensitivity reaction	2	0
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	2	0
Food allergy	6	0
Reaction to excipient	3	0
Reaction to preservatives	1	0
Reaction to sweetener	1	0
Rubber sensitivity	2	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	99	0
Anaphylactic shock	7	0
Anaphylactoid reaction	3	0
Atopic disorders		
Seasonal allergy	1	0
Autoimmune disorders NEC		
Autoimmune disorder	12	0
Overlap syndrome	1	0
Immune and associated conditions NEC		
Decreased immune responsiveness	1	0
Immune system disorder	11	0
Immunisation reaction	9	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	265	0

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MedDRA Version: MedDRA 25.0 Report Run Date: 14-Oct-2022 Earliest Reaction Date: 05-May-2006

Reaction Name	MedDRA Version: MedDRA 25.0	Total	Fatal
Infections		TOtal	ı alaı
Abdominal and gastrointestinal infections			
Abdominal abscess		1	0
Appendicitis		3	0
Appendicitis Appendicitis perforated		1	0
Gastroenteritis		1	
Gastrointestinal infection		1	0
Peritonitis		1	0
Bacterial infections NEC		I	U
Cellulitis		1	0
Folliculitis		4	0
		1	
Gastrointestinal bacterial overgrowth		2	0
Injection site cellulitis			U
Bone and joint infections		4	^
Osteomyelitis		1	0
Breast infections		4	^
Mastitis Condida infections		1	0
Candida infections		_	0
Candida infection		2	0
Vulvovaginal candidiasis		1	0
Central nervous system and spinal infections		0	0
Encephalitis		8	0
Encephalitis lethargica		1	0
Subdural abscess		1	0
Coronavirus infections			
COVID-19		1	0
Severe acute respiratory syndrome		1	0
Dental and oral soft tissue infections			
Gingivitis		1	0
Ear infections			
Ear infection		2	0
Labyrinthitis		3	0
Otitis media		1	0
Otitis media chronic		1	0
Ectoparasitic infestations			_
Acarodermatitis		1	0
Enteroviral infections NEC			_
Hand-foot-and-mouth disease		1	0
Epstein-Barr viral infections			_
Epstein-Barr virus infection		1	0
Infectious mononucleosis		11	0
Eye and eyelid infections		_	_
Conjunctivitis		3	0
Hordeolum		5	0
Female reproductive tract infections			_
Amniotic cavity infection		1	0
Pelvic inflammatory disease		1	0
Vaginal infection		1	0
Vulvovaginitis		1	0
Haemophilus infections			
Haemophilus infection		1	0
Herpes viral infections			
Genital herpes		1	0
Herpes virus infection		1	0

# Name: Human Papillomavirus Vaccine Analysis Print

Report Run Date: 14-Oct-2022 Data Lock Date: 05-Oct-2022 Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0

Infections		MedDRA Version: MedDRA 25.0	
Herpes zoster	Reaction Name	Total	<u>Fatal</u>
Oral herpes	Infections Infections cont'd		
Varicella   Infections NEC   Infection NEC   Infection   Infection susceptibility increased   7   Infection susceptibility increased   7   Infection site abscess   1   Infection site infection   5   5   Infection site infection   5   5   Infection site infection   5   5   Infection   5   Infection   5   Infection   5   Infection   1   Infectious transmissions   2   Infectious transmissions   3   Suspected transmission of an infectious agent via product   Influenza viral infections   Influenza viral infections   Influenza   6   Infectious agent via product   Influenza   6   Infections   Influenza   6   Infections   Influenza   6   Influenza   7	Herpes zoster		
Infection NEC			
Infection   Susceptibility increased   7   1   1   1   1   1   1   1   1   1	Varicella	1	0
Infection susceptibility increased	Infections NEC		
Injection site abscess   1	Infection	g	0
Injection site infection	Infection susceptibility increased	7	
Localised infection	Injection site abscess	1	0
Purulent discharge	Injection site infection	5	0
Respiratory tract infection   Infectious transmissions   Suspected transmission of an infectious agent via product   Influenza viral infections   Influenza   In	Localised infection	1	0
Infectious transmissions Suspected transmission of an infectious agent via product Influenza infections Influenza Lower respiratory tract and lung infections Bronchitis 3 Lower respiratory tract infection Bronchitis 4 Lower respiratory tract infection Bronchitis 3 Lower respiratory tract infection Pneumonia 2 Molluscum contagiosum viral infections Molluscum contagiosum viral infections Papilloma viral infections Papilloma viral infection Papilloma viral infection Papilloma viral infection Respiratory syncytial viral infection Respiratory syncytial viral infections Respiratory syncytial viral infection Retroviral infections Acquired immunodeficiency syndrome Sepsis, bacteraemia, viraemia and fungaemia NEC Neutropenic sepsis Sepsis Septic rash 1 Control of tissue infections Sepsis structures and soft tissue infections Application site pustules Impetigo 1 Pustule Skin infection 2 Skin infection 2 Skin prococcal infections Furuncle Staphylococcal infections Furuncle Staphylococcal infections Beta haemolytic streptococcal infection 2 Streptococcal sepsis 1 Upper respiratory tract infections Epiglotitits 1 Laryngitis 1 Nasopharyngitis 1 Nasopharyngitis 1 Sepsia of an infections 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Purulent discharge		
Suspected transmission of an infectious agent via product Influenza viral infections Influenza Lower respiratory tract and lung infections Bronchitis Lower respiratory tract infection  Molluscum contagiosum viral infections Molluscum contagiosum viral infections Papilloma viral infections Papilloma viral infection Papilloma viral infection Papilloma viral infection  Respiratory syncytial viral infection Respiratory syncytial viral infection Respiratory syncytial viral infection Respiratory syncytial viral infection Retroviral infections Acquired immunodeficiency syndrome Sepsis, bacteraemia, viraemia and fungaemia NEC Neutropenic sepsis Sepsis Septic rash Viraemia Skin structures and soft tissue infections Application site pustules Impetigo Pustule Skin infection Staphylococcal infections Furuncle Staphylococcal infections Furuncle Staphylococcal infections Beta haemolytic streptococcal infection Streptococcal sepsis Department of the streptococcal infection Epiglotititis Laryngitis Nasopharyngitis Nasopharyngitis Nasopharyngitis Nasopharyngitis Nasopharyngitis Sepsia On infections Sepsia on infection o	Respiratory tract infection	2	2 0
Influenza   Influenza   Influenza   Influenza   Influenza   Lower respiratory tract and lung infections   Bronchitis   3   3   3   3   3   3   3   3   3	Infectious transmissions		
Influenza	Suspected transmission of an infectious age	ent via product 1	0
Lower respiratory tract and lung infections   Bronchitis   1	Influenza viral infections		
Bronchitis	Influenza	6	0
Lower respiratory tract infection Pneumonia  Molluscum contagiosum viral infections Molluscum contagiosum Papilloma viral infections Papilloma viral infections Papilloma viral infection Papilloma viral infections Papilloma viral infections Respiratory syncytial virus infection Respiratory syncytial virus infection Retroviral infections Acquired immunodeficiency syndrome Sepsis, bacteraemia, viraemia and fungaemia NEC Neutropenic sepsis Sepsis Septic rash Viraemia Skin structures and soft tissue infections Application site pustules Impetigo Pustule Skin infection Staphylococcal infections Furuncle Staphylococcal infections Beta haemolytic streptococcal infection Streptococcal infections Beta haemolytic streptococcal infections Epiglotititis Laryngitis Nasopharyngitis Nasopharyngitis Pharyngitis	Lower respiratory tract and lung infections		
Pneumonia	Bronchitis	3	0
Molluscum contagiosum viral infections         1           Papilloma viral infections         5           Papilloma viral infection         5           Papilloma viral infection         1           Vulvovaginal human papilloma virus infection         1           Respiratory syncytial virus infections         1           Respiratory syncytial virus infection         1           Retroviral infections         1           Acquired immunodeficiency syndrome         1           Sepsis, bacteraemia, viraemia and fungaemia NEC         1           Neutropenic sepsis         3           Sepsis         3           Septic rash         1           Viraemia         1           Skin structures and soft tissue infections           Application site pustules         1           Impetigo         1           Pustule         2           Skin infection         2           Skin infection         2           Furuncle         3           Staphylococcal infections         2           Beta haemolytic streptococcal infection         2           Streptococcal sepsis         1           Upper respiratory tract infections         2           Epiglottitis <t< td=""><td>Lower respiratory tract infection</td><td>16</td><td></td></t<>	Lower respiratory tract infection	16	
Molluscum contagiosum       1         Papilloma viral infections       5         Papilloma viral infection       5         Vulvovaginal human papilloma virus infection       1         Respiratory syncytial viral infections       1         Respiratory syncytial virus infection       1         Retroviral infections       1         Acquired immunodeficiency syndrome       1         Sepsis, bacteraemia, viraemia and fungaemia NEC         Neutropenic sepsis       3         Sepsis       3         Septic rash       1         Viraemia       1         Skin structures and soft tissue infections         Application site pustules       1         Impetigo       1         Pustule       2         Skin infection       2         Staphylococcal infections       2         Furuncle       3         Staphylococcal infections       2         Beta haemolytic streptococcal infection       2         Streptococcal sepsis       1         Upper respiratory tract infections       1         Epiglottitis       1         Laryngitis       42         Pharyngitis       8	Pneumonia	2	2 0
Molluscum contagiosum       1         Papilloma viral infections       5         Papilloma viral infection       5         Vulvovaginal human papilloma virus infection       1         Respiratory syncytial viral infections       1         Respiratory syncytial virus infection       1         Retroviral infections       1         Acquired immunodeficiency syndrome       1         Sepsis, bacteraemia, viraemia and fungaemia NEC         Neutropenic sepsis       3         Sepsis       3         Septic rash       1         Viraemia       1         Skin structures and soft tissue infections         Application site pustules       1         Impetigo       1         Pustule       2         Skin infection       2         Staphylococcal infections       2         Furuncle       3         Staphylococcal infections       2         Beta haemolytic streptococcal infection       2         Streptococcal sepsis       1         Upper respiratory tract infections       1         Epiglottitis       1         Laryngitis       42         Pharyngitis       8	Molluscum contagiosum viral infections		
Papilloma viral infection         5           Vulvovaginal human papilloma virus infection         1           Respiratory syncytial viral infections         1           Respiratory syncytial virus infection         1           Retroviral infections         1           Acquired immunodeficiency syndrome         1           Sepsis, bacteraemia, viraemia and fungaemia NEC         1           Neutropenic sepsis         3           Sepsis         3           Sepsis         3           Sepsic rash         1           Viraemia         1           Skin structures and soft tissue infections         1           Impetigo         1           Pustule         2           Skin infection         2           Skin infection         2           Furuncle         3           Staphylococcal infections         2           Furptococcal infections         2           Beta haemolytic streptococcal infection         2           Streptococcal sepsis         1           Upper respiratory tract infections         1           Epiglottitis         1           Laryngitis         1           Nasopharyngitis         42		1	0
Papilloma viral infection         5           Vulvovaginal human papilloma virus infection         1           Respiratory syncytial viral infections         1           Respiratory syncytial virus infection         1           Retroviral infections         1           Acquired immunodeficiency syndrome         1           Sepsis, bacteraemia, viraemia and fungaemia NEC         1           Neutropenic sepsis         3           Sepsis         3           Sepsis         3           Sepsic rash         1           Viraemia         1           Skin structures and soft tissue infections         1           Impetigo         1           Pustule         2           Skin infection         2           Skin infection         2           Furuncle         3           Staphylococcal infections         2           Furptococcal infections         2           Beta haemolytic streptococcal infection         2           Streptococcal sepsis         1           Upper respiratory tract infections         1           Epiglottitis         1           Laryngitis         1           Nasopharyngitis         42	Papilloma viral infections		
Respiratory syncytial virus infections         1           Respiratory syncytial virus infection         1           Retroviral infections         1           Acquired immunodeficiency syndrome         1           Sepsis, bacteraemia, viraemia and fungaemia NEC         1           Neutropenic sepsis         3           Sepsis         3           Sepsis         3           Septic rash         1           Viraemia         1           Skin structures and soft tissue infections         1           Application site pustules         1           Impetigo         1           Pustule         2           Skin infection         2           Staphylococcal infections         2           Furuncle         3           Staphylococcal infections         2           Beta haemolytic streptococcal infection         2           Streptococcal sepsis         1           Upper respiratory tract infections         2           Epiglottitis         1           Laryngitis         1           Nasopharyngitis         42           Pharyngitis         8		5	0
Respiratory syncytial virus infections         1           Respiratory syncytial virus infection         1           Retroviral infections         1           Acquired immunodeficiency syndrome         1           Sepsis, bacteraemia, viraemia and fungaemia NEC         1           Neutropenic sepsis         3           Sepsis         3           Sepsis         3           Septic rash         1           Viraemia         1           Skin structures and soft tissue infections         1           Application site pustules         1           Impetigo         1           Pustule         2           Skin infection         2           Staphylococcal infections         2           Furuncle         3           Staphylococcal infections         2           Beta haemolytic streptococcal infection         2           Streptococcal sepsis         1           Upper respiratory tract infections         2           Epiglottitis         1           Laryngitis         1           Nasopharyngitis         42           Pharyngitis         8	Vulvovaginal human papilloma virus infectio	n 1	0
Respiratory syncytial virus infection       1         Retroviral infections       1         Acquired immunodeficiency syndrome       1         Sepsis, bacteraemia, viraemia and fungaemia NEC       1         Neutropenic sepsis       1         Sepsis       3         Septic rash       1         Viraemia       1         Skin structures and soft tissue infections         Application site pustules       1         Impetigo       1         Pustule       2         Skin infection       2         Staphylococcal infections       2         Furuncle       3         Staphylococcal infections       2         Beta haemolytic streptococcal infection       2         Streptococcal sepsis       1         Upper respiratory tract infections       2         Epiglottitis       1         Laryngitis       1         Nasopharyngitis       42         Pharyngitis       8			
Retroviral infections Acquired immunodeficiency syndrome Sepsis, bacteraemia, viraemia and fungaemia NEC Neutropenic sepsis Sepsis Sepsis Septic rash Viraemia Skin structures and soft tissue infections Application site pustules Impetigo Pustule Skin infection Pustule Skin infection  Staphylococcal infections Furuncle Staphylococcal infections  Staphylococcal infections Epignotic streptococcal infection  2 Construction Streptococcal sepsis Upper respiratory tract infections Epiglottitis Laryngitis Nasopharyngitis Pharyngitis Sepsis Seps		1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC         Neutropenic sepsis       1         Sepsis       3         Septic rash       1         Viraemia       1         Skin structures and soft tissue infections         Application site pustules       1         Impetigo       1         Pustule       2         Skin infection       2         Furuncle       3         Staphylococcal infections       2         Furuncle       3         Staphylococcal infections       2         Beta haemolytic streptococcal infection       2         Streptococcal sepsis       1         Upper respiratory tract infections       2         Epiglottitis       1         Laryngitis       1         Nasopharyngitis       42         Pharyngitis       8			
Sepsis, bacteraemia, viraemia and fungaemia NEC         Neutropenic sepsis       1         Sepsis       3         Septic rash       1         Viraemia       1         Skin structures and soft tissue infections         Application site pustules       1         Impetigo       1         Pustule       2         Skin infection       2         Furuncle       3         Staphylococcal infections       2         Furuncle       3         Staphylococcal infections       2         Beta haemolytic streptococcal infection       2         Streptococcal sepsis       1         Upper respiratory tract infections       2         Epiglottitis       1         Laryngitis       1         Nasopharyngitis       42         Pharyngitis       8	Acquired immunodeficiency syndrome		0
Neutropenic sepsis       1       0         Sepsis       3       0         Septic rash       1       0         Viraemia       1       0         Skin structures and soft tissue infections       1       0         Application site pustules       1       0         Impetigo       1       0         Pustule       2       0         Skin infection       2       0         Staphylococcal infections       2       0         Furuncle       3       0         Staphylococcal infections       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       2       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0		NEC	
Sepsis       3         Septic rash       1         Viraemia       1         Skin structures and soft tissue infections         Application site pustules       1         Impetigo       1         Pustule       2         Skin infection       2         Staphylococcal infections       3         Furuncle       3         Staphylococcal infection       2         Streptococcal infections       2         Beta haemolytic streptococcal infection       2         Streptococcal sepsis       1         Upper respiratory tract infections       2         Epiglottitis       1         Laryngitis       1         Nasopharyngitis       42         Pharyngitis       8			0
Septic rash       1       0         Viraemia       1       0         Skin structures and soft tissue infections       1       0         Application site pustules       1       0         Impetigo       1       0         Pustule       2       0         Skin infection       2       0         Staphylococcal infections       3       0         Furuncle       3       0         Staphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       2       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0		3	
Viraemia       1       0         Skin structures and soft tissue infections       1       0         Application site pustules       1       0         Impetigo       1       0         Pustule       2       0         Skin infection       2       0         Staphylococcal infections       3       0         Furuncle       3       0         Staphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       2       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0			0
Application site pustules       1       0         Impetigo       1       0         Pustule       2       0         Skin infection       2       0         Staphylococcal infections       3       0         Straphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       1       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0		1	
Application site pustules       1       0         Impetigo       1       0         Pustule       2       0         Skin infection       2       0         Staphylococcal infections       3       0         Straphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       1       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0	Skin structures and soft tissue infections		
Impetigo       1       0         Pustule       2       0         Skin infection       2       0         Staphylococcal infections       3       0         Streptococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       1       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0		1	0
Pustule       2       0         Skin infection       2       0         Staphylococcal infections       3       0         Staphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       1       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0	· · ·	1	0
Skin infection       2       0         Staphylococcal infections       3       0         Furuncle       3       0         Staphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       1       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0		2	
Furuncle       3       0         Staphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       1       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0	Skin infection		
Furuncle       3       0         Staphylococcal infection       2       0         Streptococcal infections       2       0         Beta haemolytic streptococcal infection       2       0         Streptococcal sepsis       1       0         Upper respiratory tract infections       1       0         Epiglottitis       1       0         Laryngitis       1       0         Nasopharyngitis       42       0         Pharyngitis       8       0	Staphylococcal infections		
Staphylococcal infection20Streptococcal infections20Beta haemolytic streptococcal infection20Streptococcal sepsis10Upper respiratory tract infections10Epiglottitis10Laryngitis10Nasopharyngitis420Pharyngitis80		3	0
Streptococcal infectionsBeta haemolytic streptococcal infection2Streptococcal sepsis1Upper respiratory tract infections1Epiglottitis1Laryngitis1Nasopharyngitis42Pharyngitis8	Staphylococcal infection	2	2 0
Beta haemolytic streptococcal infection 2 (Cartest Streptococcal sepsis 1 Cartest Streptococcal infection 2 Cartest Streptococcal infection 3 Cartest Streptococcal infectio			
Streptococcal sepsis  Upper respiratory tract infections  Epiglottitis Laryngitis Nasopharyngitis Pharyngitis 8		2	2 0
Upper respiratory tract infectionsEpiglottitis1Laryngitis1Nasopharyngitis42Pharyngitis8		1	1
Epiglottitis 1 ( Laryngitis 1 ( Nasopharyngitis 42 ( Pharyngitis 8 (			
Laryngitis 1 ( Nasopharyngitis 42 ( Pharyngitis 8 (		1	0
Nasopharyngitis 42 0 Pharyngitis 8 0		1	0
Pharyngitis 8		42	
Sinusitis 2 (			
Tonsillitis		2	0
I DITORING I SI SI	Tonsillitis		o o
Urinary tract infections			l

Name: Human Papillomavirus Vaccine Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Kidney infection	1	0
Urinary tract infection	5	0
Viral infections NEC		
Gastroenteritis viral	3	0
Hepatitis viral	1	0
Meningitis viral	1	0
Pneumonia viral	1	0
Post viral fatigue syndrome	56	0
Viral infection	20	0
Viral pharyngitis	1	0
Infections SOC TOTAL	331	1

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0	Total	Ectal
Reaction Name	Total	Fatal
<u>Injuries</u>		
Abdominal and gastrointestinal injuries NEC	4	0
Mouth injury	1	0
Bone and joint injuries NEC	4	•
Joint injury	1	0
Chemical injuries	4	•
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		
Circumstance or information capable of leading to medication error	1	0
Medication error	9	0
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	20	0
Injury	3	0
Wound	1	0
Wound haemorrhage	1	0
Off label uses		
Off label use	2	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	4	0
Extra dose administered	4	0
Inappropriate schedule of product administration	11	0
Incorrect route of product administration	1	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	' I	U
	56	0
Contusion	56	(

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Dermatitis artefacta	1	0
Scar	3	0
Skin abrasion	1	0
Thermal burns		
Thermal burn	1	0
Vaccination related complications		
Vaccination complication	1	0
Injuries SOC TOTAL	198	0

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Reaction Name  MedDRA Version: MedDRA 25.	<u> </u>	Fatal
Investigations	<u> Tolai</u>	<u>ralai</u>
Adrenal cortex tests		
Cortisol decreased	1	0
Autoimmunity analyses	'	· ·
Antinuclear antibody increased	1	0
Antinuclear antibody increased  Antinuclear antibody positive	1	0
Blood counts NEC	_ '	· ·
Full blood count abnormal	1	0
Blood gas and acid base analyses	_ '	· ·
Blood pH increased	1	0
Oxygen saturation decreased	2	0
Carbohydrate tolerance analyses (incl diabetes)		· ·
Blood glucose decreased	3	0
Blood glucose increased	6	
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Heart sounds abnormal	1	0
Cell marker analyses	'	0
Cell marker increased	1	0
Central nervous system imaging procedures	'	0
Magnetic resonance imaging head abnormal	1	0
	'	0
Cerebrospinal fluid tests (excl microbiology)  CSF cell count increased	1	_
	-	0
Chemistry analyses NEC	2	_
Histamine level increased	2	0
ECG investigations	1	_
Electrocardiogram QT prolonged	1 1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	4	0
Foetal and neonatal diagnostic procedures		_
Foetal heart rate abnormal	1	0
Heart rate and pulse investigations		_
Heart rate abnormal	6	0
Heart rate decreased	10	_
Heart rate increased	59	
Heart rate irregular	16	
Pulse abnormal	9	1
Pulse absent	3	0
Pulse pressure decreased	1	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	1	0
Liver function test increased	1	0
Imaging procedures NEC		
Positron emission tomogram abnormal	1	0
Immunoglobulin analyses		
Blood immunoglobulin A increased	1	0
Immunology analyses NEC		
Immunology test	1	0
Investigations NEC		

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Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 25.0		
Reaction Name		<u>Total</u>	Fatal
Investigations Investigations cont'd			
Quality of life decreased		3	0
Mineral and electrolyte analyses			
Blood iron decreased		6	0
Blood magnesium decreased		1	0
Blood selenium decreased		1	0
Blood sodium abnormal		1	0
Blood zinc decreased		1	0
Serum ferritin decreased		3	0
Ophthalmic function diagnostic procedures			
Corneal reflex decreased		1	0
Physical examination procedures and organ	system status		
Body temperature	_	2	0
Body temperature abnormal		4	0
Body temperature decreased		7	0
Body temperature fluctuation		8	0
Body temperature increased		105	0
Breath sounds abnormal		1	0
Grip strength decreased		3	0
Respiratory rate decreased		1	0
Respiratory rate increased		13	0
Weight decreased		27	0
Weight increased		5	0
Pituitary analyses anterior			_
Blood growth hormone abnormal		1	0
Blood thyroid stimulating hormone abnorm	ial	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		·	J
Anti-Muellerian hormone level decreased		1	0
Oestradiol decreased		1	0
Progesterone increased		1	0
Reproductive organ and breast histopatholo	av procedures		J
Smear cervix abnormal	gy procedures	1	0
Respiratory and pulmonary function diagnos	etic procedures		J
Peak expiratory flow rate decreased	nio procedures	1	0
Tissue enzyme analyses NEC			J
Blood lactate dehydrogenase increased		1	0
Enzyme level increased		1	0
Toxicology laboratory analyses			J
Blood chromium decreased		1	0
Urinalysis NEC			J
Blood urine present		2	0
Urinary tract function analyses NEC			J
Urine output decreased		1	0
Vascular tests NEC (incl blood pressure)		'	U
Blood pressure abnormal		2	0
		12	0
Blood pressure decreased		12	
Blood pressure immeasurable		8	0
Blood pressure increased		ŏ	U

Name: Human Papillomavirus Vaccine Analysis Print

Date: 14-Oct-2022
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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood pressure systolic decreased	1	0
Virus identification and serology		
HIV test positive	1	0
Vitamin analyses		
Vitamin B12 decreased	1	0
Vitamin B12 increased	1	0
Vitamin D decreased	5	0
White blood cell analyses		
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
Investigations SOC TOTAL	390	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Appetite disorder	4	0
Decreased appetite	86	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	11	0
Diabetic complications NEC		
Diabetic ketoacidosis	3	0
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	12	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	2	0
Food intolerance	9	0
Gluten sensitivity	5	0
Histamine intolerance	1	0
General nutritional disorders NEC		
Abnormal loss of weight	30	0
Abnormal weight gain	1	0
Cachexia	1	0
Feeding disorder	5	0
Malnutrition	1	0
Underweight	1	0
Weight fluctuation	1	0
Weight gain poor	1	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	4	0
Insulin resistance	1	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	5	0
Iron deficiencies		
Iron deficiency	3	0
Metabolic acidoses (excl diabetic acidoses)		
Lactic acidosis	1	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mineral related disorders NEC		
Mineral deficiency	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	3	0
Total fluid volume decreased		
Dehydration	5	0
Vitamin deficiencies NEC		
Multi-vitamin deficiency	2	0
Water soluble vitamin deficiencies		
Vitamin B12 deficiency	8	0
Vitamin C deficiency	1	0
Metabolic disorders SOC TOTAL	218	

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	MedDRA Version: MedDRA 25.0	<b></b>
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·	
Coccydynia		1 0
Pain in jaw		6 0
Spinal pain	-	7 0
Bursal disorders		
Bursitis		1 0
Cartilage disorders		
Costochondritis		2 0
Osteochondrosis		1 0
Connective tissue disorders NEC		
Mixed connective tissue disease		1 0
Morphoea		1 0
Reynold's syndrome		1 0
Sjogren's syndrome		1 0
Extremity deformities		
Finger deformity		1 0
Foot deformity		1 0
Hand deformity		1 0
Joint related disorders NEC		
Hypermobility syndrome	10	0
Joint contracture	1	1 0
Joint lock		1 0
Periarthritis		3 0
Joint related signs and symptoms		1 "
Arthralgia	260	0 0
Joint effusion		1 0
Joint chasion  Joint noise		3 0
Joint range of motion decreased		1 0
Joint stiffness	15	-
Joint swelling	36	
Ligament disorders	30	1 0
Ligament pain		1 0
Lupus erythematosus (incl subtypes)		'  '
Lupus erythematosus (mer subtypes)  Lupus-like syndrome		1 0
Systemic lupus erythematosus		3 0
Metabolic bone disorders	· ·	٥
Osteoporosis		1 0
Muscle infections and inflammations		'  '
	,	
Myositis		2 0
Muscle pains	4-	7
Fibromyalgia	17	
Myalgia	184	1
Myalgia intercostal		1 0
Muscle related signs and symptoms NEC		_
Muscle atrophy		<u> 2                                   </u>

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Reaction Name	MedDRA Version: MedDRA 25.0	Total	Fatal
Muscle & tissue disorders e & tissue disorde	rs cont'd		
Muscle discomfort		2	0
Muscle fatigue		12	0
Muscle spasms		47	0
Muscle swelling		1	0
Muscle tightness		6	0
Muscle twitching		50	0
Muscle tone abnormalities			
Muscle rigidity		35	0
Trismus		1	0
Muscle weakness conditions			
Muscular weakness		127	0
Musculoskeletal and connective tissue c	onditions NEC		
Back disorder		2	0
Growth retardation		3	0
Mastication disorder		1	0
Mobility decreased		19	0
Muscle contracture		2	0
Musculoskeletal disorder		1	0
Musculoskeletal stiffness		106	0
Posture abnormal		1	0
Weight bearing difficulty		8	0
Musculoskeletal and connective tissue p	ain and discomfort	_	
Back pain		93	0
Flank pain		2	0
Growing pains		2	0
Limb discomfort		184	0
Musculoskeletal chest pain		11	0
Musculoskeletal discomfort		4	0
Musculoskeletal pain		5	0
Neck pain		78	0
Pain in extremity		1118	0
Myopathies			·
Myopathy		1	0
Rheumatoid arthropathies			_
Juvenile idiopathic arthritis		4	0
Rheumatoid arthritis		5	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		2546	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0	Tatal	Catal
Reaction Name	Total	<u>Fatal</u>
Neoplasms		
Bladder neoplasms malignant		
Bladder cancer	1	0
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	0
Cervix neoplasms malignant		
Cervix carcinoma	1	0
Cervix carcinoma stage 0	1	0
Endocrine neoplasms malignant and unspecified NEC		
Pituitary tumour	1	0
Glial tumours malignant		
Medulloblastoma	1	0
Hepatobiliary neoplasms benign		
Focal nodular hyperplasia	1	0
Islet cell neoplasms and APUDoma NEC		
Pancreatic neuroendocrine tumour metastatic	1	0
Kaposi's sarcomas		
Kaposi's sarcoma	1	0
Leukaemias acute lymphocytic		
Acute lymphocytic leukaemia	1	0
T-cell type acute leukaemia	1	1
Leukaemias acute myeloid	4	_
Acute myeloid leukaemia	1	0
Leukaemias chronic myeloid	4	_
Chronic myeloid leukaemia	1	0
Metastases to specified sites	4	_
Metastases to liver	1	0
Neoplasms malignant site unspecified NEC	4	۱ ،
Neoplasm malignant	1	
Non-Hodgkin's lymphomas NEC	1	1
Non-Hodgkin's lymphoma	1	
Pharyngeal and laryngeal neoplasms benign	1	0
Laryngeal papilloma  Reproductive neoplasms female benign NEC	1	0
Benign hydatidiform mole	1	0
Reproductive neoplasms male benign NEC	1	0
Penile wart	1	0
Respiratory tract and pleural neoplasms benign NEC	'	J
Respiratory papilloma	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified		J
NEC		
Throat cancer	1	0
Salivary gland neoplasms malignant		_
Salivary gland cancer stage I	1	0
Skin neoplasms benign		
Anogenital warts	5	0
Melanocytic naevus	1	0
Skin papilloma	6	0
Uterine neoplasms benign		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	35	3

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	6	0
Abnormal sleep-related events		
Sleep paralysis	1	0
Absence seizures		
Petit mal epilepsy	8	0
Acute polyneuropathies		
Guillain-Barre syndrome	9	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	11	0
Autonomic neuropathy	2	0
Central nervous system haemorrhages and cerebrovascular accidents	_	Ŭ
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	1	J
Central nervous system vasculai disorders NEC	1	0
Cerebrovascular disorder	1	0
	l	U
Choreiform movements	4	0
Chorea	1	0
Chronic polyneuropathies	4	0
Demyelinating polyneuropathy	1	0
Coordination and balance disturbances	_	
Ataxia	5	0
Balance disorder	25	0
Cerebellar ataxia	1	0
Coordination abnormal	9	0
Dysstasia	19	0
Nystagmus	1	0
Cortical dysfunction NEC		
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	219	0
Loss of consciousness	113	0
Sedation	1	0
Somnolence	171	0
Syncope	892	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

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·	MedDRA Version: MedDRA 25.0		
Reaction Name		Total	Fatal
Nervous system disorders co	nt'd		
Dyskinesia		63	0
Fine motor skill dysfunction		1	0
Hypokinesia		15	0
Motor dysfunction		4	0
Movement disorder		9	0
Psychomotor hyperactivity		4	0
Dystonias			, and the second
Dystonia		1	0
Opisthotonus		2	0
Encephalitis NEC		_	
Encephalitis autoimmune		5	0
Noninfective encephalitis		1	0
Encephalopathies NEC			ŭ
Encephalopathy		1	0
Hashimoto's encephalopathy		1	0
Eye movement disorders			0
IVth nerve paralysis		1	0
VIth nerve paralysis		1	0
Facial cranial nerve disorders		ľ	U
Bell's palsy		12	0
		8	0
Facial paragia		0	
Facial paresis		2	0
Facial spasm		2	U
Generalised tonic-clonic seizures		22	^
Generalised tonic-clonic seizure		23	0
Headaches NEC		7	^
Cluster headache		4040	0
Headache		1849	0
Tension headache		4	0
Increased intracranial pressure disorders		4	0
Idiopathic intracranial hypertension		1	0
Intracranial pressure increased		2	0
Intellectual disabilities		4	
Intellectual disability		1	0
Memory loss (excl dementia)			
Amnesia		24	0
Memory impairment	, ,	32	0
Mental impairment (excl dementia and memo	ry loss)	0.4	
Cognitive disorder		21	0
Disturbance in attention		66	0
Mental impairment		4	0
Migraine headaches			_
Basilar migraine		1	0
Hemiplegic migraine		1	0
Migraine		88	0
Migraine with aura		4	0
Migraine without aura		3	0
Typical aura without headache		1	0
Mononeuropathies			
Carpal tunnel syndrome		2 2	0
Peroneal nerve palsy		2	0
Multiple sclerosis acute and progressive			
Multiple sclerosis		2	0

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Nervous system disorders us system disorders cont'd		
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	14	0
Myelitis (incl infective)		
Myelitis transverse	4	0
Narcolepsy and hypersomnia		
Cataplexy	6	0
Hypersomnia	29	0
Narcolepsy	10	0
Nervous system cysts and polyps		
Colloid brain cyst	1	0
Pineal gland cyst	1	0
Nervous system disorders NEC		
Cerebral disorder	1	0
Nervous system disorder	8	0
Neurologic visual problems NEC		
Tunnel vision	1	0
Neurological signs and symptoms NEC		
Clonus	1	0
Dizziness	2342	0
Dizziness exertional	1	0
Dizziness postural	46	0
Drooling	2	0
Head discomfort	15	0
Hyporesponsive to stimuli	1	0
Meningism	2	0
Myoclonus	3	0
Neurological symptom	1	0
Patient elopement	1	0
Presyncope	67	0
Slow response to stimuli	6	0
Unresponsive to stimuli	55	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	1	0
Parosmia	3	
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning sensation	14	0
Dysaesthesia	1	0
Formication	1	0
Hyperaesthesia	15	
Hypoaesthesia	379	
Paraesthesia	290	
Paralysis and paresis (excl cranial nerve)		
Diplegia	5	0
Hemiparesis	11	0
Hemiplegia	2	
Monoparesis	2	0

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Reaction Name	Total	Fatal
Nervous system disorders cont'd	Τοιαι	T atai
Monoplegia	1:	5 0
Paralysis	2	
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		اً ا
Change in seizure presentation		1 0
Clonic convulsion		1 0
Epilepsy	2	
Febrile convulsion		1 0
Myoclonic epilepsy		
Partial seizures		1 0 5 0
Psychogenic seizure		3 0
Seizure	17-	
Seizure anoxic		
Seizure like phenomena		5 0 6 0
Status epilepticus		1 0
Tonic clonic movements		6 0
Tonic convulsion		2 0
Sensory abnormalities NEC		
Ageusia		2 0
Allodynia		2 0 2 0
Complex regional pain syndrome	24	
Dysgeusia	10	
Electric shock sensation		1 0
Neuralgia	:	8 0
Post herpetic neuralgia		1 0
Restless legs syndrome		1 0
Sensory disturbance	2:	
Sensory loss	3	
Taste disorder		5l ol
Sleep disturbances NEC		
Sudden onset of sleep	;	3 0
Speech and language abnormalities		
Dysarthria	2:	2 0
Incoherent		4 0
Slow speech		4 0
Speech disorder	1:	3 0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial		1 0
Radiculopathy		1 0
Spinal cord oedema		1 0
Structural brain disorders NEC		
Brain injury		1 0

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Reaction Name	Total	Fatal
Nervous system disorders gus system disorders cont'd		
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	209	0
Nervous system disorders SOC TOTAL	7819	0

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

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Reaction Name	Total	<u>Fatal</u>
Product label issues		
Product lot number issue	1	0
Product quality issues NEC		
Product origin unknown	9	0
Product quality issue	1	0
Product substitution issue	1	0
null SOC TOTAL	12	0

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	MedDRA Version: MedDRA 25.0		
Reaction Name	Tota	Щ	Fatal
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		84	0
Nervousness		19	0
Stress		4	0
Behaviour and socialisation disturbances			
Aggression		9	0
Disinhibition		2	0
Disturbance in social behaviour		1	0
Impatience		1	0
Indifference		1	0
Paranoia		5	0
Personality change		11	0
Social avoidant behaviour		4	0
Bipolar disorders			
Bipolar I disorder		1	0
Bipolar disorder		3	0
Cognitive and attention disorders and disturba	ances NEC		
Mental fatigue		2	0
Confusion and disorientation			
Confusional state		50	0
Disorientation		31	0
Deliria			
Delirium		3	0
Delusional symptoms			
Delusion		2	0
Depressive disorders			
Depression		44	0
Depression suicidal		4	0
Dissociative states			
Dissociation		3	0
Disturbances in initiating and maintaining slee	ep		
Insomnia		61	0
Middle insomnia		1	0
Dyssomnias			
Poor quality sleep		5	0
Eating disorders NEC			
Anorexia nervosa		1	0
Eating disorder		3	0
Merycism		1	0
Emotional and mood disturbances NEC		]	

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedD		
Reaction Name	Total	Fatal
Psychiatric disordersPsychiatric disorders cont'd		
Anger	3	
Emotional disorder	15	
Emotional distress	13	0
Emotional poverty	1	0
Euphoric mood	1	0
Irritability	7	0
Mood altered	6	0
Fear symptoms and phobic disorders (incl social phobia)		
Autophobia	1	0
Claustrophobia	1	0
Fear	3	0
Fear of crowded places	1	
Fear of death	1	0
Phobia	1	0
Social anxiety disorder	6	0
Fluctuating mood symptoms		
Mood swings	7	0
Hallucinations (excl sleep-related)		
Hallucination	17	0
Hallucination, auditory	6	
Hallucination, visual	3	0
Hallucinations, mixed	1	0
Impulse control disorders		
Impulse-control disorder	1	0
Impulsive behaviour	1	0
Increased physical activity levels		
Restlessness	6	0
Learning disorders		
Reading disorder	1	0
Mental disorders NEC		
Mental disorder	6	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Decreased interest	4	
Depressed mood	16	0
Depressive symptom	2	
Feeling guilty	1	0
Feeling of despair	1	0
Negative thoughts	1	0
Tearfulness	30	0
Mood alterations with manic symptoms		
Hypomania	1	0
Mood disorders NEC		
Affective disorder	1	0
Apathy	3	0
Listless	5	0
Narcolepsy and associated conditions		
Sleep attacks	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive thoughts	1	0
Obsessive-compulsive disorder	2	0
Trichotillomania	1	
Panic attacks and disorders		

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0	<del></del>	F-1-1
Reaction Name	<u>  Total  </u>	Fatal
Psychiatric disordersPsychiatric disorders cont'd		
Panic attack	31	0
Panic reaction	8	0
Parasomnias		
Abnormal dreams	1 1	0
Abnormal sleep-related event	1	0
Sleep terror	2	0
Perception disturbances NEC		
Deja vu	1 1	0
Illusion	1	0
Near death experience	1	0
Personality disorders NEC		•
Self esteem decreased	3	0
Personality disorders with anxious behaviour (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 1	0
Psychotic disorder	4	0
Sexual desire disorders		0
Loss of libido	1	0
Sleep disorders NEC	20	0
Sleep disorder	30	0
Somatic symptom disorders	_	0
Conversion disorder	5	0
Somatic symptom disorder	2	0
Speech and language usage disturbances	1	0
Disorganised speech	1 1	0
Logorrhoea	1	0
Speech articulation and rhythm disturbances	2	0
Dysphemia Stereotypies and automatisms	3	0
Bruxism	1	0
Head banging	2	0
Stress disorders	4	U
Burnout syndrome	1	0
Post-traumatic stress disorder		0
Suicidal and self-injurious behaviour	'	J
Intentional self-injury	6	0
Self-injurious ideation	1	0
Suicidal ideation		0
Suicide attempt	2	0
Thinking disturbances		U
Bradyphrenia	2	0
Intrusive thoughts		0
Thinking abnormal	2	0
Thought blocking	2	0
Tic disorders	4	U
Tic	3	0
	702	0
Psychiatric disorders SOC TOTAL	102	U

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0	Total	Cotal
Reaction Name	Total	<u>Fatal</u>
Renal & urinary disorders		
Bladder and urethral symptoms	2	0
Bladder pain	3	0
Bladder spasm	1	0
Dysuria	3	0
Incontinence	3	0
Micturition urgency		0
Pollakiuria	9 22	0
Urinary incontinence	1	0
Urinary retention  Bladder disorders NEC	4	U
Bladder disorder  Bladder disorder	1	0
Bladder fibrosis	4	0
Bladder mass	1	0
Bladder infections and inflammations	<b>I</b>	
Cystitis noninfective	1	0
Genital and urinary tract disorders NEC	<b>I</b>	O
Urinary tract disorders NEC	3	O
Genitourinary tract infections and inflammations NEC	3	U
Urinary tract inflammation	1	O
Glomerulonephritis and nephrotic syndrome	1	
Focal segmental glomerulosclerosis	1	O
Henoch-Schonlein purpura nephritis	1	0
IgA nephropathy	1	0
Nephrotic syndrome	1	0
Myoneurogenic bladder disorders	'	
Bladder dysfunction	1	O
Contracted bladder	1	Ö
Hypertonic bladder	1	Ö
Loss of bladder sensation	1	O
Neurogenic bladder	1	O
Renal disorders NEC		
Renal disorder	2	O
Renal failure and impairment		-
Renal failure	1	C
Renal lithiasis		-
Nephrolithiasis	1	0
Renal vascular and ischaemic conditions		
Renal vasculitis	1	O
Urinary abnormalities		
Proteinuria	2	0
Urinary tract signs and symptoms NEC		
Haemorrhage urinary tract	1	0
Polyuria	1	O
Renal pain	1	O
Renal & urinary disorders SOC TOTAL	78	

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Reaction Name	version: MedDRA 25.0 <b>Total</b>	Fatal
Reproductive & breast disorders	Total	atai
Benign and malignant breast neoplasms		
Breast cyst	1	0
Breast disorders NEC		
Breast enlargement	1	0
Gynaecomastia		Ö
Nipple disorder	1	0
Breast signs and symptoms		
Breast discharge	1	0
Breast pain	4	
Breast swelling	1	
Breast tenderness		1
Nipple pain	2	Ö
Cervix disorders NEC		Ĭ
Cervical dysplasia	4	0
Uterine cervix atrophy	1	
Cervix infections and inflammations		Ĭ
Cervix inflammation	1	0
Menopausal effects NEC	·	
Premature menopause	5	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	22	0
Intermenstrual bleeding	4	
Menstrual discomfort	1	0
Menstrual disorder	20	
Menstruation irregular	39	
Premenstrual pain	1	0
Premenstrual syndrome	1	0
Menstruation with decreased bleeding		
Amenorrhoea	39	0
Menstruation delayed	27	
Oligomenorrhoea	3	
Menstruation with increased bleeding		_
Heavy menstrual bleeding	30	C
Polymenorrhoea	2	
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	4	.l o
Polycystic ovaries	11	l 0
Ovarian and fallopian tube disorders NEC		
Ovarian disorder	2	0
Ovarian failure	6	
Ovulation disorder	1	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	1	0
Reproductive tract signs and symptoms NEC		
Genital erythema	1	0
Genital pain	2	0
Genital rash	1	0
Genital swelling	2	( c
Pelvic pain	6	0
Sexual function and fertility disorders NEC		
Dyspareunia	1	0
Infertility	3	0
Uterine disorders NEC		

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Reaction Name	Total	Fatal
Reproductive & breastediscipling & breast disorders contid		
Endometriosis	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	12	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval ulceration	3	0
Vulvar dysplasia	1	0
Vulvovaginal disorder	1	0
Vulvovaginal signs and symptoms		
Coital bleeding	1	0
Vaginal discharge	6	0
Vaginal lesion	1	0
Vulval oedema	2	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	289	0

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	n: MedDRA 25.0	
Reaction Name	Total	<u> Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	207	0
Grunting	3	0
Hyperventilation	53	0
Hypopnoea	15	
Respiration abnormal	4	0
Respiratory arrest	6	
Respiratory distress	1	0
Tachypnoea	4	0
Bronchospasm and obstruction		
Asthma	27	0
Bronchospasm	7	0
Obstructive airways disorder	2	0
Wheezing	25	0
Coughing and associated symptoms		
Allergic cough	1	0
Cough	54	0
Haemoptysis	2	
Productive cough	4	
Laryngeal and adjacent sites disorders NEC (excl infection neoplasms)	ns and	
Vocal cord disorder	1	0
Laryngeal spasm, oedema and obstruction		
Laryngeal oedema	5	0
Laryngospasm	1	
Stridor	1	
Lower respiratory tract signs and symptoms		
Increased bronchial secretion	1	0
Pleuritic pain	2	
Nasal congestion and inflammations		
Nasal congestion	10	0
Nasal disorders NEC	10	"
Epistaxis	34	0
Nasal oedema	1	
Paranasal sinus disorders (excl infections and neoplasms)	•	"
, ,	' I	_ ر
Sinonasal obstruction		0
Pharyngeal disorders (excl infections and neoplasms)	1	١ ,
Pharyngeal and ma		0
Pharyngeal paragethesis		
Pharyngeal paraesthesia	2	
Pharyngeal yleantica	18	
Pharyngeal ulceration	1	
Tonsillar disorder	2	0
Tonsillar erythema		, and the second
Tonsillar hypertrophy	2	0
Pneumothorax and pleural effusions NEC		
Pneumothorax	2	0
Pulmonary oedemas		_
Pulmonary oedema	1	0
Respiratory failures (excl neonatal)		_
Acute respiratory failure	1	0
Respiratory signs and symptoms NEC		_
Painful respiration	1	0

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Reaction Name	Total	Fatal
Respiratory disordersRespiratory disorders cont'd		
Respiratory tract disorders NEC		
Allergic respiratory disease	1	0
Respiratory disorder	3	1
Respiratory tract inflammation	1	0
Upper respiratory tract signs and symptoms		
Aphonia	7	0
Choking	2	0
Choking sensation	2	0
Dry throat	6	0
Dysphonia	3	0
Nasal obstruction	1	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	141	0
Rhinorrhoea	9	0
Sinus pain	2	0
Sneezing	5	0
Throat irritation	27	0
Throat lesion	1	0
Throat tightness	42	0
Vascular pulmonary disorders NEC		
Pulmonary arteriopathy	2	0
Respiratory disorders SOC TOTAL	762	1

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Earliest Reaction Date: 05-May-2006  Reaction Name	MedDRA Version: MedDRA 25.0  Total	Fatal
Skin disorders	Total	T atai
Acnes		
Acne		9 0
Acne cystic		1 0
Alopecias		1
	1	
Alopecia	4	
Alopecia areata		
Alopecia totalis		2 0 3 0
Diffuse alopecia		
Madarosis		1 0
Angioedemas		
Angioedema	1	
Circumoral oedema		1 0
Apocrine and eccrine gland disorders		
Cold sweat	10	
Hyperhidrosis	10	
Miliaria		5 0
Night sweats		3 0
Bullous conditions		
Blister	2	1 0
Dermatitis bullous		1 0
Erythema multiforme	1	
Stevens-Johnson syndrome		1 0
Dermal and epidermal conditions NEC		
Dry skin	1	3 0
Pain of skin	1	1 0
Papule		5 0
Scab		1
Sensitive skin		2 0 2 0
Skin burning sensation		5 0
Skin discolouration	10	
Skin disorder		8 0
Skin fissures		1 0
Skin induration		1 0
Skin lesion		5 0
Skin reaction	1	
Skin sensitisation		2 0
Skin texture abnormal		1 0
Skin tightness		3 0
Skin warm	2	1
Yellow skin		3 0
Dermatitis and eczema		
Dermatitis and eczerna  Dermatitis		1 0
Dermatitis  Dermatitis allergic	3	
Dermatitis anergic  Dermatitis contact		4 0
Dyshidrotic eczema		1 0
Eczema	1	5 0
Eczema nummular		
		1
Eczema vesicular		1 0
Seborrhoeic dermatitis		2 0
Skin irritation	1	0 0
Dermatitis ascribed to specific agent		
Drug eruption		2 0
<u>Erythemas</u>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Erythema	237	0
Palmar erythema	1	0
Exfoliative conditions		
Skin exfoliation	7	0
Hyperkeratoses		
Hyperkeratosis	1	0
Hyperpigmentation disorders		
Melanoderma	1	0
Hypopigmentation disorders		
Skin depigmentation	1	0
Vitiligo	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	2	0
Panniculitides		
Erythema nodosum	6	0
Panniculitis	1	0
Papulosquamous conditions		
Lichen planus	1	0
Parapsoriasis	1	0
Pityriasis lichenoides et varioliformis acuta	1	0
Pityriasis rosea	3	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	19	0
Pigmentation changes NEC		
Pigmentation disorder	2	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Piloerection	1	0
Trichorrhexis	1	0
Pruritus NEC		
Pruritus	202	0
Psoriatic conditions		
Guttate psoriasis	1	0
Psoriasis	5	0
Purpura and related conditions		
Henoch-Schonlein purpura	10	0
Petechiae	11	0
Purpura	8	0
Pustular conditions		
Rash follicular	1	0
Rashes, eruptions and exanthems NEC		
Rash	474	0
Rash erythematous	47	0
Rash macular	82	0
Rash maculo-papular	6	0
Rash papular	11	0
Rash pruritic	73	0
Rash vesicular	3	0
Systemic lupus erythematosus rash	1	0
Skin and subcutaneous conditions NEC		
Skin mass	3	0
Umbilical discharge	1	0
Skin haemorrhages		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin haemorrhage	1	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin striae	4	0
Skin preneoplastic conditions NEC		
Precancerous skin lesion	1	0
Skin vasculitides		
Vasculitic rash	1	0
Skin vasomotor conditions		
Livedo reticularis	43	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	2	0
Urticaria	254	0
Urticaria chronic	3	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	2167	0

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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
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
Therapeutic procedures NEC		
Anaphylaxis treatment	1	0
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	17	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 25.0	Total	Eatal
Reaction Name	Total	<u>Fatal</u>
Vascular disorders		
Blood pressure disorders NEC	4	^
Blood pressure fluctuation	1	0
Circulatory collapse and shock	_	^
Circulatory collapse	7	0
Peripheral circulatory failure	1	0
Shock	4	0
Haemorrhages NEC		0
Haemorrhage	3	0
Venous haemorrhage	1	0
Lymphoedemas	_	
Lymphoedema	1	0
Non-site specific embolism and thrombosis		
Thrombosis	3	0
Non-site specific necrosis and vascular insufficiency NEC		_
Peripheral venous disease	3	0
Vasospasm	1	0
Non-site specific vascular disorders NEC	-	_
Capillary disorder	3	0
Vascular pain	1	0
Vasodilatation	1	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	0
Superficial vein thrombosis	1	0
Peripheral vascular disorders NEC		
Cyanosis	36	0
Erythromelalgia	1	0
Flushing	123	0
Hot flush	22	0
Peripheral vascular disorder	2	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	121	0
Poor peripheral circulation	9	0
Raynaud's phenomenon	8	0
Site specific vascular disorders NEC		
Pallor	370	0
Vascular hypertensive disorders NEC		
Hypertension	10	0
Orthostatic hypertension	1	0
Vascular hypotensive disorders		
Hypotension	41	0
Orthostatic hypotension	2	0
Vasculitides NEC		
Behcet's syndrome	1	0
Vasculitis	3	0
Vascular disorders SOC TOTAL	782	0
TOTAL REACTIONS FOR DRUG	27002	9
TOTAL REPORTS	10061	
TOTAL FATAL OUTCOME REPORTS		9