

Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

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Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	29-Oct-2015	Report origin:	DENMARK
Data lock date:	28-Oct-2015 19:00:11	Route of admin:	ALL
Period covered:	01-Jan-1968 to 28-Oct-2015	Reporter type:	ALL
Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Total number of reactions*:	13917	Total number of ADR reports:	1916	Total number of fatal ADR reports:	2
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Products included in this print - Single active constituent products (PBGs):	
GARDASIL 9	
Products included in this print - Multi active constituent products (PBGs):	
CERVARIX	NONVALENT HPV L1 VLP VACCINE (V503)
GARDASIL	SILGARD

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System Organ Class	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Blood disorders	0	0	118	0	118	0
Cardiac disorders	0	0	301	0	301	0
Congenital disorders	0	0	18	2	18	2
Ear disorders	3	0	207	0	210	0
Endocrine disorders	1	0	14	0	15	0
Eye disorders	3	0	508	0	511	0
Gastrointestinal disorders	11	0	1309	0	1320	0
General disorders	22	0	2091	0	2113	0
Hepatic disorders	1	0	8	0	9	0
Immune system disorders	2	0	131	0	133	0
Infections	1	0	308	0	309	0
Injuries	0	0	118	0	118	0
Investigations	9	0	271	0	280	0
Metabolic disorders	3	0	151	0	154	0
Muscle & tissue disorders	12	0	1587	0	1599	0
Neoplasms	0	0	20	0	20	0
Nervous system disorders	27	0	3724	0	3751	0
Pregnancy conditions	0	0	16	0	16	0
Psychiatric disorders	5	0	711	0	716	0
Renal & urinary disorders	1	0	118	0	119	0
Reproductive & breast disorders	2	0	237	0	239	0
Respiratory disorders	2	0	432	0	434	0
Skin disorders	7	0	1073	0	1080	0
Social circumstances	1	0	50	0	51	0
Surgical & medical procedures	0	0	27	0	27	0
Vascular disorders	1	0	255	0	256	0

TOTAL NUMBER OF REACTIONS	114	0	13803	2	13917	2
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TOTAL NUMBER OF FATAL ADR REPORTS*		0		2		2*
TOTAL NUMBER OF ADR REPORTS*	13		1903		1916*	

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.

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Glossary/Abbreviations

ADR - Adverse Drug Reaction

Age group - lists which age groups are included in the Drug Analysis Print – either ALL, Adolescent, Adult, Child, Elderly, Infant or Neonate

Data lock date - shows data on the database at this specified date and time

HLT - High Level Term - see definition of MedDRA

MedDRA - this stands for **Medical Dictionary for Regulatory Activities**, which is the internationally agreed list of terms used for Medicines Regulation. MedDRA groups related adverse drug reaction terms in a hierarchical structure whereby the '*preferred term*' (*PT*) (e.g. tunnel vision) is grouped under the broader heading the '*high level term*' (*HLT*) (e.g. visual field disorders). '*High level terms*' are contained within the '*system organ class*' (*SOC*) (e.g. eye disorders). The '*preferred term*' is the most specific term on the Drug Analysis Print, while the '*system organ class*' is the most general

Multi active constituent products - contain the drug constituent of interest plus one or more other drug constituents (e.g. co-codamol contains paracetamol and codeine)

NEC - appears in MedDRA and stands for Not Elsewhere Classified

NOS - appears in MedDRA and stands for Not Otherwise Specified

PBG - Product Brand Group – this means drug brand name e.g. Amoxil is a PBG for the drug substance amoxicillin

Products included in this print - this is a list of the products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). It does not provide an exhaustive list of the products which contain the named drug substance

PT - Preferred Term - see definition of MedDRA

Reaction - defines which ADRs are included in the Drug Analysis Print – either ALL, Serious or Non-Serious

Reporter type - lists the reporter types which are included in the Drug Analysis Print – either Patient, Health Professional or ALL (i.e. both)

Report run date - the date the Drug Analysis Print was produced

Route of admin - lists the route of administration of the suspect drug for which reports are included in the Drug Analysis Print, e.g. ORAL only includes reports where the suspect drug was specified as having been taken by the oral route, or ALL which includes all routes of administration

Single active constituent products - contain only the drug substance of interest

Spontaneous - suspected ADR reports sent in to the Yellow Card Scheme are called spontaneous reports

Substance - is an active ingredient in a product

Substance Variant - is a more specific substance term. A substance may have zero, one or many linked variants. For example LITHIUM is linked to the variant LITHIUM CARBONATE and LITHIUM CITRATE.

System Organ Class (SOC) - this is the highest level in MedDRA which groups together reactions that affect similar systems/organs in the body

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Blood disorders						
<i>Anaemia deficiencies</i>						
Iron deficiency anaemia	0	0	1	0	1	0
Pernicious anaemia	0	0	2	0	2	0
<i>Anaemias NEC</i>						
Anaemia	0	0	3	0	3	0
<i>Anaemias haemolytic NEC</i>						
Haemolytic anaemia	0	0	1	0	1	0
<i>Bleeding tendencies</i>						
Haemorrhagic diathesis	0	0	1	0	1	0
Increased tendency to bruise	0	0	17	0	17	0
<i>Coagulopathies</i>						
Antiphospholipid syndrome	0	0	1	0	1	0
<i>Haematological disorders</i>						
Bone marrow oedema	0	0	1	0	1	0
<i>Leukopenias NEC</i>						
Leukopenia	0	0	1	0	1	0
<i>Lymphatic system disorders NEC</i>						
Lymph node pain	0	0	14	0	14	0
Lymphadenitis	0	0	3	0	3	0
Lymphadenopathy	0	0	56	0	56	0
<i>Marrow depression and hypoplastic anaemias</i>						
Aplastic anaemia	0	0	2	0	2	0
<i>Spleen disorders</i>						
Splenomegaly	0	0	1	0	1	0
<i>Thrombocytopenias</i>						
Immune thrombocytopenic purpura	0	0	8	0	8	0
Thrombocytopenia	0	0	5	0	5	0
Thrombocytopenic purpura	0	0	1	0	1	0
Blood disorders SOC TOTAL	0	0	118	0	118	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Cardiac disorders						
Cardiac conduction disorders						
Atrioventricular block	0	0	2	0	2	0
Cardiac disorders NEC						
Cardiac disorder	0	0	2	0	2	0
Cardiovascular disorder	0	0	1	0	1	0
Cardiac signs and symptoms NEC						
Cardiac discomfort	0	0	3	0	3	0
Cyanosis	0	0	9	0	9	0
Palpitations	0	0	181	0	181	0
Ischaemic coronary artery disorders						
Angina pectoris	0	0	8	0	8	0
Mitral valvular disorders						
Mitral valve incompetence	0	0	1	0	1	0
Noninfectious myocarditis						
Myocarditis	0	0	1	0	1	0
Noninfectious pericarditis						
Pericarditis	0	0	1	0	1	0
Pericardial disorders NEC						
Pericardial effusion	0	0	1	0	1	0
Rate and rhythm disorders NEC						
Arrhythmia	0	0	7	0	7	0
Bradycardia	0	0	3	0	3	0
Extrasystoles	0	0	3	0	3	0
Postural orthostatic tachycardia syndrome	0	0	69	0	69	0
Tachycardia	0	0	5	0	5	0
Supraventricular arrhythmias						
Atrial tachycardia	0	0	1	0	1	0
Sinus tachycardia	0	0	1	0	1	0
Supraventricular tachycardia	0	0	1	0	1	0
Ventricular arrhythmias and cardiac arrest						
Cardiac arrest	0	0	1	0	1	0
Cardiac disorders SOC TOTAL	0	0	301	0	301	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Congenital disorders						
Adrenal disorders congenital						
Congenital adrenal gland hypoplasia	0	0	1	0	1	0
Autosomal chromosomal abnormalities						
Trisomy 13	0	0	1	1	1	1
Cardiac septal defects congenital						
Ventricular septal defect	0	0	1	0	1	0
Central nervous system disorders congenital NEC						
Meningomyelocele	0	0	1	0	1	0
Syringomyelia	0	0	2	0	2	0
Chromosomal abnormalities NEC						
Foetal chromosome abnormality	0	0	2	0	2	0
Diaphragmatic disorders congenital						
Congenital diaphragmatic hernia	0	0	1	0	1	0
Great vessel disorders congenital						
Coarctation of the aorta	0	0	1	0	1	0
Double outlet right ventricle	0	0	1	0	1	0
Musculoskeletal and connective tissue disorders of limbs congenital						
Congenital foot malformation	0	0	2	0	2	0
Developmental hip dysplasia	0	0	1	0	1	0
Musculoskeletal and connective tissue disorders of skull congenital						
Congenital absence of cranial vault	0	0	1	1	1	1
Optic nerve and optic disc disorders congenital						
Congenital optic nerve anomaly	0	0	1	0	1	0
Palate disorders congenital						
Cleft lip and palate	0	0	1	0	1	0
Pulmonary and bronchial disorders congenital						
Pulmonary hypoplasia	0	0	1	0	1	0
Congenital disorders SOC TOTAL	0	0	18	2	18	2

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Ear disorders						
Ear disorders NEC						
Ear discomfort	1	0	17	0	18	0
Ear disorder	0	0	2	0	2	0
Ear pain	0	0	21	0	21	0
Ear pruritus	0	0	2	0	2	0
External ear disorders NEC						
Cerumen impaction	1	0	0	0	1	0
Hearing disorders NEC						
Dysacusis	0	0	1	0	1	0
Hearing losses						
Deafness	0	0	1	0	1	0
Deafness neurosensory	0	0	1	0	1	0
Deafness transitory	0	0	3	0	3	0
Deafness unilateral	0	0	2	0	2	0
Hearing impaired	0	0	11	0	11	0
Hypoacusis	0	0	11	0	11	0
Sudden hearing loss	0	0	1	0	1	0
Hyperacusis						
Hyperacusis	0	0	69	0	69	0
Inner ear disorders NEC						
Meniere's disease	0	0	1	0	1	0
Inner ear signs and symptoms						
Motion sickness	0	0	3	0	3	0
Tinnitus	1	0	51	0	52	0
Vertigo	0	0	8	0	8	0
Vertigo positional	0	0	1	0	1	0
Middle ear disorders NEC						
Middle ear effusion	0	0	1	0	1	0
Ear disorders SOC TOTAL	3	0	207	0	210	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Endocrine disorders						
<i>Acute and chronic thyroiditis</i>						
Autoimmune thyroiditis	0	0	1	0	1	0
<i>Anterior pituitary hyperfunction</i>						
Hyperprolactinaemia	0	0	1	0	1	0
Pituitary-dependent Cushing's syndrome	0	0	1	0	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>						
Oestrogen deficiency	0	0	2	0	2	0
<i>Endocrine abnormalities of puberty</i>						
Precocious puberty	0	0	1	0	1	0
<i>Thyroid disorders NEC</i>						
Goitre	0	0	1	0	1	0
Thyroid disorder	1	0	0	0	1	0
<i>Thyroid hyperfunction disorders</i>						
Hyperthyroidism	0	0	4	0	4	0
<i>Thyroid hypofunction disorders</i>						
Hypothyroidism	0	0	3	0	3	0
Endocrine disorders SOC TOTAL	1	0	14	0	15	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Eye disorders						
<i>Blindness (excl colour blindness)</i>						
Blindness	0	0	2	0	2	0
Blindness transient	0	0	4	0	4	0
Night blindness	0	0	2	0	2	0
<i>Conjunctival infections, irritations and inflammations</i>						
Conjunctivitis allergic	0	0	2	0	2	0
<i>Eyelid movement disorders</i>						
Blepharospasm	0	0	3	0	3	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>						
Iris disorder	0	0	1	0	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>						
Iritis	0	0	2	0	2	0
<i>Lacrimation disorders</i>						
Dry eye	1	0	6	0	7	0
Lacrimation increased	0	0	6	0	6	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>						
Eyelid oedema	0	0	13	0	13	0
<i>Lid, lash and lacrimal structural disorders</i>						
Eyelid dermatochalasis	0	0	1	0	1	0
<i>Ocular disorders NEC</i>						
Dark circles under eyes	0	0	2	0	2	0
Eye disorder	0	0	4	0	4	0
Eye oedema	0	0	2	0	2	0
Eye pain	0	0	37	0	37	0
Eye swelling	0	0	13	0	13	0
Eyelid disorder	0	0	1	0	1	0
Eyelid pain	0	0	1	0	1	0
Ocular discomfort	0	0	5	0	5	0
Ocular icterus	0	0	2	0	2	0
<i>Ocular infections, inflammations and associated manifestations</i>						
Eye allergy	0	0	3	0	3	0
Eye inflammation	0	0	3	0	3	0
Eye irritation	0	0	5	0	5	0
Eye pruritus	0	0	5	0	5	0
Ocular hyperaemia	0	0	5	0	5	0
<i>Ocular nerve and muscle disorders</i>						
Eye movement disorder	0	0	4	0	4	0
Heterophoria	0	0	1	0	1	0
Strabismus	0	0	1	0	1	0
<i>Ocular sensation disorders</i>						
Abnormal sensation in eye	0	0	1	0	1	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Eye disorders cont'd						
SOC						
HLT						
PT						
Photophobia	0	0	94	0	94	0
Optic disc abnormalities NEC						
Papilloedema	0	0	2	0	2	0
Partial vision loss						
Visual acuity reduced	0	0	16	0	16	0
Pupil disorders						
Mydriasis	0	0	3	0	3	0
Pupils unequal	0	0	1	0	1	0
Refractive and accommodative disorders						
Hypermetropia	0	0	1	0	1	0
Retinal structural change, deposit and degeneration						
Maculopathy	0	0	1	0	1	0
Retinal pigment epitheliopathy	0	0	1	0	1	0
Retinal, choroid and vitreous infections and inflammations						
Retinal vasculitis	0	0	1	0	1	0
Structural change, deposit and degeneration of eye NEC						
Exophthalmos	0	0	1	0	1	0
Visual disorders NEC						
Diplopia	1	0	14	0	15	0
Photopsia	0	0	7	0	7	0
Vision blurred	1	0	78	0	79	0
Visual impairment	0	0	151	0	151	0
Eye disorders SOC TOTAL	3	0	508	0	511	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Gastrointestinal disorders						
Abdominal findings abnormal						
Gastrointestinal sounds abnormal	0	0	4	0	4	0
Anal and rectal disorders NEC						
Anal prolapse	0	0	1	0	1	0
Rectal prolapse	0	0	1	0	1	0
Anal and rectal signs and symptoms						
Anal pruritus	0	0	1	0	1	0
Anorectal discomfort	0	0	1	0	1	0
Benign oral cavity neoplasms						
Mouth cyst	0	0	1	0	1	0
Colitis (excl infective)						
Colitis ulcerative	0	0	3	0	3	0
Crohn's disease	0	0	1	0	1	0
Dental disorders NEC						
Loose tooth	0	0	1	0	1	0
Periodontal disease	0	0	1	0	1	0
Tooth deposit	0	0	1	0	1	0
Tooth disorder	0	0	2	0	2	0
Dental pain and sensation disorders						
Toothache	0	0	16	0	16	0
Diarrhoea (excl infective)						
Diarrhoea	1	0	69	0	70	0
Diarrhoea haemorrhagic	0	0	1	0	1	0
Dyspeptic signs and symptoms						
Dyspepsia	0	0	26	0	26	0
Eructation	0	0	2	0	2	0
Faecal abnormalities NEC						
Abnormal faeces	0	0	3	0	3	0
Faeces discoloured	0	0	3	0	3	0
Faeces hard	0	0	2	0	2	0
Faeces soft	0	0	1	0	1	0
Flatulence, bloating and distension						
Abdominal distension	0	0	43	0	43	0
Flatulence	0	0	2	0	2	0
Gastritis (excl infective)						
Gastritis	0	0	1	0	1	0
Gastrointestinal and abdominal pains (excl oral and throat)						
Abdominal migraine	0	0	1	0	1	0
Abdominal pain	3	0	190	0	193	0
Abdominal pain lower	0	0	37	0	37	0
Abdominal pain upper	2	0	93	0	95	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Gastrointestinal disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Gastrointestinal pain	0	0	5	0	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>						
Constipation	0	0	46	0	46	0
Gastrooesophageal reflux disease	0	0	4	0	4	0
Impaired gastric emptying	0	0	1	0	1	0
<i>Gastrointestinal disorders NEC</i>						
Functional gastrointestinal disorder	0	0	3	0	3	0
Gastrointestinal disorder	0	0	9	0	9	0
<i>Gastrointestinal dyskinetic disorders</i>						
Bowel movement irregularity	0	0	3	0	3	0
Change of bowel habit	0	0	2	0	2	0
Gastrointestinal motility disorder	0	0	3	0	3	0
<i>Gastrointestinal inflammatory disorders NEC</i>						
Gastrointestinal inflammation	0	0	1	0	1	0
Gastrointestinal tract irritation	0	0	1	0	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>						
Gastric mucosal hypertrophy	0	0	1	0	1	0
<i>Gastrointestinal signs and symptoms NEC</i>						
Abdominal discomfort	0	0	26	0	26	0
Abdominal symptom	0	0	2	0	2	0
Breath odour	0	0	7	0	7	0
Dysphagia	0	0	17	0	17	0
<i>Gastrointestinal spastic and hypermotility disorders</i>						
Defaecation urgency	0	0	1	0	1	0
Frequent bowel movements	0	0	3	0	3	0
Irritable bowel syndrome	0	0	9	0	9	0
<i>Gastrointestinal vascular occlusion and infarction</i>						
Mesenteric vein thrombosis	0	0	1	0	1	0
<i>Gingival haemorrhages</i>						
Gingival bleeding	0	0	5	0	5	0
<i>Gingival pains</i>						
Gingival pain	0	0	1	0	1	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>						
Haemorrhoids	0	0	3	0	3	0
<i>Intestinal haemorrhages</i>						
Rectal haemorrhage	0	0	1	0	1	0
<i>Malabsorption syndromes</i>						
Coeliac disease	0	0	17	0	17	0
Malabsorption	0	0	1	0	1	0
<i>Nausea and vomiting symptoms</i>						
Nausea	4	0	412	0	416	0
Retching	0	0	3	0	3	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	29-Oct-2015	Report origin:	DENMARK
Data lock date:	28-Oct-2015 19:00:11	Route of admin:	ALL
Period covered:	01-Jan-1968 to 28-Oct-2015	Reporter type:	ALL
Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Gastrointestinal disorders cont'd						
SOC						
HLT						
PT						
Vomiting	0	0	118	0	118	0
Vomiting projectile	0	0	1	0	1	0
Non-site specific gastrointestinal haemorrhages						
Haematemesis	0	0	2	0	2	0
Haematochezia	0	0	10	0	10	0
Oesophagitis (excl infective)						
Oesophagitis	0	0	2	0	2	0
Oral dryness and saliva altered						
Aptyalism	0	0	1	0	1	0
Dry mouth	1	0	10	0	11	0
Salivary hypersecretion	0	0	3	0	3	0
Oral soft tissue disorders NEC						
Chapped lips	0	0	1	0	1	0
Cheilitis	0	0	1	0	1	0
Lip ulceration	0	0	1	0	1	0
Oral disorder	0	0	2	0	2	0
Oral soft tissue haemorrhages						
Mouth haemorrhage	0	0	1	0	1	0
Oral soft tissue pain and paraesthesia						
Lip pain	0	0	1	0	1	0
Odynophagia	0	0	1	0	1	0
Oral pain	0	0	2	0	2	0
Paraesthesia oral	0	0	9	0	9	0
Oral soft tissue signs and symptoms						
Coating in mouth	0	0	2	0	2	0
Hypoaesthesia oral	0	0	5	0	5	0
Oral discomfort	0	0	1	0	1	0
Oral mucosal blistering	0	0	13	0	13	0
Oral mucosal eruption	0	0	1	0	1	0
Oral soft tissue swelling and oedema						
Lip swelling	0	0	4	0	4	0
Mouth swelling	0	0	3	0	3	0
Rectal inflammations NEC						
Proctitis	0	0	1	0	1	0
Salivary gland disorders NEC						
Salivary gland calculus	0	0	1	0	1	0
Stomatitis and ulceration						
Aphthous stomatitis	0	0	2	0	2	0
Mouth ulceration	0	0	4	0	4	0
Stomatitis	0	0	3	0	3	0
Tongue disorders						
Tongue ulceration	0	0	1	0	1	0

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MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Gastrointestinal disorders cont'd						
SOC						
HLT						
PT						
Tongue signs and symptoms						
Swollen tongue	0	0	4	0	4	0
Tongue coated	0	0	2	0	2	0
Gastrointestinal disorders SOC TOTAL	11	0	1309	0	1320	0

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Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
General disorders						
Acquired gene mutations and other alterations						
Janus kinase 2 mutation	0	0	1	0	1	0
Application and instillation site reactions						
Application site erythema	0	0	1	0	1	0
Asthenic conditions						
Asthenia	0	0	113	0	113	0
Chronic fatigue syndrome	0	0	6	0	6	0
Decreased activity	0	0	5	0	5	0
Fatigue	6	0	601	0	607	0
Malaise	5	0	164	0	169	0
Sluggishness	0	0	1	0	1	0
Body temperature altered						
Temperature regulation disorder	1	0	17	0	18	0
Device malfunction events NEC						
Undersensing	0	0	1	0	1	0
Febrile disorders						
Pyrexia	1	0	182	0	183	0
Feelings and sensations NEC						
Chills	0	0	28	0	28	0
Feeling abnormal	0	0	28	0	28	0
Feeling cold	0	0	39	0	39	0
Feeling drunk	0	0	3	0	3	0
Feeling hot	1	0	23	0	24	0
Feeling of body temperature change	0	0	16	0	16	0
Hunger	0	0	5	0	5	0
Sensation of foreign body	0	0	3	0	3	0
Sense of oppression	0	0	2	0	2	0
Temperature intolerance	0	0	10	0	10	0
Thirst	1	0	15	0	16	0
Gait disturbances						
Abasia	0	0	2	0	2	0
Gait disturbance	0	0	55	0	55	0
General signs and symptoms NEC						
Apparent death	0	0	1	0	1	0
Condition aggravated	0	0	2	0	2	0
Crying	0	0	9	0	9	0
Exercise tolerance decreased	0	0	39	0	39	0
Foaming at mouth	0	0	1	0	1	0
General physical health deterioration	0	0	5	0	5	0
General symptom	0	0	1	0	1	0
Induration	0	0	1	0	1	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
General disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Influenza like illness	1	0	94	0	95	0
Local reaction	0	0	1	0	1	0
Local swelling	0	0	5	0	5	0
Peripheral swelling	1	0	32	0	33	0
Secretion discharge	0	0	3	0	3	0
Swelling	0	0	12	0	12	0
Healing abnormal NEC						
Impaired healing	0	0	4	0	4	0
Inflammations						
Inflammation	0	0	5	0	5	0
Injection site reactions						
Injection site bruising	0	0	2	0	2	0
Injection site discomfort	0	0	2	0	2	0
Injection site eczema	0	0	2	0	2	0
Injection site erythema	0	0	23	0	23	0
Injection site extravasation	0	0	2	0	2	0
Injection site granuloma	0	0	1	0	1	0
Injection site haematoma	0	0	2	0	2	0
Injection site induration	0	0	1	0	1	0
Injection site inflammation	0	0	1	0	1	0
Injection site mass	0	0	2	0	2	0
Injection site nodule	0	0	6	0	6	0
Injection site pain	0	0	37	0	37	0
Injection site paraesthesia	0	0	2	0	2	0
Injection site pruritus	0	0	8	0	8	0
Injection site rash	0	0	2	0	2	0
Injection site reaction	0	0	6	0	6	0
Injection site swelling	0	0	30	0	30	0
Injection site urticaria	0	0	3	0	3	0
Injection site vesicles	0	0	1	0	1	0
Injection site warmth	0	0	5	0	5	0
Mass conditions NEC						
Cyst	0	0	2	0	2	0
Nodule	0	0	2	0	2	0
Mucosal findings abnormal						
Mucous membrane disorder	0	0	2	0	2	0
Oedema mucosal	0	0	1	0	1	0
Oedema NEC						
Face oedema	0	0	2	0	2	0
Generalised oedema	0	0	3	0	3	0
Localised oedema	0	0	3	0	3	0
Oedema	0	0	8	0	8	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
General disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Oedema peripheral	1	0	8	0	9	0
<i>Pain and discomfort NEC</i>						
Chest discomfort	0	0	43	0	43	0
Chest pain	1	0	89	0	90	0
Discomfort	0	0	28	0	28	0
Facial pain	0	0	2	0	2	0
Non-cardiac chest pain	0	0	1	0	1	0
Pain	2	0	155	0	157	0
Tenderness	1	0	9	0	10	0
<i>Therapeutic and nontherapeutic responses</i>						
Adverse event	0	0	1	0	1	0
Drug ineffective	0	0	1	0	1	0
Drug intolerance	0	0	1	0	1	0
<i>Trophic disorders</i>						
Dysplasia	0	0	1	0	1	0
<i>Vaccination site reactions</i>						
Extensive swelling of vaccinated limb	0	0	2	0	2	0
Vaccination site bruising	0	0	2	0	2	0
Vaccination site erythema	0	0	7	0	7	0
Vaccination site granuloma	0	0	1	0	1	0
Vaccination site induration	0	0	1	0	1	0
Vaccination site inflammation	0	0	1	0	1	0
Vaccination site nodule	0	0	4	0	4	0
Vaccination site pain	0	0	16	0	16	0
Vaccination site pruritus	0	0	4	0	4	0
Vaccination site rash	0	0	1	0	1	0
Vaccination site reaction	0	0	2	0	2	0
Vaccination site swelling	0	0	12	0	12	0
Vaccination site warmth	0	0	2	0	2	0
General disorders SOC TOTAL	22	0	2091	0	2113	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Hepatic disorders						
<i>Cholestasis and jaundice</i>						
Jaundice	0	0	1	0	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>						
Liver disorder	1	0	3	0	4	0
<i>Hepatic vascular disorders</i>						
Portal vein thrombosis	0	0	1	0	1	0
<i>Hepatobiliary signs and symptoms</i>						
Hepatomegaly	0	0	1	0	1	0
<i>Hepatocellular damage and hepatitis NEC</i>						
Autoimmune hepatitis	0	0	1	0	1	0
Liver injury	0	0	1	0	1	0
Hepatic disorders SOC TOTAL	1	0	8	0	9	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Immune system disorders						
Allergic conditions NEC						
Allergy to animal	0	0	1	0	1	0
Allergy to arthropod bite	0	0	2	0	2	0
Allergy to metals	0	0	4	0	4	0
Allergy to plants	0	0	1	0	1	0
Hypersensitivity	0	0	49	0	49	0
Multiple allergies	0	0	1	0	1	0
Allergies to foods, food additives, drugs and other chemicals						
Drug hypersensitivity	0	0	2	0	2	0
Food allergy	1	0	13	0	14	0
Milk allergy	1	0	2	0	3	0
Perfume sensitivity	0	0	3	0	3	0
Reaction to drug excipients	0	0	2	0	2	0
Reaction to preservatives	0	0	1	0	1	0
Anaphylactic responses						
Anaphylactic reaction	0	0	2	0	2	0
Anaphylactic shock	0	0	10	0	10	0
Atopic disorders						
House dust allergy	0	0	1	0	1	0
Seasonal allergy	0	0	6	0	6	0
Autoimmune disorders NEC						
Autoimmune disorder	0	0	5	0	5	0
Immune and associated conditions NEC						
Decreased immune responsiveness	0	0	10	0	10	0
Immune system disorder	0	0	8	0	8	0
Immunodeficiency disorders NEC						
Immunodeficiency	0	0	5	0	5	0
Immunosuppression	0	0	3	0	3	0
Immune system disorders SOC TOTAL	2	0	131	0	133	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Infections						
Abdominal and gastrointestinal infections						
Abdominal infection	0	0	3	0	3	0
Appendicitis	0	0	1	0	1	0
Gastroenteritis	0	0	1	0	1	0
Gastrointestinal infection	0	0	1	0	1	0
Pancreas infection	0	0	1	0	1	0
Bacterial infections NEC						
Bacterial infection	0	0	1	0	1	0
Folliculitis	0	0	3	0	3	0
Bone and joint infections						
Arthritis infective	0	0	1	0	1	0
Bone abscess	0	0	1	0	1	0
Intervertebral discitis	0	0	1	0	1	0
Central nervous system and spinal infections						
Encephalitis	0	0	2	0	2	0
Meningitis	0	0	3	0	3	0
Myelitis	0	0	2	0	2	0
Spinal cord infection	0	0	2	0	2	0
Chlamydial infections						
Pneumonia chlamydial	0	0	1	0	1	0
Clostridia infections						
Clostridial infection	0	0	1	0	1	0
Dental and oral soft tissue infections						
Abscess oral	0	0	1	0	1	0
Gingivitis	0	0	4	0	4	0
Periodontitis	0	0	1	0	1	0
Ear infections						
Ear infection	0	0	3	0	3	0
Otitis externa	0	0	1	0	1	0
Otitis media	0	0	1	0	1	0
Otitis media acute	0	0	1	0	1	0
Enteroviral infections NEC						
Meningitis enteroviral	0	0	1	0	1	0
Epstein-Barr viral infections						
Infectious mononucleosis	0	0	4	0	4	0
Eye and eyelid infections						
Chorioretinitis	0	0	1	0	1	0
Conjunctivitis	0	0	6	0	6	0
Eye infection	0	0	3	0	3	0
Hordeolum	0	0	3	0	3	0
Female reproductive tract infections						

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Infections cont'd						
SOC						
<i>HLT</i>						
PT						
Pelvic inflammatory disease	0	0	2	0	2	0
Uterine abscess	0	0	1	0	1	0
Vaginal infection	0	0	1	0	1	0
Fungal infections NEC						
Fungal infection	0	0	3	0	3	0
Fungal skin infection	0	0	2	0	2	0
Genital infection fungal	0	0	1	0	1	0
Oral fungal infection	0	0	1	0	1	0
Vulvovaginal mycotic infection	0	0	4	0	4	0
Herpes viral infections						
Genital herpes	0	0	2	0	2	0
Herpes simplex	0	0	2	0	2	0
Herpes virus infection	0	0	2	0	2	0
Herpes zoster	0	0	12	0	12	0
Oral herpes	0	0	4	0	4	0
Infections NEC						
Abscess	0	0	2	0	2	0
Infection	1	0	53	0	54	0
Infection susceptibility increased	0	0	3	0	3	0
Injection site abscess	0	0	2	0	2	0
Injection site infection	0	0	1	0	1	0
Localised infection	0	0	1	0	1	0
Pelvic infection	0	0	1	0	1	0
Respiratory tract infection	0	0	1	0	1	0
Vaccination site infection	0	0	1	0	1	0
Vestibulitis	0	0	1	0	1	0
Influenza viral infections						
Influenza	0	0	26	0	26	0
Lower respiratory tract and lung infections						
Lung infection	0	0	1	0	1	0
Pneumonia	0	0	8	0	8	0
Mycoplasma infections						
Pneumonia mycoplasmal	0	0	1	0	1	0
Neisseria infections						
Meningitis meningococcal	0	0	1	0	1	0
Meningococcal bacteraemia	0	0	1	0	1	0
Skin structures and soft tissue infections						
Eczema infected	0	0	1	0	1	0
Impetigo	0	0	1	0	1	0
Skin infection	0	0	2	0	2	0
Subcutaneous abscess	0	0	2	0	2	0
Sweat gland infection	0	0	1	0	1	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Infections cont'd						
SOC						
HLT						
PT						
<i>Streptococcal infections</i>						
Pharyngitis streptococcal	0	0	1	0	1	0
Streptococcal infection	0	0	1	0	1	0
<i>Tinea infections</i>						
Body tinea	0	0	1	0	1	0
<i>Upper respiratory tract infections</i>						
Acute tonsillitis	0	0	1	0	1	0
Chronic sinusitis	0	0	2	0	2	0
Laryngitis	0	0	1	0	1	0
Nasopharyngitis	0	0	22	0	22	0
Pharyngitis	0	0	21	0	21	0
Rhinitis	0	0	4	0	4	0
Sinusitis	0	0	9	0	9	0
Tonsillitis	0	0	4	0	4	0
Upper respiratory tract infection	0	0	1	0	1	0
<i>Urinary tract infections</i>						
Cystitis	0	0	15	0	15	0
Pyelonephritis	0	0	3	0	3	0
Urinary tract infection	0	0	7	0	7	0
<i>Viral infections NEC</i>						
Post viral fatigue syndrome	0	0	3	0	3	0
Vestibular neuronitis	0	0	3	0	3	0
Viral infection	0	0	4	0	4	0
Viral rash	0	0	1	0	1	0
Viral upper respiratory tract infection	0	0	1	0	1	0
Infections SOC TOTAL	1	0	308	0	309	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	29-Oct-2015	Report origin:	DENMARK
Data lock date:	28-Oct-2015 19:00:11	Route of admin:	ALL
Period covered:	01-Jan-1968 to 28-Oct-2015	Reporter type:	ALL
Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Injuries						
<i>Accidental exposures to product</i>						
Accidental exposure to product	0	0	1	0	1	0
Cerebral injuries NEC						
Concussion	0	0	2	0	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>						
Exposure during pregnancy	0	0	9	0	9	0
Foetal exposure during pregnancy	0	0	12	0	12	0
Maternal exposure before pregnancy	0	0	6	0	6	0
Fractures and dislocations NEC						
Fracture	0	0	1	0	1	0
Joint dislocation	0	0	3	0	3	0
Heat injuries (excl thermal burns)						
Heat stroke	0	0	1	0	1	0
Maladministrations						
Drug administered at inappropriate site	0	0	1	0	1	0
Drug administration error	0	0	1	0	1	0
Extra dose administered	0	0	1	0	1	0
Inappropriate schedule of drug administration	0	0	3	0	3	0
Incorrect dose administered	0	0	1	0	1	0
Incorrect route of drug administration	0	0	1	0	1	0
Wrong technique in drug usage process	0	0	1	0	1	0
Medication errors NEC						
Vaccination error	0	0	1	0	1	0
Muscle, tendon and ligament injuries						
Ligament injury	0	0	1	0	1	0
Nerve injuries NEC						
Nerve injury	0	0	2	0	2	0
Non-site specific injuries NEC						
Fall	0	0	18	0	18	0
Injury	0	0	1	0	1	0
Wound	0	0	3	0	3	0
Non-site specific procedural complications						
Procedural pain	0	0	1	0	1	0
Off label uses						
Off label use	0	0	2	0	2	0
Pathways and sources of exposure						
Exposure via direct contact	0	0	1	0	1	0
Poisoning and toxicity						
Metal poisoning	0	0	2	0	2	0
Product use issues NEC						
Drug administered to patient of inappropriate age	0	0	1	0	1	0

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Reaction Name Injuries cont'd	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Skin injuries NEC						
Contusion	0	0	31	0	31	0
Excoriation	0	0	1	0	1	0
Hair injury	0	0	1	0	1	0
Scar	0	0	1	0	1	0
Skin wound	0	0	2	0	2	0
Underdoses NEC						
Underdose	0	0	3	0	3	0
Vaccination related complications						
Vaccination complication	0	0	2	0	2	0
Injuries SOC TOTAL	0	0	118	0	118	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Investigations						
Autoimmunity analyses						
LE cells	0	0	1	0	1	0
Blood gas and acid base analyses						
Blood lactic acid	0	0	1	0	1	0
Carbohydrate tolerance analyses (incl diabetes)						
Blood glucose decreased	0	0	3	0	3	0
Blood glucose increased	0	0	1	0	1	0
Chromosome analyses						
Karyotype analysis abnormal	0	0	1	0	1	0
ECG investigations						
Electrocardiogram abnormal	0	0	1	0	1	0
Ear and labyrinth histopathology procedures						
Paracentesis ear	0	0	1	0	1	0
Endocrine analyses and imaging NEC						
Hormone level abnormal	1	0	6	0	7	0
Gastrointestinal function diagnostic procedures						
Gastric pH decreased	0	0	4	0	4	0
Haematological analyses NEC						
Red blood cell sedimentation rate increased	0	0	1	0	1	0
Heart rate and pulse investigations						
Heart rate abnormal	0	0	1	0	1	0
Heart rate decreased	1	0	6	0	7	0
Heart rate increased	0	0	78	0	78	0
Heart rate irregular	0	0	15	0	15	0
Orthostatic heart rate response increased	0	0	1	0	1	0
Pulse abnormal	0	0	2	0	2	0
Immune response protein analyses NEC						
Complement factor C3 decreased	0	0	1	0	1	0
Investigations NEC						
Quality of life decreased	2	0	6	0	8	0
Liver function analyses						
Alanine aminotransferase increased	0	0	2	0	2	0
Gamma-glutamyltransferase increased	0	0	1	0	1	0
Hepatic enzyme abnormal	0	0	1	0	1	0
Hepatic enzyme increased	0	0	4	0	4	0
Mineral and electrolyte analyses						
Blood iron decreased	0	0	1	0	1	0
Neurologic diagnostic procedures						
Pain threshold decreased	1	0	1	0	2	0
Physical examination procedures and organ system status						
Apgar score low	0	0	1	0	1	0

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Reaction Name Investigations cont'd	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Body temperature abnormal	0	0	2	0	2	0
Body temperature decreased	0	0	2	0	2	0
Body temperature fluctuation	0	0	16	0	16	0
Body temperature increased	0	0	3	0	3	0
General physical condition abnormal	0	0	1	0	1	0
Grip strength decreased	0	0	1	0	1	0
Lymph node palpable	0	0	2	0	2	0
Respiratory rate increased	0	0	1	0	1	0
Weight abnormal	0	0	1	0	1	0
Weight decreased	1	0	46	0	47	0
Weight increased	0	0	24	0	24	0
Platelet analyses						
Platelet count decreased	0	0	1	0	1	0
Protein analyses NEC						
C-reactive protein increased	0	0	1	0	1	0
Red blood cell analyses						
Haemoglobin decreased	0	0	3	0	3	0
Reproductive hormone analyses						
Androgens increased	1	0	0	0	1	0
Blood oestrogen increased	1	0	0	0	1	0
Progesterone decreased	1	0	0	0	1	0
Respiratory and pulmonary function diagnostic procedures						
Pulmonary function test decreased	0	0	3	0	3	0
Total lung capacity decreased	0	0	1	0	1	0
Urinalysis NEC						
Blood urine present	0	0	5	0	5	0
Vascular tests NEC (incl blood pressure)						
Blood pressure abnormal	0	0	1	0	1	0
Blood pressure decreased	0	0	5	0	5	0
Blood pressure increased	0	0	1	0	1	0
Vitamin analyses						
Nicotinamide decreased	0	0	1	0	1	0
Vitamin D decreased	0	0	3	0	3	0
White blood cell analyses						
Neutrophil count decreased	0	0	1	0	1	0
Neutrophil count increased	0	0	1	0	1	0
White blood cell count increased	0	0	4	0	4	0
Investigations SOC TOTAL	9	0	271	0	280	0

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MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Metabolic disorders						
<i>Appetite disorders</i>						
Appetite disorder	0	0	4	0	4	0
Decreased appetite	2	0	46	0	48	0
Hyperphagia	0	0	1	0	1	0
Increased appetite	0	0	4	0	4	0
Lack of satiety	0	0	2	0	2	0
Salt craving	0	0	1	0	1	0
<i>Calcium metabolism disorders</i>						
Calcium deficiency	0	0	1	0	1	0
<i>Diabetes mellitus (incl subtypes)</i>						
Type 1 diabetes mellitus	0	0	3	0	3	0
<i>Elevated cholesterol</i>						
Hypercholesterolaemia	0	0	1	0	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>						
Vitamin A deficiency	0	0	1	0	1	0
Vitamin D deficiency	0	0	12	0	12	0
<i>Fluid intake increased</i>						
Polydipsia	0	0	2	0	2	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>						
Alcohol intolerance	0	0	7	0	7	0
Cow's milk intolerance	0	0	2	0	2	0
Food intolerance	0	0	14	0	14	0
Histamine intolerance	0	0	1	0	1	0
Milk soy protein intolerance	0	0	1	0	1	0
<i>General nutritional disorders NEC</i>						
Abnormal loss of weight	0	0	1	0	1	0
Overweight	0	0	3	0	3	0
Weight fluctuation	0	0	2	0	2	0
Weight gain poor	0	0	1	0	1	0
<i>Hyperglycaemic conditions NEC</i>						
Glucose tolerance impaired	0	0	1	0	1	0
<i>Iron deficiencies</i>						
Iron deficiency	0	0	5	0	5	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>						
Lactic acidosis	0	0	1	0	1	0
<i>Metabolic disorders NEC</i>						
Hypometabolism	0	0	2	0	2	0
Metabolic disorder	0	0	3	0	3	0
<i>Potassium imbalance</i>						
Hypokalaemia	0	0	1	0	1	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Metabolic disorders cont'd						
SOC						
HLT						
PT						
<i>Sugar intolerance (excl glucose intolerance)</i>						
Fructose intolerance	0	0	2	0	2	0
Lactose intolerance	1	0	10	0	11	0
<i>Total fluid volume decreased</i>						
Dehydration	0	0	4	0	4	0
<i>Total fluid volume increased</i>						
Fluid retention	0	0	4	0	4	0
<i>Vitamin deficiencies NEC</i>						
Hypovitaminosis	0	0	2	0	2	0
<i>Water soluble vitamin deficiencies</i>						
Vitamin B complex deficiency	0	0	1	0	1	0
Vitamin B12 deficiency	0	0	5	0	5	0
Metabolic disorders SOC TOTAL	3	0	151	0	154	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Muscle & tissue disorders						
Arthropathies NEC						
Arthritis	0	0	11	0	11	0
Arthritis reactive	0	0	5	0	5	0
Arthropathy	0	0	9	0	9	0
Bone disorders NEC						
Bone cyst	0	0	1	0	1	0
Bone disorder	0	0	1	0	1	0
Medial tibial stress syndrome	0	0	2	0	2	0
Bone related signs and symptoms						
Bone pain	0	0	14	0	14	0
Coccydynia	0	0	3	0	3	0
Pain in jaw	0	0	21	0	21	0
Pubic pain	0	0	1	0	1	0
Spinal pain	0	0	3	0	3	0
Bursal disorders						
Bursitis	0	0	3	0	3	0
Connective tissue disorders NEC						
Connective tissue disorder	0	0	3	0	3	0
Extremity deformities						
Foot deformity	0	0	1	0	1	0
Intervertebral disc disorders NEC						
Intervertebral disc disorder	0	0	1	0	1	0
Intervertebral disc protrusion	0	0	3	0	3	0
Joint related disorders NEC						
Facet joint syndrome	0	0	2	0	2	0
Hypermobility syndrome	0	0	2	0	2	0
Joint contracture	0	0	1	0	1	0
Joint laxity	0	0	1	0	1	0
Joint lock	0	0	9	0	9	0
Patellofemoral pain syndrome	0	0	1	0	1	0
Periarthritis	0	0	1	0	1	0
Joint related signs and symptoms						
Arthralgia	3	0	302	0	305	0
Joint crepitation	0	0	4	0	4	0
Joint stiffness	1	0	9	0	10	0
Joint swelling	0	0	23	0	23	0
Joint warmth	0	0	1	0	1	0
Lupus erythematosus (incl subtypes)						
Systemic lupus erythematosus	0	0	4	0	4	0
Muscle infections and inflammations						
Myositis	0	0	2	0	2	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Muscle & tissue disorders cont'd						
SOC						
<i>HLT</i>						
<i>PT</i>						
<i>Muscle pains</i>						
Fibromyalgia	0	0	13	0	13	0
Myalgia	1	0	209	0	210	0
<i>Muscle related signs and symptoms NEC</i>						
Muscle atrophy	0	0	1	0	1	0
Muscle disorder	0	0	2	0	2	0
Muscle fatigue	0	0	13	0	13	0
Muscle spasms	0	0	132	0	132	0
Muscle swelling	0	0	3	0	3	0
Muscle tightness	0	0	34	0	34	0
Muscle twitching	0	0	24	0	24	0
<i>Muscle tone abnormalities</i>						
Nuchal rigidity	0	0	2	0	2	0
Trismus	0	0	2	0	2	0
<i>Muscle weakness conditions</i>						
Muscular weakness	2	0	183	0	185	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>						
Back pain	0	0	117	0	117	0
Flank pain	0	0	1	0	1	0
Growing pains	0	0	1	0	1	0
Limb discomfort	0	0	24	0	24	0
Musculoskeletal chest pain	0	0	8	0	8	0
Musculoskeletal discomfort	1	0	6	0	7	0
Musculoskeletal pain	1	0	41	0	42	0
Neck pain	0	0	77	0	77	0
Pain in extremity	3	0	178	0	181	0
Rheumatic disorder	0	0	1	0	1	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>						
Mastication disorder	0	0	1	0	1	0
Mobility decreased	0	0	1	0	1	0
Musculoskeletal stiffness	0	0	27	0	27	0
Winged scapula	0	0	1	0	1	0
<i>Myopathies</i>						
Mitochondrial myopathy acquired	0	0	1	0	1	0
Myopathy	0	0	2	0	2	0
<i>Rheumatoid arthropathies</i>						
Juvenile idiopathic arthritis	0	0	2	0	2	0
Rheumatoid arthritis	0	0	5	0	5	0
<i>Soft tissue disorders NEC</i>						
Fistula	0	0	2	0	2	0
Fistula discharge	0	0	1	0	1	0
Groin pain	0	0	10	0	10	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Muscle & tissue disorders cont'd						
SOC						
HLT						
PT						
Spine and neck deformities						
Scoliosis	0	0	4	0	4	0
Synovial disorders						
Synovial cyst	0	0	1	0	1	0
Synovitis	0	0	1	0	1	0
Tendon disorders						
Tendon discomfort	0	0	1	0	1	0
Tendon laxity	0	0	1	0	1	0
Tendon pain	0	0	6	0	6	0
Tendonitis	0	0	2	0	2	0
Tenosynovitis	0	0	1	0	1	0
Trunk deformities						
Shoulder deformity	0	0	1	0	1	0
Muscle & tissue disorders SOC TOTAL	12	0	1587	0	1599	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Neoplasms						
<i>Endocrine neoplasms benign NEC</i>						
Pituitary tumour benign	0	0	1	0	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>						
Thyroid neoplasm	0	0	1	0	1	0
<i>Female reproductive neoplasms unspecified malignancy</i>						
Cervix neoplasm	0	0	1	0	1	0
<i>Hepatobiliary neoplasms benign</i>						
Hepatic adenoma	0	0	1	0	1	0
<i>Neoplasms benign site unspecified NEC</i>						
Fibroma	0	0	1	0	1	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>						
Granular cell tumour	0	0	1	0	1	0
Neoplasm	0	0	1	0	1	0
<i>Ovarian germ cell neoplasms malignant</i>						
Ovarian germ cell teratoma	0	0	1	0	1	0
<i>Rhabdomyosarcomas</i>						
Rhabdomyosarcoma	0	0	1	0	1	0
<i>Skin neoplasms benign</i>						
Anogenital warts	0	0	6	0	6	0
Melanocytic naevus	0	0	2	0	2	0
Skin papilloma	0	0	1	0	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>						
Neoplasm skin	0	0	1	0	1	0
<i>Vaginal neoplasms benign</i>						
Vulvovaginal warts	0	0	1	0	1	0
Neoplasms SOC TOTAL	0	0	20	0	20	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	29-Oct-2015	Report origin:	DENMARK
Data lock date:	28-Oct-2015 19:00:11	Route of admin:	ALL
Period covered:	01-Jan-1968 to 28-Oct-2015	Reporter type:	ALL
Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Nervous system disorders						
Abnormal reflexes						
Areflexia	0	0	2	0	2	0
Hyporeflexia	0	0	3	0	3	0
Abnormal sleep-related events						
Sleep paralysis	0	0	2	0	2	0
Absence seizures						
Petit mal epilepsy	0	0	3	0	3	0
Acute polyneuropathies						
Guillain-Barre syndrome	0	0	5	0	5	0
Polyneuropathy	0	0	2	0	2	0
Autonomic nervous system disorders						
Autonomic nervous system imbalance	0	0	67	0	67	0
Orthostatic intolerance	0	0	54	0	54	0
Central nervous system haemorrhages and cerebrovascular accidents						
Cerebral haemorrhage	0	0	2	0	2	0
Cerebral ischaemia	0	0	1	0	1	0
Cerebral thrombosis	0	0	1	0	1	0
Central nervous system vascular disorders NEC						
Cerebrovascular disorder	0	0	1	0	1	0
Cerebrovascular venous and sinus thrombosis						
Intracranial venous sinus thrombosis	0	0	1	0	1	0
Choreiform movements						
Sydenham's chorea	0	0	1	0	1	0
Coordination and balance disturbances						
Ataxia	0	0	2	0	2	0
Balance disorder	1	0	36	0	37	0
Coordination abnormal	0	0	11	0	11	0
Dysstasia	0	0	10	0	10	0
Nystagmus	0	0	1	0	1	0
Cortical dysfunction NEC						
Aphasia	1	0	19	0	20	0
Dysgraphia	0	0	4	0	4	0
Dementia (excl Alzheimer's type)						
Dementia	0	0	2	0	2	0
Demyelinating disorders NEC						
Acute disseminated encephalomyelitis	0	0	1	0	1	0
Demyelination	0	0	2	0	2	0
Neuromyelitis optica	0	0	1	0	1	0
Disturbances in consciousness NEC						
Altered state of consciousness	1	0	2	0	3	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Nervous system disorders cont'd						
SOC						
HLT						
PT						
Depressed level of consciousness	0	0	9	0	9	0
Lethargy	0	0	3	0	3	0
Loss of consciousness	0	0	25	0	25	0
Somnolence	0	0	17	0	17	0
Syncope	2	0	235	0	237	0
Dyskinesias and movement disorders NEC						
Clumsiness	0	0	2	0	2	0
Dyskinesia	0	0	23	0	23	0
Fine motor delay	0	0	1	0	1	0
Hyperkinesia	0	0	1	0	1	0
Hypokinesia	0	0	4	0	4	0
Movement disorder	0	0	6	0	6	0
Psychomotor hyperactivity	0	0	11	0	11	0
Tardive dyskinesia	0	0	1	0	1	0
Dystonias						
Dystonia	0	0	4	0	4	0
Opisthotonus	0	0	1	0	1	0
Eye movement disorders						
VIth nerve paralysis	0	0	1	0	1	0
Facial cranial nerve disorders						
Facial paresis	0	0	10	0	10	0
VIIIth nerve paralysis	0	0	5	0	5	0
Generalised tonic-clonic seizures						
Generalised tonic-clonic seizure	0	0	3	0	3	0
Headaches NEC						
Cluster headache	0	0	1	0	1	0
Cold-stimulus headache	0	0	1	0	1	0
Exertional headache	0	0	1	0	1	0
Headache	5	0	690	0	695	0
Sinus headache	0	0	6	0	6	0
Tension headache	0	0	13	0	13	0
Hypoglossal nerve disorders						
Hypoglossal nerve paralysis	0	0	1	0	1	0
Tongue paralysis	0	0	1	0	1	0
Increased intracranial pressure disorders						
Benign intracranial hypertension	0	0	2	0	2	0
Intracranial pressure increased	0	0	2	0	2	0
Lumbar spinal cord and nerve root disorders						
Sciatica	0	0	1	0	1	0
Memory loss (excl dementia)						
Amnesia	0	0	25	0	25	0
Memory impairment	0	0	186	0	186	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Nervous system disorders cont'd						
SOC						
<i>HLT</i>						
PT						
<i>Mental impairment (excl dementia and memory loss)</i>						
Cognitive disorder	1	0	41	0	42	0
Disturbance in attention	4	0	269	0	273	0
Mental impairment	0	0	3	0	3	0
<i>Migraine headaches</i>						
Migraine	1	0	127	0	128	0
Migraine with aura	0	0	12	0	12	0
Migraine without aura	0	0	1	0	1	0
<i>Mononeuropathies</i>						
Carpal tunnel syndrome	0	0	1	0	1	0
Peroneal nerve palsy	0	0	2	0	2	0
<i>Motor neurone diseases</i>						
Motor neurone disease	0	0	1	0	1	0
<i>Multiple sclerosis acute and progressive</i>						
Multiple sclerosis	0	0	16	0	16	0
Uhthoff's phenomenon	0	0	1	0	1	0
<i>Muscle tone abnormal</i>						
Hypotonia	0	0	3	0	3	0
<i>Myelitis (incl infective)</i>						
Myelitis transverse	0	0	5	0	5	0
<i>Narcolepsy and hypersomnia</i>						
Cataplexy	0	0	4	0	4	0
Hypersomnia	1	0	35	0	36	0
Narcolepsy	0	0	8	0	8	0
<i>Nervous system cysts and polyps</i>						
Cerebral cyst	0	0	1	0	1	0
<i>Nervous system disorders NEC</i>						
Cerebral disorder	0	0	1	0	1	0
Motor dysfunction	0	0	3	0	3	0
Nervous system disorder	1	0	8	0	9	0
Psychomotor skills impaired	0	0	1	0	1	0
<i>Neurologic visual problems NEC</i>						
Tunnel vision	0	0	2	0	2	0
Visual field defect	0	0	7	0	7	0
<i>Neurological signs and symptoms NEC</i>						
Dizziness	5	0	569	0	574	0
Dizziness exertional	0	0	1	0	1	0
Dizziness postural	0	0	15	0	15	0
Head discomfort	0	0	22	0	22	0
Neurological symptom	0	0	11	0	11	0
Presyncope	0	0	93	0	93	0
Unresponsive to stimuli	0	0	1	0	1	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Nervous system disorders cont'd						
SOC						
<i>HLT</i>						
PT						
<i>Neuromuscular disorders NEC</i>						
Muscle contractions involuntary	0	0	5	0	5	0
Neuromyopathy	0	0	1	0	1	0
<i>Neuromuscular junction dysfunction</i>						
Myasthenia gravis	0	0	2	0	2	0
<i>Olfactory nerve disorders</i>						
Anosmia	0	0	1	0	1	0
Parosmia	0	0	10	0	10	0
<i>Optic nerve disorders NEC</i>						
Optic neuritis	0	0	4	0	4	0
<i>Paraesthesias and dysaesthesias</i>						
Burning sensation	0	0	28	0	28	0
Dysaesthesia	0	0	10	0	10	0
Formication	0	0	1	0	1	0
Hyperaesthesia	0	0	19	0	19	0
Hypoaesthesia	1	0	139	0	140	0
Lhermitte's sign	0	0	1	0	1	0
Paraesthesia	1	0	184	0	185	0
<i>Paralysis and paresis (excl cranial nerve)</i>						
Diplegia	0	0	1	0	1	0
Gait spastic	0	0	1	0	1	0
Hemiparesis	0	0	4	0	4	0
Hemiplegia	0	0	5	0	5	0
Monoparesis	0	0	2	0	2	0
Monoplegia	0	0	7	0	7	0
Paralysis	1	0	30	0	31	0
Paresis	0	0	3	0	3	0
Spinal cord paralysis	0	0	1	0	1	0
<i>Partial complex seizures</i>						
Dreamy state	0	0	2	0	2	0
<i>Peripheral neuropathies NEC</i>						
Neuritis	0	0	2	0	2	0
Neuropathy peripheral	0	0	5	0	5	0
Small fibre neuropathy	0	0	1	0	1	0
<i>Seizures and seizure disorders NEC</i>						
Atonic seizures	0	0	1	0	1	0
Benign rolandic epilepsy	0	0	1	0	1	0
Clonic convulsion	0	0	1	0	1	0
Epilepsy	0	0	13	0	13	0
Idiopathic generalised epilepsy	0	0	1	0	1	0
Seizure	0	0	18	0	18	0
<i>Sensory abnormalities NEC</i>						

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Nervous system disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Allodynia	0	0	2	0	2	0
Aura	0	0	1	0	1	0
Complex regional pain syndrome	0	0	4	0	4	0
Dysgeusia	0	0	8	0	8	0
Hypergeusia	0	0	1	0	1	0
Hypogeusia	0	0	1	0	1	0
Neuralgia	0	0	37	0	37	0
Restless legs syndrome	0	0	9	0	9	0
Sensory disturbance	1	0	158	0	159	0
Sensory loss	0	0	12	0	12	0
Sleep disturbances NEC						
Poor quality sleep	0	0	15	0	15	0
Sudden onset of sleep	0	0	2	0	2	0
Speech and language abnormalities						
Aphonia	0	0	5	0	5	0
Dysarthria	0	0	4	0	4	0
Dyslalia	0	0	2	0	2	0
Language disorder	0	0	2	0	2	0
Speech disorder	0	0	49	0	49	0
Spinal cord and nerve root disorders NEC						
Radicular pain	0	0	1	0	1	0
Radiculopathy	0	0	1	0	1	0
Structural brain disorders NEC						
Brain injury	0	0	1	0	1	0
Cerebral atrophy	0	0	1	0	1	0
White matter lesion	0	0	2	0	2	0
Transient cerebrovascular events						
Transient ischaemic attack	0	0	1	0	1	0
Tremor (excl congenital)						
Tremor	0	0	108	0	108	0
Trigeminal disorders						
Trigeminal neuralgia	0	0	1	0	1	0
Nervous system disorders SOC TOTAL	27	0	3724	0	3751	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Pregnancy conditions						
<i>Abortions not specified as induced or spontaneous</i>						
Abortion missed	0	0	1	0	1	0
<i>Abortions spontaneous</i>						
Abortion spontaneous	0	0	9	0	9	0
<i>Gestational age and weight conditions</i>						
Premature baby	0	0	1	0	1	0
Weight decrease neonatal	0	0	1	0	1	0
<i>Labour onset and length abnormalities</i>						
Prolonged rupture of membranes	0	0	1	0	1	0
<i>Maternal complications of pregnancy NEC</i>						
Ectopic pregnancy	0	0	1	0	1	0
<i>Placental abnormalities (excl neoplasms)</i>						
Placental disorder	0	0	1	0	1	0
<i>Stillbirth and foetal death</i>						
Foetal death	0	0	1	0	1	0
Pregnancy conditions SOC TOTAL	0	0	16	0	16	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Psychiatric disorders						
Abnormal behaviour NEC						
Abnormal behaviour	0	0	1	0	1	0
Affect alterations NEC						
Affect lability	0	0	3	0	3	0
Anxiety disorders NEC						
Neurosis	0	0	1	0	1	0
Anxiety symptoms						
Anxiety	2	0	70	0	72	0
Nervousness	0	0	3	0	3	0
Stress	0	0	33	0	33	0
Tension	0	0	2	0	2	0
Attention deficit and disruptive behaviour disorders						
Attention deficit/hyperactivity disorder	0	0	1	0	1	0
Behaviour and socialisation disturbances						
Aggression	0	0	2	0	2	0
Impatience	0	0	1	0	1	0
Personality change	0	0	4	0	4	0
Social avoidant behaviour	0	0	5	0	5	0
Cognitive and attention disorders and disturbances NEC						
Daydreaming	0	0	2	0	2	0
Distractibility	0	0	1	0	1	0
Confusion and disorientation						
Confusional state	0	0	43	0	43	0
Disorientation	0	0	6	0	6	0
Depressive disorders						
Depression	1	0	47	0	48	0
Dysthymic disorder	0	0	1	0	1	0
Major depression	0	0	1	0	1	0
Dissociative states						
Depersonalisation	0	0	2	0	2	0
Dissociation	0	0	6	0	6	0
Disturbances in initiating and maintaining sleep						
Initial insomnia	0	0	10	0	10	0
Insomnia	1	0	99	0	100	0
Eating disorders NEC						
Eating disorder	0	0	1	0	1	0
Food aversion	0	0	1	0	1	0
Emotional and mood disturbances NEC						
Anger	0	0	4	0	4	0
Emotional disorder	0	0	2	0	2	0
Irritability	0	0	14	0	14	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Psychiatric disorders cont'd						
SOC						
HLT						
PT						
Mood altered	0	0	3	0	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>						
Claustrophobia	0	0	2	0	2	0
Fear of death	0	0	1	0	1	0
Fear of falling	0	0	2	0	2	0
Phonophobia	0	0	3	0	3	0
Social fear	0	0	1	0	1	0
<i>Fluctuating mood symptoms</i>						
Mood swings	0	0	56	0	56	0
<i>Increased physical activity levels</i>						
Restlessness	0	0	57	0	57	0
<i>Learning disorders</i>						
Learning disorder	0	0	2	0	2	0
Reading disorder	0	0	2	0	2	0
<i>Mental disorders NEC</i>						
Mental disorder	0	0	10	0	10	0
<i>Mood alterations with depressive symptoms</i>						
Depressed mood	0	0	28	0	28	0
Depressive symptom	0	0	2	0	2	0
Feeling of despair	0	0	1	0	1	0
Tearfulness	0	0	1	0	1	0
<i>Mood disorders NEC</i>						
Apathy	0	0	2	0	2	0
<i>Narcolepsy and associated conditions</i>						
Hypnagogic hallucination	0	0	1	0	1	0
<i>Obsessive-compulsive disorders and symptoms</i>						
Obsessive thoughts	0	0	2	0	2	0
Obsessive-compulsive disorder	0	0	1	0	1	0
<i>Orgasmic disorders and disturbances</i>						
Female orgasmic disorder	0	0	1	0	1	0
<i>Parasomnias</i>						
Nightmare	0	0	8	0	8	0
<i>Perception disturbances</i>						
Derealisation	0	0	8	0	8	0
Hallucination	0	0	2	0	2	0
Hallucination, auditory	0	0	1	0	1	0
Hallucination, visual	0	0	1	0	1	0
Hallucinations, mixed	0	0	1	0	1	0
<i>Personality disorders NEC</i>						
Personality disorder	0	0	2	0	2	0
Self esteem decreased	0	0	4	0	4	0
<i>Personality disorders with dramatic behaviour (Cluster B)</i>						

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Psychiatric disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Borderline personality disorder	0	0	1	0	1	0
Histrionic personality disorder	0	0	1	0	1	0
Psychiatric symptoms NEC						
Abulia	0	0	2	0	2	0
Psychiatric symptom	0	0	2	0	2	0
Psychotic disorder NEC						
Psychotic disorder	0	0	2	0	2	0
Sexual arousal disorders						
Disturbance in sexual arousal	0	0	1	0	1	0
Sexual desire disorders						
Libido decreased	0	0	7	0	7	0
Sleep disorders NEC						
Hypersomnia-bulimia syndrome	0	0	2	0	2	0
Sleep disorder	1	0	73	0	74	0
Somatoform disorders						
Somatisation disorder	0	0	1	0	1	0
Somatoform disorder	0	0	2	0	2	0
Speech and language usage disturbances						
Disorganised speech	0	0	1	0	1	0
Speech articulation and rhythm disturbances						
Dysphemia	0	0	3	0	3	0
Stereotypies and automatisms						
Bruxism	0	0	2	0	2	0
Waxy flexibility	0	0	2	0	2	0
Stress disorders						
Burnout syndrome	0	0	2	0	2	0
Post-traumatic stress disorder	0	0	3	0	3	0
Suicidal and self-injurious behaviour						
Self injurious behaviour	0	0	1	0	1	0
Suicidal ideation	0	0	6	0	6	0
Suicide attempt	0	0	1	0	1	0
Thinking disturbances						
Tachyphrenia	0	0	1	0	1	0
Tic disorders						
Tic	0	0	24	0	24	0
Psychiatric disorders SOC TOTAL	5	0	711	0	716	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Renal & urinary disorders						
Bladder and urethral symptoms						
Bladder irritation	0	0	2	0	2	0
Bladder pain	0	0	2	0	2	0
Dysuria	0	0	18	0	18	0
Enuresis	0	0	2	0	2	0
Incontinence	0	0	1	0	1	0
Micturition disorder	0	0	5	0	5	0
Pollakiuria	1	0	30	0	31	0
Urethral pain	0	0	1	0	1	0
Urinary incontinence	0	0	11	0	11	0
Urinary retention	0	0	11	0	11	0
Bladder disorders NEC						
Bladder disorder	0	0	6	0	6	0
Genital and urinary tract disorders NEC						
Urinary tract disorder	0	0	1	0	1	0
Glomerulonephritis and nephrotic syndrome						
Glomerulonephritis	0	0	1	0	1	0
Glomerulonephritis acute	0	0	1	0	1	0
Myoneurogenic bladder disorders						
Bladder dysfunction	0	0	2	0	2	0
Nephritis NEC						
Tubulointerstitial nephritis	0	0	1	0	1	0
Nephropathies and tubular disorders NEC						
Renal tubular acidosis	0	0	1	0	1	0
Renal disorders NEC						
Renal haemorrhage	0	0	1	0	1	0
Urinary abnormalities						
Chromaturia	0	0	3	0	3	0
Haematuria	0	0	3	0	3	0
Leukocyturia	0	0	1	0	1	0
Proteinuria	0	0	1	0	1	0
Urine abnormality	0	0	2	0	2	0
Urinary tract signs and symptoms NEC						
Cystitis-like symptom	0	0	3	0	3	0
Nocturia	0	0	3	0	3	0
Polyuria	0	0	2	0	2	0
Renal pain	0	0	3	0	3	0
Renal & urinary disorders SOC TOTAL	1	0	118	0	119	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	29-Oct-2015	Report origin:	DENMARK
Data lock date:	28-Oct-2015 19:00:11	Route of admin:	ALL
Period covered:	01-Jan-1968 to 28-Oct-2015	Reporter type:	ALL
Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Reproductive & breast disorders						
Breast disorders NEC						
Breast enlargement	0	0	1	0	1	0
Breast mass	0	0	3	0	3	0
Nipple disorder	0	0	1	0	1	0
Breast signs and symptoms						
Breast discharge	0	0	1	0	1	0
Breast discomfort	0	0	1	0	1	0
Breast pain	0	0	8	0	8	0
Breast swelling	0	0	3	0	3	0
Breast tenderness	0	0	3	0	3	0
Cervix disorders NEC						
Cervical dysplasia	0	0	4	0	4	0
Cervical friability	0	0	1	0	1	0
Menopausal effects NEC						
Premature menopause	0	0	2	0	2	0
Menstruation and uterine bleeding NEC						
Dysmenorrhoea	0	0	49	0	49	0
Menstrual discomfort	0	0	1	0	1	0
Menstrual disorder	0	0	16	0	16	0
Menstruation irregular	0	0	40	0	40	0
Metrorrhagia	0	0	8	0	8	0
Premenstrual syndrome	0	0	1	0	1	0
Menstruation with decreased bleeding						
Amenorrhoea	0	0	15	0	15	0
Menstruation delayed	0	0	3	0	3	0
Oligomenorrhoea	0	0	2	0	2	0
Menstruation with increased bleeding						
Menometrorrhagia	0	0	1	0	1	0
Menorrhagia	1	0	14	0	15	0
Polymenorrhoea	0	0	1	0	1	0
Ovarian and fallopian tube cysts and neoplasms						
Ovarian cyst	0	0	4	0	4	0
Polycystic ovaries	0	0	3	0	3	0
Ovarian and fallopian tube disorders NEC						
Ovulation pain	0	0	2	0	2	0
Pelvis and broad ligament disorders NEC						
Adnexa uteri pain	0	0	1	0	1	0
Reproductive tract signs and symptoms NEC						
Genital pain	0	0	2	0	2	0
Oedema genital	0	0	1	0	1	0
Pelvic pain	0	0	9	0	9	0

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Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reproductive & breast disorders cont'd						
SOC						
HLT						
PT						
Pruritus genital	0	0	1	0	1	0
Sexual function and fertility disorders NEC						
Dyspareunia	0	0	2	0	2	0
Infertility	0	0	2	0	2	0
Infertility female	0	0	1	0	1	0
Uterine disorders NEC						
Endometrial dysplasia	0	0	1	0	1	0
Endometriosis	1	0	1	0	2	0
Uterine pain	0	0	2	0	2	0
Uterine neoplasms						
Uterine cyst	0	0	1	0	1	0
Uterine tone disorders						
Uterine spasm	0	0	3	0	3	0
Vulvovaginal disorders NEC						
Vaginal haemorrhage	0	0	4	0	4	0
Vulval haemorrhage	0	0	1	0	1	0
Vulvar dysplasia	0	0	1	0	1	0
Vulvovaginal signs and symptoms						
Coital bleeding	0	0	1	0	1	0
Vaginal discharge	0	0	4	0	4	0
Vaginal odour	0	0	1	0	1	0
Vaginismus	0	0	1	0	1	0
Vulvovaginal discomfort	0	0	2	0	2	0
Vulvovaginal dryness	0	0	1	0	1	0
Vulvovaginal hypoaesthesia	0	0	1	0	1	0
Vulvovaginal pain	0	0	3	0	3	0
Vulvovaginal pruritus	0	0	2	0	2	0
Reproductive & breast disorders SOC TOTAL	2	0	237	0	239	0

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Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Respiratory disorders						
Breathing abnormalities						
Apnoea	0	0	1	0	1	0
Dyspnoea	2	0	168	0	170	0
Dyspnoea at rest	0	0	1	0	1	0
Dyspnoea exertional	0	0	12	0	12	0
Hyperventilation	0	0	15	0	15	0
Hypopnoea	0	0	1	0	1	0
Nocturnal dyspnoea	0	0	1	0	1	0
Respiratory arrest	0	0	1	0	1	0
Sleep apnoea syndrome	0	0	1	0	1	0
Bronchospasm and obstruction						
Asthma	0	0	23	0	23	0
Asthma exercise induced	0	0	6	0	6	0
Bronchospasm	0	0	1	0	1	0
Wheezing	0	0	3	0	3	0
Coughing and associated symptoms						
Cough	0	0	31	0	31	0
Haemoptysis	0	0	1	0	1	0
Productive cough	0	0	1	0	1	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)						
Laryngeal dyspnoea	0	0	1	0	1	0
Vocal cord disorder	0	0	1	0	1	0
Laryngeal spasm, oedema and obstruction						
Laryngeal oedema	0	0	1	0	1	0
Lower respiratory tract inflammatory and immunologic conditions						
Lower respiratory tract inflammation	0	0	1	0	1	0
Lower respiratory tract signs and symptoms						
Bronchial irritation	0	0	2	0	2	0
Hiccups	0	0	1	0	1	0
Pulmonary pain	0	0	1	0	1	0
Nasal congestion and inflammations						
Nasal congestion	0	0	6	0	6	0
Nasal inflammation	0	0	1	0	1	0
Nasal disorders NEC						
Epistaxis	0	0	17	0	17	0
Nasal disorder	0	0	1	0	1	0
Nasal mucosal disorder	0	0	1	0	1	0
Neonatal hypoxic conditions						
Cyanosis neonatal	0	0	1	0	1	0
Neonatal asphyxia	0	0	1	0	1	0

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MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Respiratory disorders cont'd						
SOC						
HLT						
PT						
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>						
Sinus congestion	0	0	1	0	1	0
<i>Parenchymal lung disorders NEC</i>						
Atelectasis	0	0	1	0	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>						
Allergic pharyngitis	0	0	1	0	1	0
Oropharyngeal spasm	0	0	1	0	1	0
Pharyngeal erythema	0	0	1	0	1	0
Pharyngeal oedema	0	0	8	0	8	0
Tonsillar disorder	0	0	4	0	4	0
Tonsillar hypertrophy	0	0	6	0	6	0
<i>Pleural infections and inflammations</i>						
Pleurisy	0	0	1	0	1	0
<i>Pulmonary oedemas</i>						
Pulmonary oedema	0	0	1	0	1	0
<i>Pulmonary thrombotic and embolic conditions</i>						
Pulmonary embolism	0	0	1	0	1	0
<i>Respiratory signs and symptoms NEC</i>						
Diaphragmalgia	0	0	1	0	1	0
Painful respiration	0	0	1	0	1	0
Respiration abnormal	0	0	4	0	4	0
Suffocation feeling	0	0	2	0	2	0
<i>Respiratory tract disorders NEC</i>						
Lung disorder	0	0	1	0	1	0
Pulmonary mass	0	0	1	0	1	0
Respiratory disorder	0	0	1	0	1	0
Respiratory tract irritation	0	0	1	0	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>						
Tracheal disorder	0	0	1	0	1	0
<i>Upper respiratory tract signs and symptoms</i>						
Choking sensation	0	0	1	0	1	0
Chronic throat clearing	0	0	2	0	2	0
Dry throat	0	0	2	0	2	0
Dysphonia	0	0	12	0	12	0
Increased upper airway secretion	0	0	2	0	2	0
Oropharyngeal pain	0	0	44	0	44	0
Rhinorrhoea	0	0	15	0	15	0
Sneezing	0	0	1	0	1	0
Snoring	0	0	1	0	1	0
Throat irritation	0	0	3	0	3	0
Throat tightness	0	0	7	0	7	0
Respiratory disorders SOC TOTAL	2	0	432	0	434	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Skin disorders						
Acnes						
Acne	2	0	67	0	69	0
Acne conglobata	0	0	1	0	1	0
Acne cystic	0	0	1	0	1	0
Dermatitis acneiform	0	0	1	0	1	0
Alopecias						
Alopecia	1	0	72	0	73	0
Alopecia areata	0	0	3	0	3	0
Madarosis	0	0	2	0	2	0
Angioedemas						
Angioedema	0	0	5	0	5	0
Swelling face	0	0	20	0	20	0
Apocrine and eccrine gland disorders						
Cold sweat	0	0	42	0	42	0
Hyperhidrosis	1	0	70	0	71	0
Hypohidrosis	0	0	1	0	1	0
Night sweats	0	0	15	0	15	0
Bullous conditions						
Blister	0	0	2	0	2	0
Dermatitis bullous	0	0	2	0	2	0
Erythema multiforme	0	0	1	0	1	0
Pemphigus	0	0	1	0	1	0
Stevens-Johnson syndrome	0	0	1	0	1	0
Dermal and epidermal conditions NEC						
Dry skin	1	0	25	0	26	0
Pain of skin	0	0	8	0	8	0
Papule	0	0	2	0	2	0
Scab	0	0	1	0	1	0
Skin burning sensation	0	0	8	0	8	0
Skin discolouration	0	0	18	0	18	0
Skin disorder	0	0	11	0	11	0
Skin odour abnormal	0	0	3	0	3	0
Skin reaction	0	0	2	0	2	0
Skin swelling	0	0	3	0	3	0
Skin tightness	0	0	1	0	1	0
Skin warm	0	0	2	0	2	0
Yellow skin	0	0	1	0	1	0
Dermatitis and eczema						
Dermatitis	0	0	6	0	6	0
Dermatitis allergic	0	0	7	0	7	0
Dermatitis atopic	0	0	77	0	77	0

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MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Skin disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Dermatitis contact	0	0	4	0	4	0
Eczema	0	0	66	0	66	0
Eczema asteatotic	0	0	8	0	8	0
Eczema infantile	0	0	1	0	1	0
Seborrhoeic dermatitis	0	0	1	0	1	0
Skin irritation	0	0	5	0	5	0
Erythemas						
Erythema	0	0	45	0	45	0
Generalised erythema	0	0	3	0	3	0
Plantar erythema	0	0	1	0	1	0
Rash erythematous	0	0	1	0	1	0
Exfoliative conditions						
Exfoliative rash	0	0	1	0	1	0
Skin exfoliation	0	0	8	0	8	0
Hyperkeratoses						
Keratosis pilaris	0	0	1	0	1	0
Hyperpigmentation disorders						
Skin hyperpigmentation	0	0	2	0	2	0
Solar lentigo	0	0	2	0	2	0
Hypertrichoses						
Hypertrichosis	0	0	1	0	1	0
Hypopigmentation disorders						
Skin depigmentation	0	0	2	0	2	0
Skin hypopigmentation	0	0	2	0	2	0
Lipodystrophies						
Lipohypertrophy	0	0	1	0	1	0
Nail and nail bed conditions (excl infections and infestations)						
Nail bed disorder	0	0	1	0	1	0
Nail discolouration	0	0	4	0	4	0
Nail disorder	0	0	3	0	3	0
Nail growth abnormal	0	0	1	0	1	0
Onychoclasia	0	0	1	0	1	0
Panniculitides						
Erythema nodosum	0	0	3	0	3	0
Papulosquamous conditions						
Pityriasis rosea	0	0	5	0	5	0
Rash papulosquamous	0	0	1	0	1	0
Photosensitivity and photodermatosis conditions						
Photosensitivity reaction	0	0	8	0	8	0
Solar dermatitis	0	0	4	0	4	0
Pigmentation changes NEC						
Pigmentation disorder	0	0	2	0	2	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Skin disorders cont'd						
SOC						
<i>HLT</i>						
PT						
<i>Pilar disorders NEC</i>						
Hair colour changes	0	0	1	0	1	0
Hair disorder	0	0	2	0	2	0
Hair growth abnormal	0	0	5	0	5	0
Hair texture abnormal	0	0	9	0	9	0
Trichorrhexis	0	0	2	0	2	0
<i>Pruritus NEC</i>						
Pruritus	1	0	62	0	63	0
Pruritus generalised	0	0	6	0	6	0
Rash pruritic	0	0	34	0	34	0
<i>Psoriatic conditions</i>						
Psoriasis	0	0	7	0	7	0
Pustular psoriasis	0	0	1	0	1	0
<i>Purpura and related conditions</i>						
Chronic pigmented purpura	0	0	1	0	1	0
Ecchymosis	0	0	2	0	2	0
Henoch-Schonlein purpura	0	0	5	0	5	0
Petechiae	0	0	5	0	5	0
<i>Rashes, eruptions and exanthems NEC</i>						
Rash	0	0	88	0	88	0
Rash generalised	0	0	16	0	16	0
Rash macular	0	0	4	0	4	0
Rash maculo-papular	0	0	4	0	4	0
Rash papular	0	0	6	0	6	0
Rash vesicular	0	0	5	0	5	0
<i>Rosaceas</i>						
Rosacea	0	0	1	0	1	0
<i>Sebaceous gland disorders</i>						
Seborrhoea	0	0	2	0	2	0
<i>Skin and subcutaneous conditions NEC</i>						
Skin mass	0	0	2	0	2	0
<i>Skin and subcutaneous tissue ulcerations</i>						
Skin ulcer	0	0	3	0	3	0
<i>Skin dystrophies</i>						
Skin wrinkling	0	0	3	0	3	0
<i>Skin haemorrhages</i>						
Skin haemorrhage	0	0	4	0	4	0
<i>Skin hypoplasias and atrophies</i>						
Skin atrophy	0	0	1	0	1	0
Skin striae	0	0	8	0	8	0
<i>Skin vasculitides</i>						
Hypersensitivity vasculitis	0	0	1	0	1	0

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MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Skin disorders cont'd						
SOC						
HLT						
PT						
<i>Skin vasomotor conditions</i>						
Livedo reticularis	0	0	2	0	2	0
<i>Urticarias</i>						
Mechanical urticaria	0	0	1	0	1	0
Urticaria	1	0	104	0	105	0
Urticaria chronic	0	0	3	0	3	0
Urticaria contact	0	0	1	0	1	0
Urticaria papular	0	0	1	0	1	0
Urticaria thermal	0	0	1	0	1	0
Skin disorders SOC TOTAL	7	0	1073	0	1080	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Social circumstances						
Disability issues						
Activities of daily living impaired	1	0	9	0	10	0
Bedridden	0	0	3	0	3	0
Disability	0	0	2	0	2	0
Impaired driving ability	0	0	1	0	1	0
Impaired work ability	0	0	6	0	6	0
Learning disability	0	0	10	0	10	0
Mental disability	0	0	1	0	1	0
Physical disability	0	0	2	0	2	0
Sight disability	0	0	1	0	1	0
Walking aid user	0	0	1	0	1	0
Walking disability	0	0	4	0	4	0
Wheelchair user	0	0	6	0	6	0
Social issues NEC						
Exercise lack of	0	0	1	0	1	0
Social problem	0	0	3	0	3	0
Social circumstances SOC TOTAL	1	0	50	0	51	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	29-Oct-2015	Report origin:	DENMARK
Data lock date:	28-Oct-2015 19:00:11	Route of admin:	ALL
Period covered:	01-Jan-1968 to 28-Oct-2015	Reporter type:	ALL
Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Surgical & medical procedures						
Cardiac device therapeutic procedures						
Cardiac pacemaker insertion	0	0	2	0	2	0
Cervix therapeutic procedures						
Cervical conisation	0	0	2	0	2	0
Fallopian tube therapeutic procedures						
Salpingectomy	0	0	1	0	1	0
Gastrointestinal therapeutic procedures NEC						
Gastrointestinal surgery	0	0	1	0	1	0
Haematological therapeutic procedures NEC						
Bone marrow transplant	0	0	2	0	2	0
Joint therapeutic procedures						
Ankle operation	0	0	1	0	1	0
Ligament operation	0	0	1	0	1	0
Large intestine therapeutic procedures						
Appendectomy	0	0	1	0	1	0
Colostomy	0	0	1	0	1	0
Limb therapeutic procedures						
Limb operation	0	0	1	0	1	0
Lymphoid tissue therapeutic procedures						
Lymphadenectomy	0	0	1	0	1	0
Splenectomy	0	0	1	0	1	0
Thymectomy	0	0	1	0	1	0
Nasal therapeutic procedures						
Nasal cavity packing	0	0	1	0	1	0
Obstetric therapeutic procedures						
Caesarean section	0	0	1	0	1	0
Small intestine therapeutic procedures						
Small intestinal resection	0	0	1	0	1	0
Small intestine operation	0	0	1	0	1	0
Tendon therapeutic procedures						
Tendon sheath lesion excision	0	0	1	0	1	0
Therapeutic procedures NEC						
Infusion	0	0	1	0	1	0
Thyroid therapeutic procedures						
Thyroid nodule removal	0	0	1	0	1	0
Tonsillar therapeutic procedures						
Adenoidectomy	0	0	1	0	1	0
Tonsillectomy	0	0	3	0	3	0
Surgical & medical procedures SOC TOTAL	0	0	27	0	27	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Vascular disorders						
Blood pressure disorders NEC						
Blood pressure fluctuation	0	0	5	0	5	0
Labile blood pressure	0	0	2	0	2	0
Circulatory collapse and shock						
Peripheral circulatory failure	0	0	1	0	1	0
Shock	0	0	1	0	1	0
Haemorrhages NEC						
Haematoma	0	0	1	0	1	0
Haemorrhage	0	0	1	0	1	0
Lymphoedemas						
Lymphoedema	0	0	1	0	1	0
Non-site specific vascular disorders NEC						
Angiopathy	0	0	1	0	1	0
Arterial disorder	0	0	1	0	1	0
Hyperaemia	0	0	1	0	1	0
Vascular pain	0	0	1	0	1	0
Vasodilatation	0	0	1	0	1	0
Peripheral vascular disorders NEC						
Flushing	0	0	5	0	5	0
Hot flush	0	0	45	0	45	0
Peripheral vascular disorder	0	0	1	0	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency						
Peripheral coldness	0	0	87	0	87	0
Raynaud's phenomenon	0	0	7	0	7	0
Site specific vascular disorders NEC						
Pallor	0	0	24	0	24	0
Varicose veins non-site specific						
Varicose vein	0	0	1	0	1	0
Vascular hypertensive disorders NEC						
Hypertension	0	0	7	0	7	0
Vascular hypotensive disorders						
Hypotension	1	0	38	0	39	0
Orthostatic hypotension	0	0	20	0	20	0
Vasculitides NEC						
Granulomatosis with polyangiitis	0	0	1	0	1	0
Polyarteritis nodosa	0	0	1	0	1	0
Vasculitis	0	0	1	0	1	0
Vascular disorders SOC TOTAL	1	0	255	0	256	0
TOTAL NUMBER OF REACTIONS	114	0	13803	2	13917	2

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TOTAL NUMBER OF FATAL ADR REPORTS*		0		2		2*
TOTAL NUMBER OF ADR REPORTS*	13		1903		1916*	

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