

Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

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Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	01-Jul-2015	Report origin:	DENMARK
Data lock date:	30-Jun-2015 19:00:15	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Jun-2015	Reporter type:	ALL
Earliest reaction date:	07-Feb-2006	Reaction:	ALL
MedDRA version:	MedDRA 18.0	Age group:	ALL

Total number of reactions*:	9742	Total number of ADR reports:	1601	Total number of fatal ADR reports:	2
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Products included in this print - Multi active constituent products (PBGs):	
CERVARIX GARDASIL	NONVALENT HPV L1 VLP VACCINE (V503) 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	80	0	80	0
Cardiac disorders	0	0	213	0	213	0
Congenital disorders	0	0	12	2	12	2
Ear disorders	0	0	138	0	138	0
Endocrine disorders	0	0	13	0	13	0
Eye disorders	0	0	338	0	338	0
Gastrointestinal disorders	7	0	879	0	886	0
General disorders	9	0	1472	0	1481	0
Hepatic disorders	0	0	7	0	7	0
Immune system disorders	0	0	85	0	85	0
Infections	1	0	203	0	204	0
Injuries	0	0	88	0	88	0
Investigations	5	0	175	0	180	0
Metabolic disorders	1	0	97	0	98	0
Muscle & tissue disorders	5	0	1096	0	1101	0
Neoplasms	0	0	13	0	13	0
Nervous system disorders	12	0	2747	0	2759	0
Pregnancy conditions	0	0	12	0	12	0
Psychiatric disorders	0	0	425	0	425	0
Renal & urinary disorders	0	0	82	0	82	0
Reproductive & breast disorders	0	0	187	0	187	0
Respiratory disorders	1	0	282	0	283	0
Skin disorders	2	0	832	0	834	0
Social circumstances	0	0	30	0	30	0
Surgical & medical procedures	0	0	18	0	18	0
Vascular disorders	1	0	174	0	175	0

TOTAL NUMBER OF REACTIONS	44	0	9698	2	9742	2
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TOTAL NUMBER OF FATAL ADR REPORTS*		0		2		2*
TOTAL NUMBER OF ADR REPORTS*	8		1593		1601*	

*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						
HLT						
PT						
Blood disorders						
Anaemia deficiencies						
Iron deficiency anaemia	0	0	1	0	1	0
Pernicious anaemia	0	0	2	0	2	0
Anaemias NEC						
Anaemia	0	0	1	0	1	0
Anaemias haemolytic NEC						
Haemolytic anaemia	0	0	1	0	1	0
Bleeding tendencies						
Increased tendency to bruise	0	0	5	0	5	0
Coagulopathies						
Antiphospholipid syndrome	0	0	1	0	1	0
Leukopenias NEC						
Leukopenia	0	0	1	0	1	0
Lymphatic system disorders NEC						
Lymph node pain	0	0	7	0	7	0
Lymphadenitis	0	0	3	0	3	0
Lymphadenopathy	0	0	45	0	45	0
Marrow depression and hypoplastic anaemias						
Aplastic anaemia	0	0	2	0	2	0
Thrombocytopenias						
Immune thrombocytopenic purpura	0	0	6	0	6	0
Thrombocytopenia	0	0	4	0	4	0
Thrombocytopenic purpura	0	0	1	0	1	0
Blood disorders SOC TOTAL	0	0	80	0	80	0

*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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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						
Cardiovascular disorder	0	0	1	0	1	0
Cardiac signs and symptoms NEC						
Cardiac discomfort	0	0	1	0	1	0
Cyanosis	0	0	3	0	3	0
Palpitations	0	0	129	0	129	0
Ischaemic coronary artery disorders						
Angina pectoris	0	0	5	0	5	0
Noninfectious pericarditis						
Pericarditis	0	0	1	0	1	0
Rate and rhythm disorders NEC						
Arrhythmia	0	0	5	0	5	0
Bradycardia	0	0	3	0	3	0
Extrasystoles	0	0	1	0	1	0
Postural orthostatic tachycardia syndrome	0	0	56	0	56	0
Tachycardia	0	0	4	0	4	0
Supraventricular arrhythmias						
Atrial tachycardia	0	0	1	0	1	0
Supraventricular tachycardia	0	0	1	0	1	0
Cardiac disorders SOC TOTAL	0	0	213	0	213	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
Central nervous system disorders congenital NEC						
Meningomyelocele	0	0	1	0	1	0
Syringomyelia	0	0	2	0	2	0
Diaphragmatic disorders congenital						
Congenital diaphragmatic hernia	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
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	12	2	12	2

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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						
Ear disorders						
<i>Ear disorders NEC</i>						
Ear discomfort	0	0	8	0	8	0
Ear disorder	0	0	1	0	1	0
Ear pain	0	0	16	0	16	0
Ear pruritus	0	0	1	0	1	0
<i>Hearing disorders NEC</i>						
Dysacusis	0	0	1	0	1	0
<i>Hearing losses</i>						
Deafness	0	0	1	0	1	0
Deafness neurosensory	0	0	1	0	1	0
Deafness transitory	0	0	1	0	1	0
Deafness unilateral	0	0	2	0	2	0
Hearing impaired	0	0	10	0	10	0
Hypoacusis	0	0	6	0	6	0
Sudden hearing loss	0	0	1	0	1	0
<i>Hyperacusia</i>						
Hyperacusis	0	0	38	0	38	0
<i>Inner ear disorders NEC</i>						
Meniere's disease	0	0	1	0	1	0
<i>Inner ear signs and symptoms</i>						
Motion sickness	0	0	2	0	2	0
Tinnitus	0	0	39	0	39	0
Vertigo	0	0	8	0	8	0
Vertigo positional	0	0	1	0	1	0
Ear disorders SOC TOTAL	0	0	138	0	138	0

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	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
<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
<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	0	0	13	0	13	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						
Eye disorders						
<i>Blindness (excl colour blindness)</i>						
Blindness	0	0	1	0	1	0
Blindness transient	0	0	3	0	3	0
Night blindness	0	0	1	0	1	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	1	0	1	0
<i>Lacrimation disorders</i>						
Dry eye	0	0	3	0	3	0
Lacrimation increased	0	0	4	0	4	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>						
Eyelid oedema	0	0	5	0	5	0
<i>Ocular disorders NEC</i>						
Dark circles under eyes	0	0	2	0	2	0
Eye disorder	0	0	1	0	1	0
Eye oedema	0	0	1	0	1	0
Eye pain	0	0	23	0	23	0
Eye swelling	0	0	10	0	10	0
Eyelid pain	0	0	1	0	1	0
Ocular discomfort	0	0	3	0	3	0
Ocular icterus	0	0	1	0	1	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	3	0	3	0
Eye pruritus	0	0	3	0	3	0
Ocular hyperaemia	0	0	5	0	5	0
<i>Ocular nerve and muscle disorders</i>						
Eye movement disorder	0	0	3	0	3	0
Heterophoria	0	0	1	0	1	0
<i>Ocular sensation disorders</i>						
Abnormal sensation in eye	0	0	1	0	1	0
Photophobia	0	0	54	0	54	0
<i>Optic disc abnormalities NEC</i>						
Papilloedema	0	0	2	0	2	0
<i>Partial vision loss</i>						

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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						
Visual acuity reduced	0	0	13	0	13	0
Pupil disorders						
Mydriasis	0	0	3	0	3	0
Pupils unequal	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	0	0	9	0	9	0
Photopsia	0	0	3	0	3	0
Vision blurred	0	0	49	0	49	0
Visual impairment	0	0	112	0	112	0
Eye disorders SOC TOTAL	0	0	338	0	338	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Gastrointestinal disorders						
Abdominal findings abnormal						
Gastrointestinal sounds abnormal	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	1	0	1	0
Dental pain and sensation disorders						
Toothache	0	0	12	0	12	0
Diarrhoea (excl infective)						
Diarrhoea	0	0	40	0	40	0
Diarrhoea haemorrhagic	0	0	1	0	1	0
Dyspeptic signs and symptoms						
Dyspepsia	0	0	11	0	11	0
Eructation	0	0	1	0	1	0
Faecal abnormalities NEC						
Abnormal faeces	0	0	2	0	2	0
Faeces discoloured	0	0	1	0	1	0
Faeces hard	0	0	1	0	1	0
Flatulence, bloating and distension						
Abdominal distension	0	0	18	0	18	0
Flatulence	0	0	1	0	1	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	2	0	132	0	134	0
Abdominal pain lower	0	0	18	0	18	0
Abdominal pain upper	2	0	68	0	70	0
Gastrointestinal pain	0	0	4	0	4	0
Gastrointestinal atonic and hypomotility disorders NEC						
Constipation	0	0	24	0	24	0
Gastrooesophageal reflux disease	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
Gastrointestinal disorders cont'd						
SOC						
HLT						
PT						
Impaired gastric emptying	0	0	1	0	1	0
Gastrointestinal disorders NEC						
Functional gastrointestinal disorder	0	0	3	0	3	0
Gastrointestinal disorder	0	0	5	0	5	0
Gastrointestinal dyskinetic disorders						
Change of bowel habit	0	0	1	0	1	0
Gastrointestinal motility disorder	0	0	1	0	1	0
Gastrointestinal inflammatory disorders NEC						
Gastrointestinal tract irritation	0	0	1	0	1	0
Gastrointestinal signs and symptoms NEC						
Abdominal discomfort	0	0	13	0	13	0
Abdominal symptom	0	0	2	0	2	0
Breath odour	0	0	3	0	3	0
Dysphagia	0	0	10	0	10	0
Gastrointestinal spastic and hypermotility disorders						
Defaecation urgency	0	0	1	0	1	0
Irritable bowel syndrome	0	0	4	0	4	0
Gingival haemorrhages						
Gingival bleeding	0	0	3	0	3	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)						
Haemorrhoids	0	0	2	0	2	0
Intestinal haemorrhages						
Rectal haemorrhage	0	0	1	0	1	0
Malabsorption syndromes						
Coeliac disease	0	0	11	0	11	0
Nausea and vomiting symptoms						
Nausea	3	0	310	0	313	0
Vomiting	0	0	91	0	91	0
Vomiting projectile	0	0	1	0	1	0
Non-site specific gastrointestinal haemorrhages						
Haematemesis	0	0	2	0	2	0
Haematochezia	0	0	7	0	7	0
Oral dryness and saliva altered						
Dry mouth	0	0	6	0	6	0
Salivary hypersecretion	0	0	2	0	2	0
Oral soft tissue disorders NEC						
Cheilitis	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

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	01-Jul-2015	Report origin:	DENMARK
Data lock date:	30-Jun-2015 19:00:15	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Jun-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
Reaction Name Gastrointestinal disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Odynophagia	0	0	1	0	1	0
Oral pain	0	0	1	0	1	0
Paraesthesia oral	0	0	9	0	9	0
Oral soft tissue signs and symptoms						
Hypoaesthesia oral	0	0	4	0	4	0
Oral discomfort	0	0	1	0	1	0
Oral mucosal blistering	0	0	7	0	7	0
Oral mucosal eruption	0	0	1	0	1	0
Oral soft tissue swelling and oedema						
Lip swelling	0	0	3	0	3	0
Mouth swelling	0	0	2	0	2	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	2	0	2	0
Stomatitis	0	0	2	0	2	0
Tongue disorders						
Tongue ulceration	0	0	1	0	1	0
Tongue signs and symptoms						
Swollen tongue	0	0	4	0	4	0
Tongue coated	0	0	2	0	2	0
Gastrointestinal disorders SOC TOTAL	7	0	879	0	886	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

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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						
General disorders						
<i>Application and instillation site reactions</i>						
Application site erythema	0	0	1	0	1	0
<i>Asthenic conditions</i>						
Asthenia	0	0	72	0	72	0
Chronic fatigue syndrome	0	0	6	0	6	0
Decreased activity	0	0	2	0	2	0
Fatigue	4	0	409	0	413	0
Malaise	3	0	121	0	124	0
Sluggishness	0	0	1	0	1	0
<i>Body temperature altered</i>						
Temperature regulation disorder	0	0	7	0	7	0
<i>Device malfunction events NEC</i>						
Undersensing	0	0	1	0	1	0
<i>Febrile disorders</i>						
Pyrexia	0	0	152	0	152	0
<i>Feelings and sensations NEC</i>						
Chills	0	0	18	0	18	0
Feeling abnormal	0	0	17	0	17	0
Feeling cold	0	0	22	0	22	0
Feeling drunk	0	0	2	0	2	0
Feeling hot	0	0	13	0	13	0
Feeling of body temperature change	0	0	9	0	9	0
Hunger	0	0	2	0	2	0
Sensation of foreign body	0	0	3	0	3	0
Sense of oppression	0	0	2	0	2	0
Temperature intolerance	0	0	6	0	6	0
Thirst	0	0	9	0	9	0
<i>Gait disturbances</i>						
Abasia	0	0	1	0	1	0
Gait disturbance	0	0	35	0	35	0
<i>General signs and symptoms NEC</i>						
Condition aggravated	0	0	3	0	3	0
Crying	0	0	5	0	5	0
Exercise tolerance decreased	0	0	11	0	11	0
Foaming at mouth	0	0	1	0	1	0
General physical health deterioration	0	0	4	0	4	0
General symptom	0	0	1	0	1	0
Induration	0	0	1	0	1	0
Influenza like illness	0	0	68	0	68	0
Local reaction	0	0	1	0	1	0
Local swelling	0	0	2	0	2	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

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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
General disorders cont'd						
SOC						
HLT						
PT						
Peripheral swelling	0	0	27	0	27	0
Secretion discharge	0	0	2	0	2	0
Swelling	0	0	7	0	7	0
Healing abnormal NEC						
Impaired healing	0	0	1	0	1	0
Inflammations						
Inflammation	0	0	4	0	4	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	22	0	22	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	1	0	1	0
Injection site nodule	0	0	6	0	6	0
Injection site pain	0	0	35	0	35	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	1	0	1	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	1	0	1	0
Localised oedema	0	0	2	0	2	0
Oedema	0	0	4	0	4	0
Oedema peripheral	0	0	6	0	6	0
Pain and discomfort NEC						
Chest discomfort	0	0	26	0	26	0

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Drug Analysis Print
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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
<i>General disorders cont'd</i>						
SOC						
HLT						
PT						
Chest pain	0	0	66	0	66	0
Discomfort	0	0	19	0	19	0
Facial pain	0	0	2	0	2	0
Non-cardiac chest pain	0	0	1	0	1	0
Pain	1	0	101	0	102	0
Tenderness	1	0	9	0	10	0
Therapeutic and nontherapeutic responses						
Adverse event	0	0	1	0	1	0
Drug ineffective	0	0	1	0	1	0
Drug intolerance	0	0	1	0	1	0
Trophic disorders						
Dysplasia	0	0	1	0	1	0
Vaccination site reactions						
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	6	0	6	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	1	0	1	0
Vaccination site pain	0	0	11	0	11	0
Vaccination site pruritus	0	0	2	0	2	0
Vaccination site rash	0	0	1	0	1	0
Vaccination site reaction	0	0	2	0	2	0
Vaccination site swelling	0	0	8	0	8	0
Vaccination site warmth	0	0	2	0	2	0
General disorders SOC TOTAL	9	0	1472	0	1481	0

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Drug Analysis Print
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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						
Cholestasis and jaundice						
Jaundice	0	0	1	0	1	0
Hepatic and hepatobiliary disorders NEC						
Liver disorder	0	0	3	0	3	0
Hepatobiliary signs and symptoms						
Hepatomegaly	0	0	1	0	1	0
Hepatocellular damage and hepatitis NEC						
Autoimmune hepatitis	0	0	1	0	1	0
Liver injury	0	0	1	0	1	0
Hepatic disorders SOC TOTAL	0	0	7	0	7	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	1	0	1	0
Allergy to metals	0	0	3	0	3	0
Allergy to plants	0	0	1	0	1	0
Hypersensitivity	0	0	37	0	37	0
Allergies to foods, food additives, drugs and other chemicals						
Drug hypersensitivity	0	0	2	0	2	0
Food allergy	0	0	7	0	7	0
Perfume sensitivity	0	0	2	0	2	0
Reaction to drug excipients	0	0	1	0	1	0
Anaphylactic responses						
Anaphylactic reaction	0	0	2	0	2	0
Anaphylactic shock	0	0	8	0	8	0
Atopic disorders						
House dust allergy	0	0	1	0	1	0
Seasonal allergy	0	0	2	0	2	0
Autoimmune disorders NEC						
Autoimmune disorder	0	0	4	0	4	0
Immune and associated conditions NEC						
Decreased immune responsiveness	0	0	5	0	5	0
Immune system disorder	0	0	6	0	6	0
Immunodeficiency disorders NEC						
Immunodeficiency	0	0	1	0	1	0
Immunosuppression	0	0	1	0	1	0
Immune system disorders SOC TOTAL	0	0	85	0	85	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						
Infections						
Abdominal and gastrointestinal infections						
Abdominal infection	0	0	1	0	1	0
Appendicitis	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	2	0	2	0
Bone and joint infections						
Arthritis infective	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	3	0	3	0
Periodontitis	0	0	1	0	1	0
Ear infections						
Ear infection	0	0	2	0	2	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	3	0	3	0
Eye and eyelid infections						
Chorioretinitis	0	0	1	0	1	0
Conjunctivitis	0	0	5	0	5	0
Eye infection	0	0	1	0	1	0
Hordeolum	0	0	2	0	2	0
Female reproductive tract infections						
Pelvic inflammatory disease	0	0	2	0	2	0
Vaginal 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						
Fungal infections NEC						
Fungal infection	0	0	3	0	3	0
Fungal skin infection	0	0	1	0	1	0
Vulvovaginal mycotic infection	0	0	4	0	4	0
Herpes viral infections						
Genital herpes	0	0	1	0	1	0
Herpes simplex	0	0	1	0	1	0
Herpes virus infection	0	0	1	0	1	0
Herpes zoster	0	0	12	0	12	0
Oral herpes	0	0	3	0	3	0
Infections NEC						
Abscess	0	0	1	0	1	0
Infection	1	0	36	0	37	0
Infection susceptibility increased	0	0	2	0	2	0
Injection site abscess	0	0	2	0	2	0
Injection site 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	18	0	18	0
Lower respiratory tract and lung infections						
Pneumonia	0	0	6	0	6	0
Mycoplasma infections						
Pneumonia mycoplasmal	0	0	1	0	1	0
Skin structures and soft tissue infections						
Impetigo	0	0	1	0	1	0
Skin infection	0	0	2	0	2	0
Subcutaneous abscess	0	0	1	0	1	0
Streptococcal infections						
Pharyngitis streptococcal	0	0	1	0	1	0
Streptococcal infection	0	0	1	0	1	0
Upper respiratory tract infections						
Chronic sinusitis	0	0	1	0	1	0
Nasopharyngitis	0	0	12	0	12	0
Pharyngitis	0	0	11	0	11	0
Rhinitis	0	0	1	0	1	0
Sinusitis	0	0	4	0	4	0
Tonsillitis	0	0	3	0	3	0
Urinary tract infections						
Cystitis	0	0	11	0	11	0
Urinary tract infection	0	0	4	0	4	0
Viral infections NEC						

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Infections cont'd						
SOC						
<i>HLT</i>						
PT						
Post viral fatigue syndrome	0	0	3	0	3	0
Vestibular neuronitis	0	0	3	0	3	0
Viral infection	0	0	3	0	3	0
Infections SOC TOTAL	1	0	203	0	204	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						
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	9	0	9	0
Maternal exposure before pregnancy	0	0	3	0	3	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	1	0	1	0
Non-site specific injuries NEC						
Fall	0	0	14	0	14	0
Injury	0	0	1	0	1	0
Wound	0	0	3	0	3	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	1	0	1	0
Product use issues NEC						
Drug administered to patient of inappropriate age	0	0	1	0	1	0
Skin injuries NEC						
Contusion	0	0	18	0	18	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						
Scar	0	0	1	0	1	0
Skin wound	0	0	1	0	1	0
Underdoses NEC						
Underdose	0	0	3	0	3	0
Vaccination related complications						
Vaccination complication	0	0	1	0	1	0
Injuries SOC TOTAL	0	0	88	0	88	0

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Drug Analysis Print
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Report run date:	01-Jul-2015	Report origin:	DENMARK
Data lock date:	30-Jun-2015 19:00:15	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Jun-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						
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	2	0	2	0
Blood glucose increased	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	0	0	5	0	5	0
Gastrointestinal function diagnostic procedures						
Gastric pH decreased	0	0	3	0	3	0
Haematological analyses NEC						
Red blood cell sedimentation rate increased	0	0	1	0	1	0
Heart rate and pulse investigations						
Heart rate decreased	1	0	3	0	4	0
Heart rate increased	0	0	53	0	53	0
Heart rate irregular	0	0	10	0	10	0
Orthostatic heart rate response increased	0	0	1	0	1	0
Pulse abnormal	0	0	1	0	1	0
Investigations NEC						
Quality of life decreased	2	0	5	0	7	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
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
Body temperature abnormal	0	0	1	0	1	0
Body temperature decreased	0	0	1	0	1	0
Body temperature fluctuation	0	0	7	0	7	0
Lymph node palpable	0	0	2	0	2	0
Weight abnormal	0	0	1	0	1	0
Weight decreased	1	0	34	0	35	0
Weight increased	0	0	13	0	13	0
Protein analyses NEC						
C-reactive protein increased	0	0	1	0	1	0

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Drug Analysis Print
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MedDRA version:	MedDRA 18.0	Age group:	ALL

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						
<i>Red blood cell analyses</i>						
Haemoglobin decreased	0	0	2	0	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>						
Pulmonary function test decreased	0	0	1	0	1	0
Total lung capacity decreased	0	0	1	0	1	0
<i>Urinalysis NEC</i>						
Blood urine present	0	0	3	0	3	0
<i>Vascular tests NEC (incl blood pressure)</i>						
Blood pressure decreased	0	0	4	0	4	0
<i>Vitamin analyses</i>						
Vitamin D decreased	0	0	1	0	1	0
<i>White blood cell analyses</i>						
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	3	0	3	0
Investigations SOC TOTAL	5	0	175	0	180	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						
Metabolic disorders						
<i>Appetite disorders</i>						
Appetite disorder	0	0	2	0	2	0
Decreased appetite	1	0	29	0	30	0
Hyperphagia	0	0	1	0	1	0
Increased appetite	0	0	1	0	1	0
Lack of satiety	0	0	2	0	2	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	7	0	7	0
<i>Fluid intake increased</i>						
Polydipsia	0	0	1	0	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>						
Alcohol intolerance	0	0	4	0	4	0
Cow's milk intolerance	0	0	1	0	1	0
Food intolerance	0	0	8	0	8	0
Histamine 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	1	0	1	0
Weight fluctuation	0	0	1	0	1	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 disorders NEC</i>						
Metabolic disorder	0	0	3	0	3	0
<i>Potassium imbalance</i>						
Hypokalaemia	0	0	1	0	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>						
Fructose intolerance	0	0	1	0	1	0
Lactose intolerance	0	0	7	0	7	0
<i>Total fluid volume decreased</i>						
Dehydration	0	0	2	0	2	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
Metabolic disorders cont'd						
SOC						
HLT						
PT						
Total fluid volume increased						
Fluid retention	0	0	3	0	3	0
Vitamin deficiencies NEC						
Hypovitaminosis	0	0	2	0	2	0
Water soluble vitamin deficiencies						
Vitamin B complex deficiency	0	0	1	0	1	0
Vitamin B12 deficiency	0	0	4	0	4	0
Metabolic disorders SOC TOTAL	1	0	97	0	98	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	9	0	9	0
Arthritis reactive	0	0	5	0	5	0
Arthropathy	0	0	6	0	6	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	1	0	1	0
Bone related signs and symptoms						
Bone pain	0	0	11	0	11	0
Coccydynia	0	0	2	0	2	0
Pain in jaw	0	0	11	0	11	0
Pubic pain	0	0	1	0	1	0
Spinal pain	0	0	3	0	3	0
Bursal disorders						
Bursitis	0	0	2	0	2	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 protrusion	0	0	2	0	2	0
Joint related disorders NEC						
Facet joint syndrome	0	0	1	0	1	0
Hypermobility syndrome	0	0	1	0	1	0
Joint contracture	0	0	1	0	1	0
Joint laxity	0	0	1	0	1	0
Joint lock	0	0	7	0	7	0
Periarthritis	0	0	1	0	1	0
Joint related signs and symptoms						
Arthralgia	0	0	202	0	202	0
Joint crepitation	0	0	3	0	3	0
Joint stiffness	0	0	5	0	5	0
Joint swelling	0	0	14	0	14	0
Joint warmth	0	0	1	0	1	0
Lupus erythematosus (incl subtypes)						
Systemic lupus erythematosus	0	0	3	0	3	0
Muscle infections and inflammations						
Myositis	0	0	2	0	2	0
Muscle pains						
Fibromyalgia	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						
Myalgia	1	0	152	0	153	0
Muscle related signs and symptoms NEC						
Muscle atrophy	0	0	1	0	1	0
Muscle disorder	0	0	2	0	2	0
Muscle fatigue	0	0	7	0	7	0
Muscle spasms	0	0	95	0	95	0
Muscle swelling	0	0	2	0	2	0
Muscle tightness	0	0	24	0	24	0
Muscle twitching	0	0	20	0	20	0
Muscle tone abnormalities						
Trismus	0	0	2	0	2	0
Muscle weakness conditions						
Muscular weakness	1	0	133	0	134	0
Musculoskeletal and connective tissue pain and discomfort						
Back pain	0	0	79	0	79	0
Growing pains	0	0	1	0	1	0
Limb discomfort	0	0	12	0	12	0
Musculoskeletal chest pain	0	0	4	0	4	0
Musculoskeletal discomfort	0	0	5	0	5	0
Musculoskeletal pain	0	0	23	0	23	0
Neck pain	0	0	42	0	42	0
Pain in extremity	3	0	132	0	135	0
Rheumatic disorder	0	0	1	0	1	0
Musculoskeletal and connective tissue signs and symptoms NEC						
Mastication disorder	0	0	1	0	1	0
Musculoskeletal stiffness	0	0	19	0	19	0
Winged scapula	0	0	1	0	1	0
Myopathies						
Mitochondrial myopathy acquired	0	0	1	0	1	0
Myopathy	0	0	2	0	2	0
Rheumatoid arthropathies						
Rheumatoid arthritis	0	0	3	0	3	0
Soft tissue disorders NEC						
Fistula	0	0	2	0	2	0
Fistula discharge	0	0	1	0	1	0
Groin pain	0	0	9	0	9	0
Spine and neck deformities						
Scoliosis	0	0	2	0	2	0
Tendon disorders						
Tendon laxity	0	0	1	0	1	0
Tendon pain	0	0	3	0	3	0
Tendonitis	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
Muscle & tissue disorders cont'd						
SOC						
HLT						
PT						
Tenosynovitis	0	0	1	0	1	0
Trunk deformities						
Shoulder deformity	0	0	1	0	1	0
Muscle & tissue disorders SOC TOTAL	5	0	1096	0	1101	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>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>Rhabdomyosarcomas</i>						
Rhabdomyosarcoma	0	0	1	0	1	0
<i>Skin neoplasms benign</i>						
Anogenital warts	0	0	5	0	5	0
Melanocytic naevus	0	0	1	0	1	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	13	0	13	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						
Nervous system disorders						
Abnormal reflexes						
Areflexia	0	0	2	0	2	0
Hyporeflexia	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	52	0	52	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	0	0	24	0	24	0
Coordination abnormal	0	0	7	0	7	0
Dysstasia	0	0	9	0	9	0
Cortical dysfunction NEC						
Aphasia	1	0	19	0	20	0
Dysgraphia	0	0	3	0	3	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	0	0	2	0	2	0
Depressed level of consciousness	0	0	5	0	5	0
Lethargy	0	0	2	0	2	0
Loss of consciousness	0	0	22	0	22	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						
Somnolence	0	0	12	0	12	0
Syncope	1	0	172	0	173	0
Dyskinesias and movement disorders NEC						
Clumsiness	0	0	2	0	2	0
Dyskinesia	0	0	18	0	18	0
Fine motor delay	0	0	1	0	1	0
Hyperkinesia	0	0	1	0	1	0
Hypokinesia	0	0	3	0	3	0
Movement disorder	0	0	4	0	4	0
Psychomotor hyperactivity	0	0	10	0	10	0
Tardive dyskinesia	0	0	1	0	1	0
Dystonias						
Dystonia	0	0	3	0	3	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	9	0	9	0
VIIIth nerve paralysis	0	0	4	0	4	0
Generalised tonic-clonic seizures						
Generalised tonic-clonic seizure	0	0	2	0	2	0
Headaches NEC						
Cluster headache	0	0	1	0	1	0
Cold-stimulus headache	0	0	1	0	1	0
Headache	3	0	505	0	508	0
Sinus headache	0	0	5	0	5	0
Tension headache	0	0	6	0	6	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	17	0	17	0
Memory impairment	0	0	128	0	128	0
Mental impairment (excl dementia and memory loss)						
Cognitive disorder	0	0	33	0	33	0
Disturbance in attention	3	0	184	0	187	0
Migraine headaches						

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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						
Migraine	0	0	79	0	79	0
Migraine with aura	0	0	11	0	11	0
Migraine without aura	0	0	1	0	1	0
Mononeuropathies						
Peroneal nerve palsy	0	0	1	0	1	0
Motor neurone diseases						
Motor neurone disease	0	0	1	0	1	0
Multiple sclerosis acute and progressive						
Multiple sclerosis	0	0	14	0	14	0
Uhthoff's phenomenon	0	0	1	0	1	0
Muscle tone abnormal						
Hypotonia	0	0	3	0	3	0
Myelitis (incl infective)						
Myelitis transverse	0	0	5	0	5	0
Narcolepsy and hypersomnia						
Cataplexy	0	0	4	0	4	0
Hypersomnia	0	0	21	0	21	0
Narcolepsy	0	0	4	0	4	0
Nervous system cysts and polyps						
Cerebral cyst	0	0	1	0	1	0
Nervous system disorders NEC						
Motor dysfunction	0	0	2	0	2	0
Nervous system disorder	1	0	3	0	4	0
Neurologic visual problems NEC						
Tunnel vision	0	0	2	0	2	0
Visual field defect	0	0	7	0	7	0
Neurological signs and symptoms NEC						
Dizziness	2	0	419	0	421	0
Dizziness postural	0	0	9	0	9	0
Head discomfort	0	0	15	0	15	0
Neurological symptom	0	0	10	0	10	0
Presyncope	0	0	69	0	69	0
Unresponsive to stimuli	0	0	1	0	1	0
Neuromuscular disorders NEC						
Muscle contractions involuntary	0	0	3	0	3	0
Neuromyopathy	0	0	1	0	1	0
Neuromuscular junction dysfunction						
Myasthenia gravis	0	0	2	0	2	0
Olfactory nerve disorders						
Anosmia	0	0	1	0	1	0
Parosmia	0	0	7	0	7	0
Optic nerve disorders NEC						

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	01-Jul-2015	Report origin:	DENMARK
Data lock date:	30-Jun-2015 19:00:15	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Jun-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
Nervous system disorders cont'd						
SOC						
HLT						
PT						
Optic neuritis	0	0	4	0	4	0
Paraesthesias and dysaesthesias						
Burning sensation	0	0	20	0	20	0
Dysaesthesia	0	0	10	0	10	0
Formication	0	0	1	0	1	0
Hyperaesthesia	0	0	9	0	9	0
Hypoaesthesia	0	0	101	0	101	0
Paraesthesia	0	0	144	0	144	0
Paralysis and paresis (excl cranial nerve)						
Diplegia	0	0	1	0	1	0
Gait spastic	0	0	1	0	1	0
Hemiparesis	0	0	3	0	3	0
Hemiplegia	0	0	4	0	4	0
Monoparesis	0	0	2	0	2	0
Monoplegia	0	0	3	0	3	0
Paralysis	0	0	26	0	26	0
Paresis	0	0	2	0	2	0
Spinal cord paralysis	0	0	1	0	1	0
Partial complex seizures						
Dreamy state	0	0	2	0	2	0
Peripheral neuropathies NEC						
Neuritis	0	0	2	0	2	0
Neuropathy peripheral	0	0	4	0	4	0
Seizures and seizure disorders NEC						
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	11	0	11	0
Idiopathic generalised epilepsy	0	0	1	0	1	0
Seizure	0	0	15	0	15	0
Sensory abnormalities NEC						
Allodynia	0	0	2	0	2	0
Complex regional pain syndrome	0	0	2	0	2	0
Dysgeusia	0	0	7	0	7	0
Neuralgia	0	0	23	0	23	0
Restless legs syndrome	0	0	5	0	5	0
Sensory disturbance	1	0	121	0	122	0
Sensory loss	0	0	12	0	12	0
Sleep disturbances NEC						
Poor quality sleep	0	0	11	0	11	0
Sudden onset of sleep	0	0	1	0	1	0
Speech and language abnormalities						

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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 Nervous system disorders cont'd						
SOC						
HLT						
PT						
Aphonia	0	0	2	0	2	0
Dysarthria	0	0	4	0	4	0
Dyslalia	0	0	2	0	2	0
Language disorder	0	0	1	0	1	0
Speech disorder	0	0	32	0	32	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	1	0	1	0
Transient cerebrovascular events						
Transient ischaemic attack	0	0	1	0	1	0
Tremor (excl congenital)						
Tremor	0	0	76	0	76	0
Trigeminal disorders						
Trigeminal neuralgia	0	0	1	0	1	0
Nervous system disorders SOC TOTAL	12	0	2747	0	2759	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						
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	7	0	7	0
<i>Gestational age and weight conditions</i>						
Premature baby	0	0	1	0	1	0
<i>Labour onset and length abnormalities</i>						
Prolonged rupture of membranes	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	12	0	12	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	2	0	2	0
Anxiety symptoms						
Anxiety	0	0	39	0	39	0
Nervousness	0	0	2	0	2	0
Stress	0	0	17	0	17	0
Tension	0	0	2	0	2	0
Behaviour and socialisation disturbances						
Aggression	0	0	2	0	2	0
Impatience	0	0	1	0	1	0
Personality change	0	0	3	0	3	0
Social avoidant behaviour	0	0	1	0	1	0
Cognitive and attention disorders and disturbances NEC						
Daydreaming	0	0	1	0	1	0
Distractibility	0	0	1	0	1	0
Confusion and disorientation						
Confusional state	0	0	30	0	30	0
Disorientation	0	0	5	0	5	0
Depressive disorders						
Depression	0	0	24	0	24	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	3	0	3	0
Disturbances in initiating and maintaining sleep						
Initial insomnia	0	0	5	0	5	0
Insomnia	0	0	62	0	62	0
Eating disorders NEC						
Food aversion	0	0	1	0	1	0
Emotional and mood disturbances NEC						
Anger	0	0	3	0	3	0
Emotional disorder	0	0	1	0	1	0
Irritability	0	0	9	0	9	0
Mood altered	0	0	1	0	1	0
Fear symptoms and phobic disorders (incl social phobia)						
Claustrophobia	0	0	2	0	2	0
Fear of falling	0	0	2	0	2	0
Phonophobia	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
Psychiatric disorders cont'd						
SOC						
HLT						
PT						
Social fear	0	0	1	0	1	0
Fluctuating mood symptoms						
Mood swings	0	0	36	0	36	0
Increased physical activity levels						
Restlessness	0	0	31	0	31	0
Learning disorders						
Learning disorder	0	0	1	0	1	0
Reading disorder	0	0	2	0	2	0
Mental disorders NEC						
Mental disorder	0	0	6	0	6	0
Mood alterations with depressive symptoms						
Depressed mood	0	0	16	0	16	0
Mood disorders NEC						
Apathy	0	0	1	0	1	0
Obsessive-compulsive disorders and symptoms						
Obsessive thoughts	0	0	2	0	2	0
Obsessive-compulsive disorder	0	0	1	0	1	0
Orgasmic disorders and disturbances						
Female orgasmic disorder	0	0	1	0	1	0
Parasomnias						
Nightmare	0	0	7	0	7	0
Perception disturbances						
Derealisation	0	0	5	0	5	0
Hallucination	0	0	2	0	2	0
Hallucination, visual	0	0	1	0	1	0
Hallucinations, mixed	0	0	1	0	1	0
Personality disorders NEC						
Personality disorder	0	0	1	0	1	0
Self esteem decreased	0	0	2	0	2	0
Personality disorders with dramatic behaviour (Cluster B)						
Borderline personality disorder	0	0	1	0	1	0
Psychiatric symptoms NEC						
Abulia	0	0	1	0	1	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	6	0	6	0
Sleep disorders NEC						
Hypersomnia-bulimia syndrome	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
Psychiatric disorders cont'd						
SOC						
HLT						
PT						
Sleep disorder	0	0	39	0	39	0
Speech articulation and rhythm disturbances						
Dysphemia	0	0	2	0	2	0
Stereotypies and automatisms						
Bruxism	0	0	1	0	1	0
Waxy flexibility	0	0	1	0	1	0
Stress disorders						
Post-traumatic stress disorder	0	0	2	0	2	0
Suicidal and self-injurious behaviour						
Suicidal ideation	0	0	1	0	1	0
Suicide attempt	0	0	1	0	1	0
Tic disorders						
Tic	0	0	20	0	20	0
Psychiatric disorders SOC TOTAL	0	0	425	0	425	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	15	0	15	0
Enuresis	0	0	2	0	2	0
Incontinence	0	0	1	0	1	0
Micturition disorder	0	0	4	0	4	0
Pollakiuria	0	0	19	0	19	0
Urethral pain	0	0	1	0	1	0
Urinary incontinence	0	0	5	0	5	0
Urinary retention	0	0	8	0	8	0
Bladder disorders NEC						
Bladder disorder	0	0	4	0	4	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
Urinary abnormalities						
Chromaturia	0	0	1	0	1	0
Haematuria	0	0	1	0	1	0
Proteinuria	0	0	1	0	1	0
Urine abnormality	0	0	1	0	1	0
Urinary tract signs and symptoms NEC						
Cystitis-like symptom	0	0	3	0	3	0
Nocturia	0	0	2	0	2	0
Polyuria	0	0	1	0	1	0
Renal pain	0	0	3	0	3	0
Renal & urinary disorders SOC TOTAL	0	0	82	0	82	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						
Reproductive & breast disorders						
<i>Breast disorders NEC</i>						
Breast enlargement	0	0	1	0	1	0
Breast mass	0	0	2	0	2	0
Nipple disorder	0	0	1	0	1	0
<i>Breast signs and symptoms</i>						
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
<i>Cervix disorders NEC</i>						
Cervical dysplasia	0	0	3	0	3	0
<i>Menopausal effects NEC</i>						
Premature menopause	0	0	2	0	2	0
<i>Menstruation and uterine bleeding NEC</i>						
Dysmenorrhoea	0	0	37	0	37	0
Menstrual disorder	0	0	15	0	15	0
Menstruation irregular	0	0	28	0	28	0
Metrorrhagia	0	0	7	0	7	0
Premenstrual syndrome	0	0	1	0	1	0
<i>Menstruation with decreased bleeding</i>						
Amenorrhoea	0	0	12	0	12	0
Menstruation delayed	0	0	3	0	3	0
Oligomenorrhoea	0	0	1	0	1	0
<i>Menstruation with increased bleeding</i>						
Menometrorrhagia	0	0	1	0	1	0
Menorrhagia	0	0	10	0	10	0
Polymenorrhoea	0	0	1	0	1	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>						
Ovarian cyst	0	0	3	0	3	0
Polycystic ovaries	0	0	3	0	3	0
<i>Ovarian and fallopian tube disorders NEC</i>						
Ovulation pain	0	0	1	0	1	0
<i>Pelvis and broad ligament disorders NEC</i>						
Adnexa uteri pain	0	0	1	0	1	0
<i>Reproductive tract signs and symptoms NEC</i>						
Genital pain	0	0	2	0	2	0
Oedema genital	0	0	1	0	1	0
Pelvic pain	0	0	5	0	5	0
<i>Sexual function and fertility disorders NEC</i>						
Dyspareunia	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
Reproductive & breast disorders cont'd						
SOC						
HLT						
PT						
Infertility	0	0	1	0	1	0
Infertility female	0	0	1	0	1	0
Uterine disorders NEC						
Endometrial dysplasia	0	0	1	0	1	0
Endometriosis	0	0	1	0	1	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	2	0	2	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	2	0	2	0
Vulvovaginal pruritus	0	0	2	0	2	0
Reproductive & breast disorders SOC TOTAL	0	0	187	0	187	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						
Respiratory disorders						
Breathing abnormalities						
Dyspnoea	1	0	109	0	110	0
Dyspnoea exertional	0	0	9	0	9	0
Hyperventilation	0	0	11	0	11	0
Hypopnoea	0	0	1	0	1	0
Nocturnal dyspnoea	0	0	1	0	1	0
Bronchospasm and obstruction						
Asthma	0	0	17	0	17	0
Asthma exercise induced	0	0	6	0	6	0
Bronchospasm	0	0	1	0	1	0
Wheezing	0	0	2	0	2	0
Coughing and associated symptoms						
Cough	0	0	20	0	20	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	4	0	4	0
Nasal inflammation	0	0	1	0	1	0
Nasal disorders NEC						
Epistaxis	0	0	7	0	7	0
Nasal disorder	0	0	1	0	1	0
Nasal mucosal disorder	0	0	1	0	1	0
Pharyngeal disorders (excl infections and neoplasms)						
Oropharyngeal spasm	0	0	1	0	1	0
Pharyngeal erythema	0	0	1	0	1	0
Pharyngeal oedema	0	0	5	0	5	0
Tonsillar disorder	0	0	4	0	4	0
Tonsillar hypertrophy	0	0	5	0	5	0
Pleural infections and inflammations						

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Respiratory disorders cont'd						
SOC						
<i>HLT</i>						
<i>PT</i>						
Pleurisy	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	3	0	3	0
Suffocation feeling	0	0	1	0	1	0
<i>Respiratory tract disorders NEC</i>						
Lung disorder	0	0	1	0	1	0
Pulmonary mass	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>						
Chronic throat clearing	0	0	2	0	2	0
Dry throat	0	0	1	0	1	0
Dysphonia	0	0	3	0	3	0
Oropharyngeal pain	0	0	29	0	29	0
Rhinorrhoea	0	0	9	0	9	0
Sneezing	0	0	1	0	1	0
Throat irritation	0	0	1	0	1	0
Throat tightness	0	0	7	0	7	0
Respiratory disorders SOC TOTAL	1	0	282	0	283	0

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	01-Jul-2015	Report origin:	DENMARK
Data lock date:	30-Jun-2015 19:00:15	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Jun-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						
Skin disorders						
Acnes						
Acne	0	0	44	0	44	0
Acne conglobata	0	0	1	0	1	0
Dermatitis acneiform	0	0	1	0	1	0
Alopecias						
Alopecia	0	0	42	0	42	0
Alopecia areata	0	0	3	0	3	0
Madarosis	0	0	1	0	1	0
Angioedemas						
Angioedema	0	0	5	0	5	0
Swelling face	0	0	14	0	14	0
Apocrine and eccrine gland disorders						
Cold sweat	0	0	36	0	36	0
Hyperhidrosis	0	0	51	0	51	0
Night sweats	0	0	9	0	9	0
Bullous conditions						
Blister	0	0	1	0	1	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	0	0	15	0	15	0
Pain of skin	0	0	6	0	6	0
Papule	0	0	2	0	2	0
Scab	0	0	1	0	1	0
Skin burning sensation	0	0	5	0	5	0
Skin discolouration	0	0	8	0	8	0
Skin disorder	0	0	7	0	7	0
Skin reaction	0	0	2	0	2	0
Skin swelling	0	0	1	0	1	0
Skin tightness	0	0	1	0	1	0
Skin warm	0	0	1	0	1	0
Dermatitis and eczema						
Dermatitis	0	0	6	0	6	0
Dermatitis allergic	0	0	6	0	6	0
Dermatitis atopic	0	0	77	0	77	0
Eczema	0	0	53	0	53	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

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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						
HLT						
PT						
Skin irritation	0	0	3	0	3	0
Erythemas						
Erythema	0	0	36	0	36	0
Generalised erythema	0	0	2	0	2	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	4	0	4	0
Hyperkeratoses						
Keratosis pilaris	0	0	1	0	1	0
Hyperpigmentation disorders						
Skin hyperpigmentation	0	0	2	0	2	0
Solar lentigo	0	0	1	0	1	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
Nail and nail bed conditions (excl infections and infestations)						
Nail discolouration	0	0	1	0	1	0
Nail disorder	0	0	3	0	3	0
Nail growth abnormal	0	0	1	0	1	0
Panniculitides						
Erythema nodosum	0	0	2	0	2	0
Papulosquamous conditions						
Pityriasis rosea	0	0	4	0	4	0
Rash papulosquamous	0	0	1	0	1	0
Photosensitivity and photodermatitis conditions						
Photosensitivity reaction	0	0	6	0	6	0
Solar dermatitis	0	0	3	0	3	0
Pigmentation changes NEC						
Pigmentation disorder	0	0	1	0	1	0
Pilar disorders NEC						
Hair disorder	0	0	2	0	2	0
Hair growth abnormal	0	0	4	0	4	0
Hair texture abnormal	0	0	4	0	4	0
Pruritus NEC						
Pruritus	1	0	49	0	50	0
Pruritus generalised	0	0	5	0	5	0
Rash pruritic	0	0	32	0	32	0
Psoriatic conditions						

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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						
Psoriasis	0	0	4	0	4	0
Pustular psoriasis	0	0	1	0	1	0
Purpura and related conditions						
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	4	0	4	0
Rashes, eruptions and exanthems NEC						
Rash	0	0	74	0	74	0
Rash generalised	0	0	15	0	15	0
Rash macular	0	0	3	0	3	0
Rash maculo-papular	0	0	4	0	4	0
Rash papular	0	0	6	0	6	0
Rash vesicular	0	0	4	0	4	0
Rosaceas						
Rosacea	0	0	1	0	1	0
Skin and subcutaneous conditions NEC						
Skin mass	0	0	2	0	2	0
Skin and subcutaneous tissue ulcerations						
Skin ulcer	0	0	3	0	3	0
Skin dystrophies						
Skin wrinkling	0	0	1	0	1	0
Skin haemorrhages						
Skin haemorrhage	0	0	3	0	3	0
Skin hypoplasias and atrophies						
Skin atrophy	0	0	1	0	1	0
Skin striae	0	0	4	0	4	0
Skin vasculitides						
Hypersensitivity vasculitis	0	0	1	0	1	0
Urticarias						
Mechanical urticaria	0	0	1	0	1	0
Urticaria	1	0	97	0	98	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	2	0	832	0	834	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	0	0	3	0	3	0
Bedridden	0	0	1	0	1	0
Disability	0	0	2	0	2	0
Impaired driving ability	0	0	1	0	1	0
Impaired work ability	0	0	2	0	2	0
Learning disability	0	0	5	0	5	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	3	0	3	0
Wheelchair user	0	0	5	0	5	0
Social issues NEC						
Social problem	0	0	3	0	3	0
Social circumstances SOC TOTAL	0	0	30	0	30	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						
Surgical & medical procedures						
<i>Cardiac device therapeutic procedures</i>						
Cardiac pacemaker insertion	0	0	2	0	2	0
<i>Cervix therapeutic procedures</i>						
Cervical conisation	0	0	1	0	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>						
Gastrointestinal surgery	0	0	1	0	1	0
<i>Haematological therapeutic procedures NEC</i>						
Bone marrow transplant	0	0	2	0	2	0
<i>Joint therapeutic procedures</i>						
Ligament operation	0	0	1	0	1	0
<i>Large intestine therapeutic procedures</i>						
Colostomy	0	0	1	0	1	0
<i>Limb therapeutic procedures</i>						
Limb operation	0	0	1	0	1	0
<i>Lymphoid tissue therapeutic procedures</i>						
Lymphadenectomy	0	0	1	0	1	0
Splenectomy	0	0	1	0	1	0
Thymectomy	0	0	1	0	1	0
<i>Nasal therapeutic procedures</i>						
Nasal cavity packing	0	0	1	0	1	0
<i>Obstetric therapeutic procedures</i>						
Caesarean section	0	0	1	0	1	0
<i>Small intestine therapeutic procedures</i>						
Small intestine operation	0	0	1	0	1	0
<i>Therapeutic procedures NEC</i>						
Infusion	0	0	1	0	1	0
<i>Tonsillar therapeutic procedures</i>						
Adenoidectomy	0	0	1	0	1	0
Tonsillectomy	0	0	1	0	1	0
Surgical & medical procedures SOC TOTAL	0	0	18	0	18	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	4	0	4	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						
Arterial disorder	0	0	1	0	1	0
Hyperaemia	0	0	1	0	1	0
Vascular pain	0	0	1	0	1	0
Peripheral vascular disorders NEC						
Flushing	0	0	2	0	2	0
Hot flush	0	0	33	0	33	0
Peripheral vasoconstriction, necrosis and vascular insufficiency						
Peripheral coldness	0	0	52	0	52	0
Raynaud's phenomenon	0	0	5	0	5	0
Site specific vascular disorders NEC						
Pallor	0	0	15	0	15	0
Vascular hypertensive disorders NEC						
Hypertension	0	0	4	0	4	0
Vascular hypotensive disorders						
Hypotension	1	0	30	0	31	0
Orthostatic hypotension	0	0	16	0	16	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	174	0	175	0

TOTAL NUMBER OF REACTIONS	44	0	9698	2	9742	2
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TOTAL NUMBER OF FATAL ADR REPORTS*		0		2		2*
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TOTAL NUMBER OF ADR REPORTS*	8		1593		1601*	
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