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

Report Run Date:31-May-2023Data Lock Date:30-May-2023 18:30:04Earliest Reaction Date:05-May-2006MedDRA Version:MedDRA 26.0

Human Papillomavirus
(HPV) Vaccine
Analysis Print:FOI 23/323 - All UK spontaneous suspected Adverse
Drug Reaction (ADR) reports associated with the HPV
vaccine up to and including 30/05/2023.

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Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0	
Reaction Name	Total	<u>Fatal</u>
Blood disorders		
Anaemia deficiencies		
Anaemia vitamin B12 deficiency		2 0
Iron deficiency anaemia		1 0
Pernicious anaemia		1 0
Anaemias NEC		
Anaemia	11	1 0
Anaemias haemolytic mechanical factor		
Haemolytic uraemic syndrome		1 0
Bleeding tendencies		
Increased tendency to bruise	Ę	5 0
Coagulopathies		
Coagulopathy		2 0
Eosinophilic disorders		
Eosinophilia		1 0
Haematological disorders		
Blood disorder		1 0
Mast cell activation syndrome	6	6 0
Lymphatic system disorders NEC		
Lymph node pain		3 0
Lymphadenitis		1 0
Lymphadenopathy	66	6 0
Marrow depression and hypoplastic anaemia	IS	
Aplastic anaemia		1 0
Pancytopenia		1 0
Neutropenias		
Autoimmune neutropenia		2 0
Neutropenia		3 0
Spleen disorders		
Splenomegaly		з о
Thrombocytopenias		
Immune thrombocytopenia	10	o l
Thrombocytopenia		2 0
Blood disorders SOC TOTAL	123	

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Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0	Total	Fatal
Cardiac disorders		
Cardiac conduction disorders		
Atrioventricular block	1	C
Cardiac disorders NEC		
Cardiac disorder	4	C
Cardiac signs and symptoms NEC		
Palpitations	62	C
Ischaemic coronary artery disorders		
Angina pectoris	3	0
Noninfectious pericarditis		
Pericarditis lupus	1	C
Pericardial disorders NEC		
Pericardial effusion	1	0
Pulmonary valvular disorders		
Pulmonary valve stenosis	2	0
Rate and rhythm disorders NEC		
Arrhythmia	3	C
Bradycardia	7	0
Postural orthostatic tachycardia syndrome	87	C
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	C
Cardiac disorders SOC TOTAL	239	2

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

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Reaction Name	-	Fotal	Fatal
Ear disorders			
Ear disorders NEC			
Ear discomfort		4	0
Ear pain		19	0
Eustachian tube disorders			
Eustachian tube dysfunction		1	0
Hearing disorders NEC			
Auditory disorder		1	0
Hearing losses			
Deafness		17	0
Deafness bilateral		1	0
Deafness transitory		4	0
Hypoacusis		23	0
Hyperacusia			
Hyperacusis		26	0
Inner ear disorders NEC			
Inner ear disorder		1	0
Vestibular disorder		1	0
Inner ear signs and symptoms			
Motion sickness		3	0
Tinnitus		17	0
Vertigo		16	0
Ear disorders SOC TOTAL		134	0

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Adrenal cortical hypofunctionsAdrenal insufficiencyAdrenocortical insufficiency acuteEndocrine abnormalities of gonadal function NECOestrogen deficiencyEndocrine abnormalities of pubertyDelayed puberty	Fata	al 0 0
Acute and chronic thyroiditisAutoimmune thyroiditisAdrenal cortical hypofunctionsAdrenal insufficiencyAdrenocortical insufficiency acuteAdrenocortical insufficiency acuteEndocrine abnormalities of gonadal function NECOestrogen deficiencyEndocrine abnormalities of pubertyDelayed puberty		0 0 0
Autoimmune thyroiditis Adrenal cortical hypofunctions Adrenal insufficiency Adrenocortical insufficiency acute Adrenocortical insufficiency acute Adrenocortical insufficiency acute Endocrine abnormalities of gonadal function NEC Adrenocortical insufficiency Oestrogen deficiency Endocrine abnormalities of puberty Delayed puberty Delayed puberty		0 0 0
Adrenal cortical hypofunctions		0 0 0
Adrenal insufficiency Image: Second Seco	2 2	0 0
Adrenocortical insufficiency acute :: Endocrine abnormalities of gonadal function NEC : Oestrogen deficiency : Endocrine abnormalities of puberty : Delayed puberty :	2 2 1	0 0
Endocrine abnormalities of gonadal function NEC Oestrogen deficiency Endocrine abnormalities of puberty Delayed puberty	2	0
Oestrogen deficiency <i>Endocrine abnormalities of puberty</i> Delayed puberty	1	
Endocrine abnormalities of puberty Delayed puberty	1	
Delayed puberty		0
	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		
Graves' disease	1	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	2	0
Hypothyroidism 1	ו	0
Endocrine disorders SOC TOTAL 3	1	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0	Total	Ental
Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		0
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	26	0
Eye swelling	39	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	2	0
Ocular sensation disorders		
Abnormal sensation in eye	1	0
Asthenopia	3	0
Foreign body sensation in eyes	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Photophobia	63	C
Optic disc abnormalities NEC		
Optic disc disorder	1	C
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	1	C
Pupil disorders		
Miosis	2	C
Mydriasis	22	C
Pupil fixed	3	C
Pupillary disorder	1	C
Pupillary reflex impaired	1	C
Refractive and accommodative disorders		
Accommodation disorder	1	C
Altered visual depth perception	1	C
Муоріа	1	C
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	1	C
Retinal, choroid and vitreous infections and inflammations		
Choroiditis	1	C
Retinal vasculitis	1	C
Visual disorders NEC		
Diplopia	14	C
Halo vision	1	C
Metamorphopsia	1	C
Photopsia	6	C
Vision blurred	167	C
Visual field disorders		
Visual field defect	8	C
Visual impairment and blindness (excl colour blindness)		
Blindness	16	C
Blindness transient	22	C
Blindness unilateral	1	C
Visual acuity reduced	1	(
Visual impairment	80	C
Eye disorders SOC TOTAL	627	C

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Anal and rectal disorders NEC 1 Anal fissure 1 Colitis (col infective) 2 Colitis (col infective) 4 Crohn's disease 2 Dental disorders NEC 1 Tooth erosion 1 Diaphragmatic hemias 1 Hiatus hernia 1 Diarhoea (excl infective) 1 Diarhoea haemorrhagic 2 Dyspeptic signs and symptoms 2 Dyspeptic signs and symptoms 2 Paecal abnormalities NEC 1 Abnormal faceces 1 Flatulence, bloating and distension 17 Abdominal distension 17 Flatulence, bloating and distension 1 Abdominal distension 1 Gastric ucler		DRA Version: MedDRA 26.0	E . (. l
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Gastrointestinal disorder17Gastrointestinal dyskinetic disorders17			
Gastrointestinal dyskinetic disorders		17	

Name: Human Papillomavirus(HPV) Vaccine Analysis Printrt Run Date: 31-May-2023
st Reaction Date: 05-May-2006Data Lock Date: 30-May-2023 18:30:04
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Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders ointestinal disorders	s cont'd	
Gastrointestinal motility disorder		2 0
Gastrointestinal inflammatory disorders N	IEC	
Duodenitis		1 0
Gastrointestinal inflammation		3 0
Gastrointestinal mucosal dystrophies and	secretion disorders	
Oesophageal mucosal hyperplasia		1 0
Gastrointestinal signs and symptoms NE	C	
Abdominal discomfort	5	
Dysphagia	2	7 0
Odynophagia		2 0
Oesophageal discomfort		1 0
Gastrointestinal spastic and hypermotility	disorders	
Defaecation urgency		1 0
Frequent bowel movements		3 0
Irritable bowel syndrome	23	3 0
Gastrointestinal ulcers and perforation, si	te unspecified	
Gastrointestinal ulcer		1 0
Gingival disorders, signs and symptoms l	NEC	
Gingival disorder		1 0
Gingival pain		2 0
Gingival swelling		1 0
Gingival ulceration	· · · · · · · · · · · · · · · · · · ·	1 0
Gingival haemorrhages		
Gingival bleeding		1 0
Haemorrhoids and gastrointestinal varice	s (excl oesophageal)	
Haemorrhoids		1 0
Inguinal hernias		
Inguinal hernia		2 0
Intestinal haemorrhages		
Rectal haemorrhage		2 0
Malabsorption syndromes		
Bile acid malabsorption		1 0
Coeliac disease	1	0 0
Malabsorption		2 0
Nausea and vomiting symptoms		
Cyclic vomiting syndrome		1 0
Nausea	175	в О
Regurgitation	· · · · · · · · · · · · · · · · · · ·	1 0
Retching		7 0
Vomiting	76	6 0
Vomiting projectile	;	2 0
Non-site specific gastrointestinal haemon	rhages	
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		

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

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	
Oral mucosal blistering	3	0
Oral mucosal eruption	1	0
Oral pain	6	0
Oral pruritus	2	0
Paraesthesia oral	40	0
Oral soft tissue swelling and oedema		
Lip swelling	65	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	3635	0

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0	
Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site pain		1 C
Administration site swelling		0
Puncture site reaction	· · · · · · · · · · · · · · · · · · ·	0
Asthenic conditions		
Asthenia	192	
Chronic fatigue syndrome	108	
Decreased activity		
Fatigue	813	
Malaise	797	7 0
Body temperature altered		
Temperature regulation disorder	15	5 0
Complications associated with device NEC		
Injury associated with device		0 0
Death and sudden death		
Death		1
Febrile disorders		
Hyperpyrexia		
Pyrexia	599	9 C
Feelings and sensations NEC		
Chills	113	
Feeling abnormal	52	
Feeling cold	83	3 C
Feeling drunk	Ę	5 0
Feeling hot	223	
Feeling jittery	Ę	-
Feeling of body temperature change	26	
Sensation of foreign body		3 C
Temperature intolerance		7 C
Thirst	8	3 C
Gait disturbances		
Gait disturbance	34	
Gait inability	29	9 0
Loss of control of legs	Ę	5 0
General signs and symptoms NEC		
Condition aggravated	16	6 0
Crying	13	3 C
Disease recurrence		
Exercise tolerance decreased		7 C
Foaming at mouth		4 C
General physical health deterioration		2 0
Glassy eyes	2	2 0
III-defined disorder		7 0
Illness	102	2 0
Induration	4	4 C
Influenza like illness	127	7 0
Local reaction	32	2 0
Organ failure		
Peripheral swelling	364	4 C
Screaming		3 O
Secretion discharge		
Swelling	89	
Swelling face	95	

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

	<u>Total</u>	<u>Fatal</u>
General disorders General disorders cont'd		
Healing abnormal NEC		
Impaired healing	2	2 C
Hernias NEC		
Hernia	2	
Inflammations		
Inflammation	23	s c
Serositis	1	C
Systemic inflammatory response syndrom	ne 1	
Infusion site reactions		
Infusion site hypoaesthesia	1	
Injection site reactions		
Injected limb mobility decreased	5	i c
Injection site bruising	29	
Injection site coldness	4	C
Injection site discharge	3	
Injection site discolouration	6	1
Injection site discomfort	3	
Injection site erythema	127	
Injection site granuloma	1	
Injection site haemorrhage	5	1
Injection site hypoaesthesia	16	
Injection site induration	11	
Injection site inflammation	28	
Injection site injury	1	
Injection site irritation	6	
Injection site joint movement impairment	1	
Injection site joint pain	3	
Injection site mass	68	
Injection site movement impairment	3	
Injection site nerve damage	1	
Injection site nodule	8	
Injection site oedema	1	
Injection site pain	151	
Injection site papule	1	
Injection site paraesthesia	2	
Injection site pruritus	29	
Injection site rash	52	
Injection site reaction	36	
Injection site scab	2	
Injection site scar	1	
Injection site swelling	176	
Injection site urticaria	6	
Injection site vesicles	5	
Injection site warmth	28	
Interactions		
Drug interaction	1	C
Mass conditions NEC		
Cyst	1	C
Mass	5	
Nodule	2	
Mucosal findings abnormal	2	
Mucosal findings abnormal Mucosal ulceration	1	
	1	C

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Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0	Eatol
Reaction Name General disorders General disorders cont'd	Total	Fatal
Face oedema		5 0
Localised oedema		1 0
Oedema peripheral	1:	2 0
Pain and discomfort NEC		
Axillary pain		5 0
Chest discomfort	7:	
Chest pain	120	
Discomfort	20	8 0
Facial pain	·	4 0
Non-cardiac chest pain	;	3 0
Pain	288	в О
Tenderness	2	1 0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	20	6 0
Adverse event	· · · · · · · · · · · · · · · · · · ·	1 0
Adverse reaction		3 0
Drug ineffective		3 0
Drug ineffective for unapproved indication		1 0
Drug resistance		1 0
Immediate post-injection reaction	· · · · · · · · · · · · · · · · · · ·	1 0
Therapeutic product effective for unapprove	d 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 arrophy Vaccination site bruising		
Vaccination site ordinary Vaccination site coldness		1 0
Vaccination site discolouration		2 0
Vaccination site disconfort		2 0
		-
Vaccination site erythema	11	
Vaccination site haemorrhage		2 0
Vaccination site hypersensitivity		
Vaccination site hypoaesthesia		1 0
Vaccination site induration		
Vaccination site inflammation		3 0
Vaccination site irritation		1 0
Vaccination site joint movement impairment		1 0
Vaccination site joint pain		1 0
Vaccination site mass	1	1 0
Vaccination site movement impairment		3 0
Vaccination site nerve damage	· · · · · ·	1 0
Vaccination site nodule		1 0
Vaccination site pain	40	0 0
Vaccination site paraesthesia		1 0
Vaccination site pruritus		5 0
Vaccination site rash		3 0
Vaccination site swelling	23	30

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site warmth	3	0
General disorders SOC TOTAL	5591	1

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Popular Namo	Total	Eatal
Reaction Name	<u>Total</u>	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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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergic oedema	1	0
Allergy to animal	3	0
Hypersensitivity	88	0
Multiple allergies	6	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	3	0
Type IV hypersensitivity reaction	2	0
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	2	0
Food allergy	6	0
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	104	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
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	261	0

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Reaction Date: 05-May-2006 MedL	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Abdominal abscess	1	0
Appendicitis	3	0
Appendicitis perforated	1	0
Gastroenteritis	1	0
Gastrointestinal infection	1	0
Peritonitis	1	0
Bacterial infections NEC		
Cellulitis	4	0
Folliculitis	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	2 0
Bone and joint infections		
Osteomyelitis	1	0
Breast infections		
Mastitis	1	0
Candida infections		
Candida infection	2	2 0
Vulvovaginal candidiasis	1	0
Central nervous system and spinal infections		
Encephalitis	8	0
Encephalitis lethargica	1	0
Subdural abscess	1	0
Coronavirus infections		
COVID-19	7	0
Severe acute respiratory syndrome	1	0
Dental and oral soft tissue infections		
Gingivitis	1	0
Ear infections		
Ear infection	2	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	33	
Hordeolum	5	
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	C
Herpes viral infections		
Genital herpes	1	C
Herpes virus infection	1	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0 Reaction Name	Total	Fatal
	Total	гаіаі
	40	0
Herpes zoster	19	0
Oral herpes	3	0
Varicella	1	C
Infections NEC		-
Infection	9	0
Infection susceptibility increased	7	C
Injection site abscess	1	C
Injection site infection	5	C
Localised infection	1	0
Purulent discharge	1	C
Respiratory tract infection	2	0
Infectious transmissions		
Suspected transmission of an infectious agent via product	1	C
Influenza viral infections		
Influenza	7	C
Lower respiratory tract and lung infections		
Bronchitis	3	C
Lower respiratory tract infection	16	C
Pneumonia	2	C
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	C
Papilloma viral infections		Ŭ
Papilloma viral infection	5	C
Vulvovaginal human papilloma virus infection	1	C
Respiratory syncytial viral infections	1	Ŭ
Respiratory syncytial virus infection	1	C
Retroviral infections	1	Ū
Acquired immunodeficiency syndrome	1	C
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	U
	1	0
Neutropenic sepsis Sepsis	3	C C
	3	
Septic rash		0
Viraemia		C
Skin structures and soft tissue infections		0
Application site pustules	1	0
Impetigo	1	0
Pustule	2	0
Skin infection	2	C
Staphylococcal infections		-
Furuncle	4	C
Staphylococcal infection	2	0
Streptococcal infections		
Beta haemolytic streptococcal infection	2	C
Streptococcal sepsis	1	1
Upper respiratory tract infections		
Epiglottitis	1	C
Laryngitis	1	0
Nasopharyngitis	45	C
Pharyngitis	8	0
Sinusitis	2	C
Tonsillitis	9	C
Upper respiratory tract infection	3	C
Urinary tract infections	5	L.

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Earliest Reaction Date: 00 May 2000		
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	57	0
Viral infection	20	0
Viral pharyngitis	1	0
Infections SOC TOTAL	343	1

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Injuries		
Abdominal and gastrointestinal injuries NEC		-
Mouth injury	1	0
Bone and joint injuries NEC		-
Joint injury	1	0
Chemical injuries		-
Chemical burn	1	0
Exposures associated with pregnancy, delivery and lactation		-
Exposure during pregnancy	25	0
Foetal exposure during pregnancy	9	0
Maternal exposure before pregnancy	2	0
Maternal exposure during pregnancy	1	0
Maternal exposure timing unspecified	11	0
Fractures and dislocations NEC		
Joint dislocation	4	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	1	0
Medication error	20	0
Wrong technique in product usage process	2	0
Muscle, tendon and ligament injuries		
Muscle injury	2	0
Nerve injuries NEC		
Nerve injury	4	0
Neurological and psychiatric procedural complications		
Procedural dizziness	2	0
Non-site specific injuries NEC		
Fall	20	0
Injury	3	0
Wound	1	0
Wound haemorrhage	1	0
Off label uses		
Off label use	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	C
Product administration errors and issues		
Expired product administered	4	C
Extra dose administered	5	C
Inappropriate schedule of product administration	16	C
Incorrect route of product administration	1	C
Product administered at inappropriate site	4	C
Product administered to patient of inappropriate age	2	0
Wrong product administered	1	C
Site specific injuries NEC		
Face injury	1	C
Head injury	1	C
Skin injuries NEC		
Contusion	57	0

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Earliest Reaction Date: 05 May 2000		
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		
Immunisation reaction	9	0
Vaccination complication	1	0
Injuries SOC TOTAL	227	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0	T - 1 - 1	
Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		-
Cortisol decreased	1	0
Autoimmunity analyses		-
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Blood counts NEC		-
Full blood count abnormal	1	0
Blood gas and acid base analyses		-
Blood pH increased	1	0
Oxygen saturation decreased	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	3	0
Blood glucose increased	7	0
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Heart sounds abnormal	1	0
Cell marker analyses		
Cell marker increased	1	0
Central nervous system imaging procedures		
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF cell count increased	1	0
Chemistry analyses NEC		
Histamine level increased	2	0
ECG investigations		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	4	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	1	0
Heart rate and pulse investigations		
Heart rate abnormal	6	0
Heart rate decreased	10	0
Heart rate increased	59	
Heart rate irregular	16	
Pulse abnormal	9	0
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 26.0	Tatal	Fatal
Reaction Name	Total	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	3	0
Body temperature abnormal	4	0
Body temperature decreased	8	0
Body temperature fluctuation	8	0
Body temperature increased	107	0
Breath sounds abnormal	1	0
Grip strength decreased	3	0
Respiratory rate decreased	1	0
Respiratory rate increased	13	0
Weight decreased	28	0
Weight increased	5	0
Pituitary analyses anterior		-
Blood growth hormone abnormal	1	0
Blood thyroid stimulating hormone abnormal	1	0
Platelet analyses		
Platelet count decreased	3	0
Protein analyses NEC		
Blood albumin abnormal	1	0
C-reactive protein increased	2	0
Protein total abnormal	1	0
Reproductive hormone analyses		-
Anti-Muellerian hormone level decreased	1	0
Oestradiol decreased	1	0
Progesterone increased	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix abnormal	1	0
Respiratory and pulmonary function diagnostic procedures		-
Peak expiratory flow rate decreased	1	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses		-
Blood chromium decreased	1	0
Urinalysis NEC		-
Blood urine present	2	0
Urinary tract function analyses NEC		-
Urine output decreased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	2	0
Blood pressure decreased	12	0
Blood pressure immeasurable	1	0
Blood pressure increased	8	0

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Earliest Reaction Date. 05-May-2006	WEUDRA VEISION. WEUDRA 20.0		
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		396	0

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0		
Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	4	0
Decreased appetite	88	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	6	0
Malnutrition	1	0
Underweight	1	0
Weight fluctuation	1	0
Weight gain poor	1	0
Hyperglycaemic conditions NEC		Ŭ
Hyperglycaemia	4	0
Insulin resistance	1	0
Hypoglycaemic conditions NEC		Ū
Hypoglycaemia	5	0
Iron deficiencies	J	J
Iron deficiency	3	0
Metabolic acidoses (excl diabetic acidoses)	J	0
Lactic acidosis	1	0
Metabolic disorders NEC		0
Metabolic disorder	1	0
Mineral related disorders NEC		0
Mineral deficiency	1	0
Sugar intolerance (excl glucose intolerance)		0
Lactose intolerance	3	0
Total fluid volume decreased	5	0
	5	0
Dehydration	5	0
Vitamin deficiencies NEC		
Multi-vitamin deficiency	2	C
Water soluble vitamin deficiencies		
Vitamin B12 deficiency	8	C
Vitamin C deficiency	1	C
Metabolic disorders SOC TOTAL	221	

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Earliest Reaction Date: 05-May-2006	MedDRA Version: MedDRA 26.0	Cata!
Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	7	
Arthropathy	7	7 C
Palindromic rheumatism	1	(C
Seronegative arthritis	1	(C
Bone disorders NEC		
Osteitis	1	(C
Bone related signs and symptoms		
Bone pain	11	(C
Coccydynia	1	(C
Pain in jaw	6	
Spinal pain	7	' C
Bursal disorders		
Bursitis	1	C
Cartilage disorders		
Costochondritis	2	2 C
Osteochondrosis	1	C
Connective tissue disorders NEC		
Mixed connective tissue disease	1	C
Morphoea	1	C
Reynold's syndrome	1	C
Sjogren's syndrome	1	C
Extremity deformities		
Finger deformity	1	C
Foot deformity	1	C
Hand deformity	1	C
Joint related disorders NEC		
Joint contracture	1	C
Joint lock	1	(C
Periarthritis	3	3 C
Joint related signs and symptoms		
Arthralgia	266	6 C
Joint effusion	1	(C
Joint noise	3	3 C
Joint range of motion decreased	1	C
Joint stiffness	15	
Joint swelling	37	7 C
Ligament disorders		
Ligament pain	1	C
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	C
Systemic lupus erythematosus	3	3 C
Metabolic bone disorders		
Osteoporosis	1	C
Muscle infections and inflammations		
Myositis	2	2 (
Muscle pains		
Fibromyalgia	17	7 (
Myalgia	190	
Myalgia intercostal	1	
Muscle related signs and symptoms NEC		
Muscle atrophy	2	
Muscle discomfort	2	

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Reaction Name	d 1	Total	Fatal
Muscle & tissue disolders & tissue disorders	cont'd		
Muscle fatigue		13	C
Muscle spasms		48	C
Muscle swelling		1	C
Muscle tightness		6	C
Muscle twitching		50	C
Trigger points		1	C
Muscle tone abnormalities			
Muscle rigidity		36	C
Trismus		2	C
Muscle weakness conditions			
Muscular weakness		128	C
Musculoskeletal and connective tissue con	ditions NEC		
Back disorder		2	C
Growth retardation		3	C
Mastication disorder		1	C
Mobility decreased		19	C
Muscle contracture		2	C
Musculoskeletal disorder		1	C
Musculoskeletal stiffness		107	C
Posture abnormal		107	C
Weight bearing difficulty		8	C
Musculoskeletal and connective tissue pair	and diacomfort	0	Ľ
	r and discomion	05	C
Back pain		95	C
Flank pain		2	C
Growing pains		2	C
Limb discomfort		185	C
Musculoskeletal chest pain		11	C
Musculoskeletal discomfort		4	C
Musculoskeletal pain		5	C
Neck pain		79	C
Pain in extremity		1129	C
Myopathies			
Myopathy		1	C
Rheumatoid arthropathies			
Juvenile idiopathic arthritis		4	C
Rheumatoid arthritis		5	C
Soft tissue disorders NEC			
Axillary mass		2	C
Groin pain		5	C
Neck mass		1	C
Soft tissue disorder		1	C
Spine and neck deformities			
Scoliosis		3	C
Spondyloarthropathies			
Arthritis reactive		4	C
Synovial disorders			
Synovitis		1	(
Tendon disorders			
Tendon pain		1	(
Tendonitis		1	C
Muscle & tissue disorders SOC TOTAL		2571	(

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Reaction Name	Total	Fatal
Neoplasms		
Bladder neoplasms malignant		
Bladder cancer	1	0
Bone neoplasms malignant (excl sarcomas)		-
Bone cancer	1	0
Cervix neoplasms malignant		Ū
Cervix carcinoma	1	0
Cervix carcinoma stage 0	1	0
Endocrine neoplasms malignant and unspecified NEC		Ŭ
Pituitary tumour	1	0
Glial tumours malignant		Ŭ
Medulloblastoma	1	0
Hepatobiliary neoplasms benign		Ŭ
Focal nodular hyperplasia	1	0
Islet cell neoplasms and APUDoma NEC		Ŭ
Pancreatic neuroendocrine tumour metastatic	1	0
Kaposi's sarcomas		Ū
Kaposi's sarcoma	1	0
Leukaemias acute NEC		
Acute leukaemia	1	0
Leukaemias acute lymphocytic		
Acute lymphocytic leukaemia	1	0
T-cell type acute leukaemia	1	1
Leukaemias acute myeloid		
Acute myeloid leukaemia	1	0
Leukaemias chronic myeloid		-
Chronic myeloid leukaemia	1	0
Metastases to specified sites		
Metastases to liver	1	0
Neoplasms malignant site unspecified NEC		
Neoplasm malignant	1	1
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	1	1
Pharyngeal and laryngeal neoplasms benign		
Laryngeal papilloma	1	0
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	1	0
Reproductive neoplasms male benign NEC		
Penile wart	1	0
Respiratory tract and pleural neoplasms benign NEC		
Respiratory papilloma	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified		
NEC		
Throat cancer	1	0
Salivary gland neoplasms malignant		
Salivary gland cancer stage I	1	0
Skin neoplasms benign		
Anogenital warts	5	0
Melanocytic naevus	1	0
Skin papilloma	7	0
Uterine neoplasms benign		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	37	3

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Reaction Name	<u>Total</u>	Fatal
Nervous system disorders		
Abnormal reflexes		
Areflexia	6	C
Abnormal sleep-related events		
Sleep paralysis	1	C
Absence seizures		
Petit mal epilepsy	8	C
Acute polyneuropathies		
Guillain-Barre syndrome	9	C
Autonomic nervous system disorders		
Autonomic nervous system imbalance	11	C
Autonomic neuropathy	2	C
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia stroke	1	C
Brain stem stroke	1	C
Cerebral thrombosis	1	C
Cerebrovascular accident	3	C
Lacunar infarction	1	C
Central nervous system vascular disorders NEC		
Central nervous system vasculitis	1	C
Cerebrovascular disorder	1	C
Choreiform movements		
Chorea	1	C
Chronic polyneuropathies		
Demyelinating polyneuropathy	1	C
Coordination and balance disturbances		
Ataxia	5	C
Balance disorder	25	C
Cerebellar ataxia	1	C
Coordination abnormal	9	C
Dysstasia	19	C
Nystagmus	1	C
Cortical dysfunction NEC		
Agnosia	1	C
Aphasia	11	C
Dyslexia	1	C
Dyspraxia	2	C
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	1	C
Demyelination	1	C
Disturbances in consciousness NEC		
Altered state of consciousness	4	C
Consciousness fluctuating	5	C
Depressed level of consciousness	8	0
Lethargy	220	C
Loss of consciousness	115	0
Sedation	1	C
Somnolence	175	0
Syncope	913	-
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	C
Irregular sleep wake rhythm disorder	4	C
Dyskinesias and movement disorders NEC	-	U
Clumsiness	2	C

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	Version: MedDRA 26.0	Eatal
Reaction Name	Total	Fatal
Nervous system disordersous system disorders cont'd		
Dyskinesia	64	-
Fine motor skill dysfunction	1	
Hypokinesia	15	
Motor dysfunction	4	0
Movement disorder	g	
Psychomotor hyperactivity	4	C C
Dystonias		
Dystonia	2	
Opisthotonus	2	2 0
Encephalitis NEC		
Encephalitis autoimmune	5	
Noninfective encephalitis	1	C
Encephalopathies NEC		
Encephalopathy	1	0
Hashimoto's encephalopathy	1	0
Eye movement disorders		
IVth nerve paralysis	1	0
VIth nerve paralysis	1	C
Facial cranial nerve disorders		
Bell's palsy	12	
Facial paralysis	8	
Facial paresis	1	0
Facial spasm	2	2 0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	23	6 C
Headaches NEC		
Cluster headache	/	
Headache	1878	
Tension headache	4	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	1	
Intracranial pressure increased	2	2 0
Intellectual disabilities		
Intellectual disability	1	0
Memory loss (excl dementia)		
Amnesia	24	
Memory impairment	32	2 0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	22	
Disturbance in attention	66	
Mental impairment	4	C C
Migraine headaches	1	
Basilar migraine	1	
Hemiplegic migraine	1	
Migraine	89	
Migraine with aura	4	
Migraine without aura	3	
Typical aura without headache	1	
Mononeuropathies		
Carpal tunnel syndrome	2	
Peroneal nerve palsy	2	2 C
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	2 0

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

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Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Monoparesis	2	0
Monoplegia	15	0
Paralysis	23	0
Paraplegia	2	0
Peripheral paralysis	1	0
Quadriparesis	1	C
Quadriplegia	1	C
Parkinson's disease and parkinsonism		-
Reduced facial expression	1	C
Peripheral neuropathies NEC		-
Autoimmune neuropathy	1	C
Brachial plexopathy	1	(
Lumbosacral plexus lesion	1	C
Neuritis	1	C
Peripheral sensory neuropathy	2	C
Seizures and seizure disorders NEC		
Change in seizure presentation	1	C
Clonic convulsion	1	C
Epilepsy	27	C
Febrile convulsion	1	C
Myoclonic epilepsy	1	C
Partial seizures	5	C
Psychogenic seizure	3	C
Seizure	175	C
Seizure anoxic	5	C
Seizure like phenomena	6	C
Status epilepticus	1	C
Tonic clonic movements	7	C
Tonic convulsion	2	C
Sensory abnormalities NEC		
Ageusia	2	C
Allodynia	2	C
Complex regional pain syndrome	24	C
Dysgeusia	10	C
Electric shock sensation	1	C
Neuralgia	8	C
Post herpetic neuralgia	1	C
Restless legs syndrome	1	C
Sensory disturbance	22	C
Sensory loss	35	C
Taste disorder	5	C
Sleep disturbances NEC		
Sudden onset of sleep	3	C
Speech and language abnormalities		
Dysarthria	22	C
Incoherent	4	C
Slow speech	4	(
Speech disorder	13	(
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	1	(
Radiculopathy	1	(
Spinal cord disorder	1	(
Spinal cord oedema	1	(

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023st Reaction Date: 05-May-2006Data Lock Date: 30-May-2023 18:30:04MedDRA Version: MedDRA 26.0

Tamest Reaction Date: 05 May 2000 MedDIA Version. MedDIA 20.0		
Reaction Name	Total	Fatal
Nervous system disordersus system disorders cont'd		
Structural brain disorders NEC		
Brain injury	1	0
Cerebellar atrophy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	212	0
Nervous system disorders SOC TOTAL	7963	0

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

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

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Product label issues		
Product lot number issue	2	0
Product quality issues NEC		
Product origin unknown	9	0
Product quality issue	1	0
Product substitution issue	1	0
null SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	12	C
Behaviour disorder	1	
Staring	1	
Adjustment disorders		
Adjustment disorder with mixed anxiety and depressed mood	2	C
Affect alterations NEC	_	
Affect lability	1	C
Inappropriate affect	1	
Anxiety disorders NEC	·	
Anxiety disorder	1	C
Generalised anxiety disorder	1	
Anxiety symptoms		
Agitation	8	C
Anxiety	86	
Nervousness	19	
Stress	4	
Behaviour and socialisation disturbances		
Aggression	9	C
Disinhibition	2	
Disturbance in social behaviour	1	
Impatience	1	
Indifference	1	
Paranoia	5	
Personality change	11	
Social avoidant behaviour	4	
Bipolar disorders		
Bipolar I disorder	1	C
Bipolar disorder	3	
Cognitive and attention disorders and disturbances NEC	Ŭ	
Mental fatigue	2	C
Confusion and disorientation	-	
Confusional state	53	C
Disorientation	31	
Deliria	01	
Delirium	3	c
Delusional symptoms	5	
Delusion	2	c
Depressive disorders	2	
Depression	45	C
Depression suicidal	43	
Dissociative states		
Dissociation	3	c
Disturbances in initiating and maintaining sleep	5	
Insomnia	62	c
Middle insomnia	1	
Dyssomnias		
	5	C
Poor quality sleep	5	
Eating disorders NEC		
Anorexia nervosa	1	
Eating disorder	3	
Merycism	1	
Emotional and mood disturbances NEC		

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0 Reaction Name	Total	Fatal
Psychiatric disorders ^P sychiatric disorders cont'd		i atai
Anger	3	C
Emotional disorder	15	0
Emotional distress	14	0
Emotional poverty	1	0
Euphoric mood	1	0
Irritability	7	0
Mood altered	6	C
Fear symptoms and phobic disorders (incl social phobia)	0	U
Autophobia	1	C
Claustrophobia	1	0
Fear	3	0
Fear of crowded places	1	0
Fear of death	1	0
Phobia	1	0
Social anxiety disorder	6	C
Fluctuating mood symptoms	Ŭ	
Mood swings	7	C
Hallucinations (excl sleep-related)		U
Hallucination	18	C
Hallucination, auditory	6	0
Hallucination, visual	3	0
Hallucinations, mixed	1	0
Impulse control disorders	1	0
Impulse-control disorder	1	C
Impulsive behaviour	1	C
Increased physical activity levels		U
Restlessness	6	C
Learning disorders	0	U
Reading disorder	1	C
Mental disorders NEC		U
Mental disorder	6	C
Mental status changes	1	0
Mood alterations with depressive symptoms	1	0
Decreased interest	1	C
Depressed mood	16	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	1	0
Negative thoughts	1	0
Tearfulness	30	0
Mood alterations with manic symptoms		U
Hypomania	1	C
Mood disorders NEC	1	U
Affective disorder	1	C
Apathy	3	0
Listless	5	C
	5	t
Narcolepsy and associated conditions	1	·
Sleep attacks		C
Obsessive-compulsive disorders and symptoms		-
Obsessive thoughts	1	(
Obsessive-compulsive disorder	2	0
Trichotillomania	1	C
Panic attacks and disorders		

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0 Reaction Name	Total	Fatal
Psychiatric disorders ^P sychiatric disorders cont'd	Total	i alai
Panic attack	31	C
Panic reaction	8	0
Parasomnias	Ū	,
Abnormal dreams	1	C
Abnormal sleep-related event	1	C
Sleep terror	3	C
Perception disturbances NEC	Ū	,
Deja vu	1	C
Illusion	1	C
Near death experience	1	C
Personality disorders NEC		
Self esteem decreased	3	C
Personality disorders with anxious behaviour (Cluster C)	J	,
Dependent personality disorder	1	C
Pervasive developmental disorders NEC		,
Autism spectrum disorder	4	C
Psychiatric symptoms NEC		,
Psychiatric symptom	3	C
Psychotic disorder NEC	Ū	,
Acute psychosis	1	C
Psychotic disorder	4	C
Sexual desire disorders		
Loss of libido	1	C
Sleep disorders NEC		
Sleep disorder	30	C
Somatic symptom disorders		-
Conversion disorder	5	C
Somatic symptom disorder	2	C
Speech and language usage disturbances		-
Disorganised speech	1	C
Logorrhoea	1	C
Speech articulation and rhythm disturbances		
Dysphemia	3	C
Stereotypies and automatisms		
Bruxism	1	C
Head banging	2	C
Stress disorders		
Burnout syndrome	1	C
Post-traumatic stress disorder	1	C
Suicidal and self-injurious behaviour		
Intentional self-injury	6	C
Self-injurious ideation	1	C
Suicidal ideation	7	C
Suicide attempt	2	C
Thinking disturbances		
Bradyphrenia	2	C
Intrusive thoughts	2	C
Thinking abnormal	3	C
Thought blocking	2	C
Tic disorders		
Tic	3	C
Psychiatric disorders SOC TOTAL	712	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder pain	3	0
Bladder spasm	1	
Dysuria	3	
Incontinence	3	
Micturition urgency	4	
Pollakiuria	9	0
Stress urinary incontinence	1	
Urinary incontinence	22	
Urinary retention	4	
Bladder disorders NEC		
Bladder disorder	4	0
Bladder fibrosis	1	0
Bladder mass	1	0
Bladder infections and inflammations		
Cystitis noninfective	1	0
Genital and urinary tract disorders NEC		
Urinary tract disorder	3	0
Genitourinary tract infections and inflammations NEC		
Urinary tract inflammation	1	C
Glomerulonephritis and nephrotic syndrome		
Focal segmental glomerulosclerosis	1	C
Henoch-Schonlein purpura nephritis	1	0
IgA nephropathy	1	0
Nephrotic syndrome	1	0
Myoneurogenic bladder disorders		
Bladder dysfunction	1	C
Contracted bladder	1	C
Hypertonic bladder	1	C
Loss of bladder sensation	1	C
Neurogenic bladder	1	0
Renal disorders NEC		
Renal disorder	2	C
Renal failure and impairment		
Renal failure	1	C
Renal lithiasis		
Nephrolithiasis	1	C
Renal vascular and ischaemic conditions		
Renal vasculitis	1	C
Urinary abnormalities		
Proteinuria	2	C
Urinary tract signs and symptoms NEC		
Haemorrhage urinary tract	1	0
Polyuria	1	(
Renal pain	1	(
Renal & urinary disorders SOC TOTAL	80	

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Earliest Reaction Date: 05-May-2006 MedD Reaction Name	RA Version: MedDRA 26.0 Total	Fatal
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst	1	C
Breast disorders NEC		
Breast enlargement	1	
Gynaecomastia	1	0
Nipple disorder		C
Breast signs and symptoms	1	
Breast discharge		
Breast pain Breast swelling	4	0
Breast tenderness		
	2	-
Nipple pain Cervix disorders NEC		0
Cervical dysplasia	4	
Uterine cervix atrophy Cervix infections and inflammations		0
	1	
Cervix inflammation		0
Menopausal effects NEC	F	
Premature menopause	5	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	23	
Intermenstrual bleeding	1	
Menstrual discomfort	1	0
Menstrual disorder	20	
Menstruation irregular	39	
Premenstrual pain	1	0
Premenstrual syndrome	1	0
Menstruation with decreased bleeding		
Amenorrhoea	39	
Menstruation delayed	31	1
Oligomenorrhoea	ť	0
Menstruation with increased bleeding	24	
Heavy menstrual bleeding	31	
Polymenorrhoea	2	2 0
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	4	
Polycystic ovaries	11	0
Ovarian and fallopian tube disorders NEC		
Ovarian disorder	2	
Ovarian failure	7	
Ovulation disorder	1	
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain		0
Reproductive tract disorders NEC (excl neoplasms		
Genital haemorrhage	3	
Reproductive tract signs and symptoms NEC		
Genital erythema	1	
Genital pain	2	
Genital rash		
Genital swelling	2	-
Pelvic pain	6	
Sexual function and fertility disorders NEC		-
Dyspareunia	1	

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Reaction Name	Total	Fatal
Reproductive & breast disorders & breast disorders cont'd		
Infertility	3	0
Uterine disorders NEC		
Endometriosis	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	12	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval ulceration	3	0
Vulvar dysplasia	1	0
Vulvovaginal disorder	1	0
Vulvovaginal signs and symptoms		
Coital bleeding	1	0
Vaginal discharge	6	0
Vaginal lesion	1	0
Vulval oedema	2	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	302	0

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Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023st Reaction Date: 05-May-2006Data Lock Date: 30-May-2023 18:30:04MedDRA Version: MedDRA 26.0

Eanlest Reaction Date: 05-May-2006	Meddra Version. Meddra 26.0		
Reaction Name		Total	Fatal
Respiratory disorders Respiratory 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		145	0
Rhinorrhoea		10	0
Sinus pain		2	0
Sneezing		6	0
Throat irritation		28	0
Throat lesion		1	0
Throat tightness		43	0
Vascular pulmonary disorders NEC			
Pulmonary arteriopathy		2	0
Respiratory disorders SOC TOTAL		778	1

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Reaction Name	 Total	Fatal
Skin disorders		
Acnes		
Acne	9	(
Acne cystic	1	(
Alopecias		
Alopecia	43	(
Alopecia areata	11	(
Alopecia totalis	2	C
Diffuse alopecia	3	C
Madarosis	1	C
Angioedemas		
Angioedema	16	C
Circumoral oedema	1	C
Apocrine and eccrine gland disorders		
Cold sweat	106	C
Hyperhidrosis	110	C
Miliaria	6	C
Night sweats	3	C
Bullous conditions	Ŭ	
Blister	22	C
Dermatitis bullous	1	C
Erythema multiforme	11	C
Stevens-Johnson syndrome	1	C
Dermal and epidermal conditions NEC	1	Ľ
Dry skin	13	C
Pain of skin	13	
	5	0
Papule Scab		0
Scab Sensitive skin	2 2	0
	2	0
Skin burning sensation	107	0
Skin discolouration		C
Skin disorder	8	0
Skin fissures	1	C
Skin induration	1	0
Skin lesion	5 14	C
Skin reaction		0
Skin sensitisation	2	0
Skin texture abnormal	1	0
Skin tightness	3	0
Skin warm	30	(
Yellow skin	3	C
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	37	(
Dermatitis contact	4	0
Dyshidrotic eczema	1	C
Eczema	15	(
Eczema nummular	1	(
Eczema vesicular	1	(
Seborrhoeic dermatitis	2	(
Skin irritation	10	(
Dermatitis ascribed to specific agent		
Drug eruption	2	(
Erythemas		

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Earliest Reaction Date: 05-May-2006 MedDRA Version: MedDRA 26.0	Total	Cotol
Reaction Name Skin disorders Skin disorders cont'd	Total	Fatal
Erythema	240	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	000	~
Pruritus	206	0
Psoriatic conditions		~
Guttate psoriasis	1	0
Psoriasis	5	0
Purpura and related conditions	10	
Henoch-Schonlein purpura	10	0
Petechiae	11	0
Purpura	8	0
Pustular conditions		
Rash follicular	1	0
Rashes, eruptions and exanthems NEC		-
Rash	489	0
Rash erythematous	50	0
Rash macular	86	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	C
Umbilical discharge	1	0
Skin haemorrhages		

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

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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		44	0
Urticarias			
Chronic spontaneous urticaria		1	0
Mechanical urticaria		2	0
Urticaria		272	0
Urticaria chronic		3	0
Urticaria pigmentosa		1	0
Skin disorders SOC TOTAL		2224	0

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

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

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Gastrointestinal therapeutic procedures NEC		
Prophylaxis of nausea and vomiting	1	0
Hernia repairs		
Inguinal hernia repair	1	0
Induced abortions		
Abortion induced	6	0
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	18	0

Name: Human Papillomavirus (HPV) Vaccine Analysis Printrt Run Date: 31-May-2023Data Lock Date: 30-May-2023 18:30:04st Reaction Date: 05-May-2006MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Vascular disorders		
Blood pressure disorders NEC		
Blood pressure fluctuation	1	
Circulatory collapse and shock		
Circulatory collapse	7	. (
Neurogenic shock	1	
Peripheral circulatory failure	1	
Shock	1	
	4	
Haemorrhages NEC		
Haemorrhage	4	
Venous haemorrhage	1	(
Lymphoedemas		
Lymphoedema	1	(
Non-site specific embolism and thrombosis		
Thrombosis	3	(
Non-site specific necrosis and vascular insuffic		
Peripheral venous disease	3	
Vasospasm	1	(
Non-site specific vascular disorders NEC		
Capillary disorder	3	
Vascular pain	1	(
Vasodilatation	1	(
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	(
Superficial vein thrombosis	1	(
Peripheral vascular disorders NEC		
Cyanosis	36	(
Erythromelalgia	1	
Flushing	123	(
Hot flush	22	
Peripheral vascular disorder	2	
Peripheral vasoconstriction, necrosis and vasc	ular insufficiencv	
Peripheral coldness	123	(
Poor peripheral circulation	g	
Raynaud's phenomenon	8	
Site specific vascular disorders NEC		
Pallor	371	
Vascular hypertensive disorders NEC	011	Ì
Hypertension	10	(
Orthostatic hypertension	1	
Vascular hypotensive disorders		l '
Hypotension	41	
Orthostatic hypotension	41	
Vasculitides NEC	2	
	1	
Behcet's syndrome	1	
Vasculitis	3	
Vascular disorders SOC TOTAL	787	
TOTAL REACTIONS FOR DRUG	27456	1
TOTAL REPORTS	10244	
TOTAL FATAL OUTCOME REPORTS		