

Drug Analysis Print
 Drug name: HUMAN PAPILLOMA VIRUS

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Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	31-Oct-2013	Report origin:	DENMARK
Data lock date:	30-Oct-2013 23:33:49	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Oct-2013	Reporter type:	ALL
Earliest reaction date:	01-Jan-2005	Reaction:	ALL
MedDRA version:	MedDRA 16.0	Age group:	ALL

Total number of reactions*: 3124 **Total number of ADR reports:** 971 **Total number of fatal ADR reports:** 1

Products included in this print - Multi active constituent products (PBGs):
 CERVARIX
 GARDASIL
 SILGARD

*It is important to note that one report may contain one or more reactions.

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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	33	0	33	0
Cardiac disorders	2	0	36	0	38	0
Congenital disorders	0	0	8	1	8	1
Ear disorders	0	0	18	0	18	0
Endocrine disorders	0	0	1	0	1	0
Eye disorders	1	0	85	0	86	0
Gastrointestinal disorders	7	0	241	0	248	0
General disorders	10	0	585	0	595	0
Hepatic disorders	0	0	5	0	5	0
Immune system disorders	0	0	35	0	35	0
Infections	1	0	52	0	53	0
Injuries	0	0	47	0	47	0
Investigations	3	0	45	0	48	0
Metabolic disorders	1	0	23	0	24	0
Muscle & tissue disorders	4	0	299	0	303	0
Neoplasms	0	0	7	0	7	0
Nervous system disorders	11	0	806	0	817	0
Pregnancy conditions	0	0	8	0	8	0
Psychiatric disorders	0	0	82	0	82	0
Renal & urinary disorders	0	0	15	0	15	0
Reproductive & breast disorders	2	0	51	0	53	0
Respiratory disorders	2	0	86	0	88	0
Skin disorders	0	0	465	0	465	0
Social circumstances	0	0	3	0	3	0
Surgical & medical procedures	0	0	5	0	5	0
Vascular disorders	1	0	38	0	39	0

TOTAL NUMBER OF REACTIONS	45	0	3079	1	3124	1
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TOTAL NUMBER OF FATAL ADR REPORTS*		0		1		1*
TOTAL NUMBER OF ADR REPORTS*	4		967		971*	

*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 ¹	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Blood disorders						
Anaemia deficiencies						
Pernicious anaemia	0	0	1	0	1	0
Anaemias NEC						
Anaemia	0	0	1	0	1	0
Lymphatic system disorders NEC						
Lymph node pain	0	0	3	0	3	0
Lymphadenitis	0	0	2	0	2	0
Lymphadenopathy	0	0	19	0	19	0
Marrow depression and hypoplastic anaemias						
Aplastic anaemia	0	0	1	0	1	0
Thrombocytopenias						
Autoimmune thrombocytopenia	0	0	1	0	1	0
Idiopathic thrombocytopenic purpura	0	0	3	0	3	0
Thrombocytopenia	0	0	2	0	2	0
Blood disorders SOC TOTAL	0	0	33	0	33	0

¹This 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 signs and symptoms NEC						
Cyanosis	0	0	2	0	2	0
Palpitations	1	0	20	0	21	0
Ischaemic coronary artery disorders						
Angina pectoris	0	0	1	0	1	0
Rate and rhythm disorders NEC						
Arrhythmia	0	0	3	0	3	0
Bradycardia	0	0	2	0	2	0
Postural orthostatic tachycardia syndrome	1	0	6	0	7	0
Tachycardia	0	0	1	0	1	0
Supraventricular arrhythmias						
Supraventricular tachycardia	0	0	1	0	1	0
Cardiac disorders SOC TOTAL	2	0	36	0	38	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						
Congenital disorders						
<i>Adrenal disorders congenital</i>						
Congenital adrenal gland hypoplasia	0	0	1	0	1	0
<i>Central nervous system disorders congenital NEC</i>						
Syringomyelia	0	0	1	0	1	0
<i>Diaphragmatic disorders congenital</i>						
Congenital diaphragmatic hernia	0	0	1	0	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>						
Congenital foot malformation	0	0	2	0	2	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>						
Congenital absence of cranial vault	0	0	1	1	1	1
<i>Palate disorders congenital</i>						
Cleft lip and palate	0	0	1	0	1	0
<i>Pulmonary and bronchial disorders congenital</i>						
Pulmonary hypoplasia	0	0	1	0	1	0
Congenital disorders SOC TOTAL	0	0	8	1	8	1

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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	0	0	1	0	1	0
Ear pain	0	0	2	0	2	0
Hearing losses						
Deafness unilateral	0	0	1	0	1	0
Hearing impaired	0	0	2	0	2	0
Hypoacusis	0	0	1	0	1	0
Hyperacusia						
Hyperacusis	0	0	4	0	4	0
Inner ear signs and symptoms						
Motion sickness	0	0	1	0	1	0
Tinnitus	0	0	4	0	4	0
Vertigo	0	0	2	0	2	0
Ear disorders 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						
<i>HLT</i>						
PT						
Endocrine disorders						
<i>Adrenal cortical hypofunctions</i>						
Addison's disease	0	0	1	0	1	0
Endocrine disorders SOC TOTAL	0	0	1	0	1	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Eye disorders						
Blindness (excl colour blindness)						
Blindness transient	0	0	1	0	1	0
Conjunctival infections, irritations and inflammations						
Conjunctivitis	0	0	2	0	2	0
Conjunctivitis allergic	0	0	1	0	1	0
Eyelid movement disorders						
Blepharospasm	0	0	2	0	2	0
Iris and ciliary body structural change, deposit and degeneration						
Iris disorder	0	0	1	0	1	0
Iris and uveal tract infections, irritations and inflammations						
Iritis	0	0	1	0	1	0
Lacrimation disorders						
Dry eye	0	0	1	0	1	0
Lacrimation increased	0	0	1	0	1	0
Lid, lash and lacrimal infections, irritations and inflammations						
Eyelid oedema	0	0	1	0	1	0
Ocular disorders NEC						
Eye oedema	0	0	1	0	1	0
Eye pain	0	0	4	0	4	0
Eye swelling	0	0	3	0	3	0
Ocular infections, inflammations and associated manifestations						
Eye allergy	0	0	2	0	2	0
Eye pruritus	0	0	2	0	2	0
Ocular hyperaemia	0	0	2	0	2	0
Ocular nerve and muscle disorders						
Eye movement disorder	0	0	1	0	1	0
Ocular sensation disorders						
Abnormal sensation in eye	0	0	1	0	1	0
Photophobia	0	0	6	0	6	0
Partial vision loss						
Visual acuity reduced	0	0	4	0	4	0
Retinal, choroid and vitreous infections and inflammations						
Retinal vasculitis	0	0	1	0	1	0
Visual disorders NEC						
Diplopia	0	0	2	0	2	0
Photopsia	0	0	1	0	1	0
Vision blurred	0	0	11	0	11	0
Visual impairment	1	0	33	0	34	0
Eye disorders SOC TOTAL	1	0	85	0	86	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Gastrointestinal disorders						
<i>Colitis (excl infective)</i>						
Colitis ulcerative	0	0	2	0	2	0
<i>Diarrhoea (excl infective)</i>						
Diarrhoea	0	0	10	0	10	0
<i>Dyspeptic signs and symptoms</i>						
Dyspepsia	0	0	2	0	2	0
<i>Gastritis (excl infective)</i>						
Gastritis	0	0	1	0	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>						
Abdominal migraine	0	0	1	0	1	0
Abdominal pain	1	0	27	0	28	0
Abdominal pain lower	0	0	5	0	5	0
Abdominal pain upper	2	0	18	0	20	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>						
Constipation	0	0	1	0	1	0
<i>Gastrointestinal disorders NEC</i>						
Functional gastrointestinal disorder	0	0	1	0	1	0
Gastrointestinal disorder	0	0	2	0	2	0
<i>Gastrointestinal dyskinetic disorders</i>						
Gastrointestinal motility disorder	0	0	1	0	1	0
<i>Gastrointestinal signs and symptoms NEC</i>						
Abdominal discomfort	0	0	2	0	2	0
Dysphagia	0	0	2	0	2	0
<i>Nausea and vomiting symptoms</i>						
Nausea	3	0	110	0	113	0
Vomiting	1	0	29	0	30	0
Vomiting projectile	0	0	1	0	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>						
Haematochezia	0	0	2	0	2	0
<i>Oral dryness and saliva altered</i>						
Dry mouth	0	0	2	0	2	0
Salivary hypersecretion	0	0	1	0	1	0
<i>Oral soft tissue disorders NEC</i>						
Cheilitis	0	0	1	0	1	0
<i>Oral soft tissue haemorrhages</i>						
Mouth haemorrhage	0	0	1	0	1	0
<i>Oral soft tissue pain and paraesthesia</i>						
Lip pain	0	0	1	0	1	0
Odynophagia	0	0	1	0	1	0
Oral pain	0	0	1	0	1	0
Paraesthesia oral	0	0	3	0	3	0

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	All	Fatal	All	Fatal	All	Fatal
Gastrointestinal disorders cont'd						
SOC						
HLT						
PT						
Oral soft tissue signs and symptoms						
Hypoaesthesia oral	0	0	3	0	3	0
Oral discomfort	0	0	1	0	1	0
Oral mucosal blistering	0	0	2	0	2	0
Oral soft tissue swelling and oedema						
Lip swelling	0	0	1	0	1	0
Stomatitis and ulceration						
Apthous stomatitis	0	0	2	0	2	0
Mouth ulceration	0	0	1	0	1	0
Tongue signs and symptoms						
Swollen tongue	0	0	3	0	3	0
Gastrointestinal disorders SOC TOTAL	7	0	241	0	248	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
<i>PT</i>						
General disorders						
<i>Adverse effect absent</i>						
No adverse event	0	0	1	0	1	0
<i>Application and instillation site reactions</i>						
Application site erythema	0	0	1	0	1	0
<i>Asthenic conditions</i>						
Asthenia	0	0	18	0	18	0
Chronic fatigue syndrome	0	0	1	0	1	0
Fatigue	3	0	105	0	108	0
Malaise	3	0	63	0	66	0
Sluggishness	0	0	1	0	1	0
<i>Body temperature altered</i>						
Temperature regulation disorder	0	0	1	0	1	0
<i>Febrile disorders</i>						
Pyrexia	0	0	84	0	84	0
<i>Feelings and sensations NEC</i>						
Chills	1	0	5	0	6	0
Feeling abnormal	0	0	8	0	8	0
Feeling cold	0	0	4	0	4	0
Feeling drunk	0	0	1	0	1	0
Feeling hot	0	0	3	0	3	0
Sensation of foreign body	0	0	1	0	1	0
Sense of oppression	0	0	1	0	1	0
Temperature intolerance	0	0	1	0	1	0
Thirst	0	0	1	0	1	0
<i>Gait disturbances</i>						
Abasia	0	0	1	0	1	0
Gait disturbance	0	0	5	0	5	0
<i>General signs and symptoms NEC</i>						
Condition aggravated	0	0	1	0	1	0
Crying	0	0	5	0	5	0
Foaming at mouth	0	0	1	0	1	0
General physical health deterioration	0	0	1	0	1	0
General symptom	0	0	1	0	1	0
Induration	0	0	1	0	1	0
Influenza like illness	0	0	33	0	33	0
Irritability	0	0	2	0	2	0
Local reaction	0	0	1	0	1	0
Local swelling	0	0	2	0	2	0
Swelling	0	0	3	0	3	0
<i>Inflammations</i>						
Inflammation	0	0	3	0	3	0

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	All	Fatal	All	Fatal	All	Fatal
General disorders cont'd						
SOC						
HLT						
PT						
Vestibulitis	0	0	1	0	1	0
Injection site reactions						
Injection site bruising	0	0	1	0	1	0
Injection site discomfort	0	0	2	0	2	0
Injection site eczema	0	0	2	0	2	0
Injection site erythema	0	0	16	0	16	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 mass	0	0	1	0	1	0
Injection site nodule	0	0	6	0	6	0
Injection site pain	1	0	32	0	33	0
Injection site paraesthesia	0	0	2	0	2	0
Injection site pruritus	0	0	7	0	7	0
Injection site rash	0	0	2	0	2	0
Injection site reaction	0	0	6	0	6	0
Injection site swelling	1	0	24	0	25	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						
Nodule	0	0	2	0	2	0
Mucosal findings abnormal						
Mucous membrane disorder	0	0	1	0	1	0
Oedema mucosal	0	0	1	0	1	0
Oedema NEC						
Extensive swelling of vaccinated limb	0	0	2	0	2	0
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	2	0	2	0
Oedema peripheral	0	0	16	0	16	0
Pain and discomfort NEC						
Chest discomfort	0	0	5	0	5	0
Chest pain	0	0	11	0	11	0
Discomfort	0	0	5	0	5	0
Non-cardiac chest pain	0	0	1	0	1	0
Pain	1	0	29	0	30	0
Spinal pain	0	0	1	0	1	0
Tenderness	0	0	4	0	4	0
Therapeutic and nontherapeutic responses						

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Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	31-Oct-2013	Report origin:	DENMARK
Data lock date:	30-Oct-2013 23:33:49	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Oct-2013	Reporter type:	ALL
Earliest reaction date:	01-Jan-2005	Reaction:	ALL
MedDRA version:	MedDRA 16.0	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						
Drug ineffective	0	0	1	0	1	0
Vaccination site reactions						
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 pain	0	0	7	0	7	0
Vaccination site pruritus	0	0	2	0	2	0
Vaccination site rash	0	0	1	0	1	0
Vaccination site reaction	0	0	1	0	1	0
Vaccination site swelling	0	0	2	0	2	0
Vaccination site warmth	0	0	1	0	1	0
General disorders SOC TOTAL	10	0	585	0	595	0

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MedDRA version:	MedDRA 16.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports ^a	
	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	0	0	3	0	3	0
Liver injury	0	0	1	0	1	0
Hepatic disorders SOC TOTAL	0	0	5	0	5	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 plants	0	0	1	0	1	0
Hypersensitivity	0	0	19	0	19	0
Allergies to foods, food additives, drugs and other chemicals						
Food allergy	0	0	2	0	2	0
Anaphylactic responses						
Anaphylactic reaction	0	0	2	0	2	0
Anaphylactic shock	0	0	5	0	5	0
Atopic disorders						
House dust allergy	0	0	1	0	1	0
Seasonal allergy	0	0	2	0	2	0
Immune and associated conditions NEC						
Immune system disorder	0	0	1	0	1	0
Immunodeficiency disorders NEC						
Immunosuppression	0	0	1	0	1	0
Immune system disorders SOC TOTAL	0	0	35	0	35	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						
Bacterial infections NEC						
Folliculitis	0	0	1	0	1	0
Central nervous system and spinal infections						
Meningitis	0	0	3	0	3	0
Myelitis	0	0	2	0	2	0
Chlamydial infections						
Pneumonia chlamydial	0	0	1	0	1	0
Dental and oral soft tissue infections						
Gingival infection	0	0	1	0	1	0
Epstein-Barr viral infections						
Infectious mononucleosis	0	0	1	0	1	0
Herpes viral infections						
Herpes simplex	0	0	1	0	1	0
Herpes zoster	0	0	8	0	8	0
Oral herpes	0	0	3	0	3	0
Infections NEC						
Abscess	0	0	1	0	1	0
Infection	1	0	10	0	11	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
Influenza viral infections						
Influenza	0	0	1	0	1	0
Lower respiratory tract and lung infections						
Pneumonia	0	0	2	0	2	0
Mycoplasma infections						
Pneumonia mycoplasmal	0	0	1	0	1	0
Skin structures and soft tissue infections						
Impetigo	0	0	1	0	1	0
Upper respiratory tract infections						
Nasopharyngitis	0	0	6	0	6	0
Rhinitis	0	0	1	0	1	0
Urinary tract infections						
Cystitis	0	0	1	0	1	0
Viral infections NEC						
Vestibular neuronitis	0	0	1	0	1	0
Viral infection	0	0	2	0	2	0
Infections SOC TOTAL	1	0	52	0	53	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						
Accidental exposures to product						
Accidental exposure to product	0	0	1	0	1	0
Cerebral injuries NEC						
Concussion	0	0	1	0	1	0
Exposures associated with pregnancy, delivery and lactation						
Exposure during pregnancy	0	0	11	0	11	0
Foetal exposure during pregnancy	0	0	7	0	7	0
Maternal exposure before pregnancy	0	0	1	0	1	0
Fractures and dislocations NEC						
Joint dislocation	0	0	1	0	1	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 administered to patient of inappropriate age	0	0	1	0	1	0
Drug administration error	0	0	1	0	1	0
Inappropriate schedule of drug administration	0	0	2	0	2	0
Incorrect dose administered	0	0	1	0	1	0
Incorrect route of drug administration	0	0	1	0	1	0
Underdose	0	0	3	0	3	0
Wrong technique in drug usage process	0	0	1	0	1	0
Medication errors NEC						
Incorrect storage of drug	0	0	1	0	1	0
Non-site specific injuries NEC						
Fall	0	0	7	0	7	0
Pathways and sources of exposure						
Exposure via direct contact	0	0	1	0	1	0
Skin injuries NEC						
Contusion	0	0	3	0	3	0
Scar	0	0	1	0	1	0
Injuries SOC TOTAL	0	0	47	0	47	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						
Carbohydrate tolerance analyses (incl diabetes)						
Blood glucose increased	0	0	1	0	1	0
Endocrine analyses and imaging NEC						
Hormone level abnormal	0	0	1	0	1	0
Gastrointestinal function diagnostic procedures						
Gastric pH decreased	0	0	1	0	1	0
Haematological analyses NEC						
Red blood cell sedimentation rate increased	0	0	1	0	1	0
Heart rate and pulse investigations						
Heart rate decreased	0	0	1	0	1	0
Heart rate increased	1	0	10	0	11	0
Heart rate irregular	0	0	1	0	1	0
Pulse abnormal	0	0	1	0	1	0
Investigations NEC						
Quality of life decreased	0	0	1	0	1	0
Liver function analyses						
Alanine aminotransferase increased	0	0	2	0	2	0
Gamma-glutamyltransferase increased	0	0	1	0	1	0
Hepatic enzyme increased	0	0	2	0	2	0
Neurologic diagnostic procedures						
Pain threshold decreased	1	0	1	0	2	0
Physical examination procedures and organ system status						
Body temperature fluctuation	0	0	1	0	1	0
Lymph node palpable	0	0	2	0	2	0
Weight decreased	1	0	8	0	9	0
Weight increased	0	0	3	0	3	0
Red blood cell analyses						
Haemoglobin decreased	0	0	1	0	1	0
Respiratory and pulmonary function diagnostic procedures						
Pulmonary function test decreased	0	0	1	0	1	0
Total lung capacity decreased	0	0	1	0	1	0
Urinalysis NEC						
Blood urine present	0	0	1	0	1	0
Vascular tests NEC (incl blood pressure)						
Blood pressure decreased	0	0	2	0	2	0
White blood cell analyses						
White blood cell count increased	0	0	1	0	1	0
Investigations SOC TOTAL	3	0	45	0	48	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>						
Decreased appetite	1	0	9	0	10	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>Fat soluble vitamin deficiencies and disorders</i>						
Vitamin A deficiency	0	0	1	0	1	0
Vitamin D deficiency	0	0	1	0	1	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	2	0	2	0
<i>General nutritional disorders NEC</i>						
Overweight	0	0	1	0	1	0
<i>Iron deficiencies</i>						
Iron deficiency	0	0	1	0	1	0
<i>Metabolic disorders NEC</i>						
Metabolic disorder	0	0	1	0	1	0
<i>Potassium imbalance</i>						
Hypokalaemia	0	0	1	0	1	0
<i>Total fluid volume decreased</i>						
Dehydration	0	0	1	0	1	0
Metabolic disorders SOC TOTAL	1	0	23	0	24	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	3	0	3	0
Arthritis reactive	0	0	3	0	3	0
Bone related signs and symptoms						
Bone pain	0	0	1	0	1	0
Pain in jaw	0	0	1	0	1	0
Bursal disorders						
Bursitis	0	0	1	0	1	0
Connective tissue disorders (excl LE)						
Connective tissue disorder	0	0	1	0	1	0
Joint related disorders NEC						
Joint contracture	0	0	1	0	1	0
Joint lock	0	0	1	0	1	0
Periarthritis	0	0	1	0	1	0
Joint related signs and symptoms						
Arthralgia	0	0	50	0	50	0
Joint stiffness	0	0	2	0	2	0
Joint swelling	0	0	7	0	7	0
Joint warmth	0	0	1	0	1	0
Lupus erythematosus (incl subtypes)						
Systemic lupus erythematosus	0	0	2	0	2	0
Muscle infections and inflammations						
Myositis	0	0	1	0	1	0
Muscle pains						
Fibromyalgia	0	0	1	0	1	0
Myalgia	1	0	50	0	51	0
Muscle related signs and symptoms NEC						
Muscle disorder	0	0	1	0	1	0
Muscle spasms	0	0	21	0	21	0
Muscle swelling	0	0	1	0	1	0
Muscle tightness	0	0	8	0	8	0
Muscle twitching	0	0	2	0	2	0
Muscle tone abnormalities						
Trismus	0	0	1	0	1	0
Muscle weakness conditions						
Muscular weakness	1	0	25	0	26	0
Musculoskeletal and connective tissue pain and discomfort						
Back pain	0	0	21	0	21	0
Growing pains	0	0	1	0	1	0
Musculoskeletal chest pain	0	0	1	0	1	0
Musculoskeletal discomfort	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
Muscle & tissue disorders cont'd						
SOC						
HLT						
PT						
Musculoskeletal pain	0	0	12	0	12	0
Neck pain	0	0	12	0	12	0
Pain in extremity	2	0	51	0	53	0
Musculoskeletal and connective tissue signs and symptoms NEC						
Musculoskeletal stiffness	0	0	6	0	6	0
Sensation of heaviness	0	0	3	0	3	0
Myopathies						
Mitochondrial myopathy acquired	0	0	1	0	1	0
Soft tissue disorders NEC						
Fistula	0	0	1	0	1	0
Groin pain	0	0	3	0	3	0
Muscle & tissue disorders SOC TOTAL	4	0	299	0	303	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>Rhabdomyosarcomas</i>						
Rhabdomyosarcoma	0	0	1	0	1	0
<i>Skin neoplasms benign</i>						
Anogenital warts	0	0	4	0	4	0
Skin papilloma	0	0	1	0	1	0
<i>Vaginal neoplasms benign</i>						
Vulvovaginal human papilloma virus infection	0	0	1	0	1	0
Neoplasms SOC TOTAL	0	0	7	0	7	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports ¹	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
<i>PT</i>						
Nervous system disorders						
<i>Abnormal reflexes</i>						
Hyporeflexia	0	0	1	0	1	0
<i>Absence seizures</i>						
Petit mal epilepsy	0	0	2	0	2	0
<i>Acute polyneuropathies</i>						
Guillain-Barre syndrome	0	0	4	0	4	0
<i>Autonomic nervous system disorders</i>						
Autonomic nervous system imbalance	0	0	1	0	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>						
Cerebral haemorrhage	0	0	1	0	1	0
<i>Choreiform movements</i>						
Sydenham's chorea	0	0	1	0	1	0
<i>Coordination and balance disturbances</i>						
Balance disorder	0	0	5	0	5	0
Coordination abnormal	0	0	2	0	2	0
Dysstasia	1	0	1	0	2	0
<i>Cortical dysfunction NEC</i>						
Aphasia	1	0	4	0	5	0
Dysgraphia	0	0	1	0	1	0
<i>Demyelinating disorders NEC</i>						
Neuromyelitis optica	0	0	1	0	1	0
<i>Disturbances in consciousness NEC</i>						
Depressed level of consciousness	0	0	2	0	2	0
Loss of consciousness	0	0	5	0	5	0
Somnolence	0	0	4	0	4	0
Syncope	1	0	40	0	41	0
<i>Dyskinesias and movement disorders NEC</i>						
Dyskinesia	0	0	1	0	1	0
Fine motor delay	0	0	1	0	1	0
Hyperkinesia	0	0	1	0	1	0
Hypokinesia	0	0	1	0	1	0
Movement disorder	0	0	2	0	2	0
Tardive dyskinesia	0	0	1	0	1	0
<i>Dystonias</i>						
Opisthotonus	0	0	1	0	1	0
<i>Encephallitis NEC</i>						
Encephalitis	0	0	1	0	1	0
<i>Facial cranial nerve disorders</i>						
Facial paresis	0	0	6	0	6	0
VIIth nerve paralysis	0	0	3	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						
<i>HLT</i>						
<i>PT</i>						
Generalised tonic-clonic seizures						
Grand mal convulsion	0	0	2	0	2	0
Headaches NEC						
Cold-stimulus headache	0	0	1	0	1	0
Headache	2	0	183	0	185	0
Hypoglossal nerve disorders						
Hypoglossal nerve paralysis	0	0	1	0	1	0
Tongue paralysis	0	0	1	0	1	0
Memory loss (excl dementia)						
Amnesia	0	0	5	0	5	0
Memory impairment	0	0	33	0	33	0
Mental Impairment (excl dementia and memory loss)						
Cognitive disorder	0	0	3	0	3	0
Disturbance in attention	2	0	37	0	39	0
Migraine headaches						
Migraine	0	0	16	0	16	0
Migraine with aura	0	0	5	0	5	0
Multiple sclerosis acute and progressive						
Multiple sclerosis	0	0	2	0	2	0
Uhthoff's phenomenon	0	0	1	0	1	0
Muscle tone abnormal						
Hypotonia	0	0	1	0	1	0
Myelitis (Incl infective)						
Myelitis transverse	0	0	2	0	2	0
Narcolepsy and hypersomnia						
Cataplexy	0	0	1	0	1	0
Hypersomnia	0	0	2	0	2	0
Neurologic visual problems NEC						
Visual field defect	0	0	1	0	1	0
Neurological signs and symptoms NEC						
Dizziness	3	0	156	0	159	0
Dizziness postural	0	0	1	0	1	0
Neurological symptom	0	0	1	0	1	0
Presyncope	0	0	25	0	25	0
Unresponsive to stimuli	0	0	1	0	1	0
Neuromuscular disorders NEC						
Muscle contractions involuntary	0	0	1	0	1	0
Neuromuscular junction dysfunction						
Myasthenia gravis	0	0	2	0	2	0
Optic nerve disorders NEC						
Optic neuritis	0	0	1	0	1	0
Paraesthesias and dysaesthesias						

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Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	31-Oct-2013	Report origin:	DENMARK
Data lock date:	30-Oct-2013 23:33:49	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Oct-2013	Reporter type:	ALL
Earliest reaction date:	01-Jan-2005	Reaction:	ALL
MedDRA version:	MedDRA 16.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports ^a	
	All	Fatal	All	Fatal	All	Fatal
Reaction Name Nervous system disorders cont'd						
SOC						
<i>HLT</i>						
PT						
Burning sensation	0	0	8	0	8	0
Dysaesthesia	0	0	4	0	4	0
Paraesthesia	0	0	61	0	61	0
Paralysis and paresis (excl cranial nerve)						
Hemiparesis	0	0	1	0	1	0
Monoplegia	0	0	1	0	1	0
Paralysis	0	0	10	0	10	0
Spinal cord paralysis	0	0	1	0	1	0
Partial complex seizures						
Dreamy state	0	0	1	0	1	0
Peripheral neuropathies NEC						
Neuritis	0	0	1	0	1	0
Neuropathy peripheral	0	0	2	0	2	0
Seizures and seizure disorders NEC						
Benign rolandic epilepsy	0	0	1	0	1	0
Clonic convulsion	0	0	1	0	1	0
Convulsion	0	0	8	0	8	0
Epilepsy	0	0	3	0	3	0
Idiopathic generalised epilepsy	0	0	1	0	1	0
Sensory abnormalities NEC						
Hypoaesthesia	0	0	29	0	29	0
Neuralgia	0	0	4	0	4	0
Sensory disturbance	1	0	47	0	48	0
Sensory loss	0	0	6	0	6	0
Sleep disturbances NEC						
Poor quality sleep	0	0	1	0	1	0
Speech and language abnormalities						
Aphonia	0	0	2	0	2	0
Dysarthria	0	0	3	0	3	0
Speech disorder	0	0	11	0	11	0
Spinal cord and nerve root disorders NEC						
Radiculopathy	0	0	1	0	1	0
Transient cerebrovascular events						
Transient ischaemic attack	0	0	1	0	1	0
Tremor (excl congenital)						
Tremor	0	0	18	0	18	0
Trigeminal disorders						
Trigeminal neuralgia	0	0	1	0	1	0
Nervous system disorders SOC TOTAL	11	0	806	0	817	0

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MedDRA version:	MedDRA 16.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Pregnancy conditions						
Abortions spontaneous						
Abortion spontaneous	0	0	4	0	4	0
Gestational age and weight conditions						
Premature baby	0	0	1	0	1	0
Labour onset and length abnormalities						
Prolonged rupture of membranes	0	0	1	0	1	0
Placental abnormalities (excl neoplasms)						
Placental disorder	0	0	1	0	1	0
Stillbirth and foetal death						
Foetal death	0	0	1	0	1	0
Pregnancy conditions SOC TOTAL	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
SOC						
HLT						
PT						
Psychiatric disorders						
Affect alterations NEC						
Affect lability	0	0	1	0	1	0
Anxiety symptoms						
Anxiety	0	0	8	0	8	0
Stress	0	0	3	0	3	0
Behaviour and socialisation disturbances						
Aggression	0	0	1	0	1	0
Cognitive and attention disorders and disturbances NEC						
Daydreaming	0	0	1	0	1	0
Communications disorders						
Expressive language disorder	0	0	1	0	1	0
Confusion and disorientation						
Confusional state	0	0	10	0	10	0
Disorientation	0	0	3	0	3	0
Decreased physical activity levels						
Decreased activity	0	0	1	0	1	0
Depressive disorders						
Depression	0	0	2	0	2	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						
Insomnia	0	0	10	0	10	0
Emotional and mood disturbances NEC						
Anger	0	0	1	0	1	0
Fear symptoms and phobic disorders (incl social phobia)						
Phonophobia	0	0	1	0	1	0
Fluctuating mood symptoms						
Mood swings	0	0	7	0	7	0
Increased physical activity levels						
Restlessness	0	0	7	0	7	0
Mental disorders NEC						
Mental disorder	0	0	1	0	1	0
Mood alterations with depressive symptoms						
Depressed mood	0	0	4	0	4	0
Psychotic disorder NEC						
Psychotic disorder	0	0	1	0	1	0
Sexual desire disorders						
Libido decreased	0	0	3	0	3	0
Sleep disorders NEC						

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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	5	0	5	0
<i>Tic disorders</i>						
Tic	0	0	5	0	5	0
Psychiatric 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						
HLT						
PT						
Renal & urinary disorders						
Bladder and urethral symptoms						
Dysuria	0	0	1	0	1	0
Enuresis	0	0	2	0	2	0
Micturition disorder	0	0	1	0	1	0
Pollakiuria	0	0	2	0	2	0
Urinary incontinence	0	0	3	0	3	0
Bladder disorders NEC						
Bladder disorder	0	0	2	0	2	0
Glomerulonephritis and nephrotic syndrome						
Glomerulonephritis	0	0	1	0	1	0
Nephritis NEC						
Tubulointerstitial nephritis	0	0	1	0	1	0
Urinary abnormalities						
Proteinuria	0	0	1	0	1	0
Urinary tract signs and symptoms NEC						
Renal pain	0	0	1	0	1	0
Renal & urinary disorders SOC TOTAL	0	0	15	0	15	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports ^a	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Reproductive & breast disorders						
Breast disorders NEC						
Breast mass	0	0	1	0	1	0
Breast signs and symptoms						
Breast pain	0	0	3	0	3	0
Breast swelling	0	0	2	0	2	0
Breast tenderness	0	0	3	0	3	0
Cervix disorders NEC						
Cervical dysplasia	0	0	1	0	1	0
Menstruation and uterine bleeding NEC						
Dysmenorrhoea	1	0	8	0	9	0
Menstrual disorder	0	0	2	0	2	0
Menstruation irregular	0	0	8	0	8	0
Metrorrhagia	0	0	3	0	3	0
Premenstrual syndrome	0	0	1	0	1	0
Menstruation with decreased bleeding						
Amenorrhoea	1	0	3	0	4	0
Menstruation delayed	0	0	1	0	1	0
Oligomenorrhoea	0	0	1	0	1	0
Menstruation with increased bleeding						
Menorrhagia	0	0	2	0	2	0
Ovarian and fallopian tube cysts and neoplasms						
Polycystic ovaries	0	0	1	0	1	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	1	0	1	0
Pelvic pain	0	0	1	0	1	0
Sexual function and fertility disorders NEC						
Infertility	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	1	0	1	0
Vulvovaginal disorders NEC						
Vaginal haemorrhage	0	0	2	0	2	0
Vulval haemorrhage	0	0	1	0	1	0
Vulvar dysplasia	0	0	1	0	1	0
Reproductive & breast disorders SOC TOTAL	2	0	51	0	53	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>						
<i>PT</i>						
Respiratory disorders						
<i>Breathing abnormalities</i>						
Dyspnoea	2	0	29	0	31	0
Dyspnoea exertional	0	0	1	0	1	0
Hyperventilation	0	0	4	0	4	0
Nocturnal dyspnoea	0	0	1	0	1	0
<i>Bronchospasm and obstruction</i>						
Asthma	0	0	7	0	7	0
Asthma exercise induced	0	0	3	0	3	0
Bronchospasm	0	0	1	0	1	0
<i>Coughing and associated symptoms</i>						
Cough	0	0	8	0	8	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>						
Laryngeal dyspnoea	0	0	1	0	1	0
Vocal cord disorder	0	0	1	0	1	0
<i>Laryngeal spasm, oedema and obstruction</i>						
Laryngeal oedema	0	0	1	0	1	0
<i>Lower respiratory tract signs and symptoms</i>						
Bronchial irritation	0	0	1	0	1	0
<i>Nasal disorders NEC</i>						
Epistaxis	0	0	1	0	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>						
Pharyngeal oedema	0	0	3	0	3	0
Tonsillar disorder	0	0	3	0	3	0
<i>Respiratory signs and symptoms NEC</i>						
Respiration abnormal	0	0	1	0	1	0
<i>Respiratory tract disorders NEC</i>						
Respiratory tract irritation	0	0	1	0	1	0
<i>Upper respiratory tract signs and symptoms</i>						
Dry throat	0	0	1	0	1	0
Dysphonia	0	0	2	0	2	0
Oropharyngeal pain	0	0	10	0	10	0
Rhinorrhoea	0	0	2	0	2	0
Throat irritation	0	0	1	0	1	0
Throat tightness	0	0	3	0	3	0
Respiratory disorders SOC TOTAL	2	0	86	0	88	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>						
<i>PT</i>						
Skin disorders						
<i>Acnes</i>						
Acne	0	0	5	0	5	0
Acne conglobata	0	0	1	0	1	0
<i>Alopecias</i>						
Alopecia	0	0	6	0	6	0
Alopecia areata	0	0	2	0	2	0
<i>Angioedemas</i>						
Angioedema	0	0	3	0	3	0
Swelling face	0	0	9	0	9	0
<i>Apocrine and eccrine gland disorders</i>						
Cold sweat	0	0	10	0	10	0
Hyperhidrosis	0	0	14	0	14	0
Night sweats	0	0	2	0	2	0
<i>Bullous conditions</i>						
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
<i>Dermal and epidermal conditions NEC</i>						
Dry skin	0	0	3	0	3	0
Pain of skin	0	0	1	0	1	0
Papule	0	0	2	0	2	0
Skin burning sensation	0	0	3	0	3	0
Skin discolouration	0	0	3	0	3	0
Skin swelling	0	0	1	0	1	0
<i>Dermatitis and eczema</i>						
Dermatitis	0	0	5	0	5	0
Dermatitis allergic	0	0	3	0	3	0
Dermatitis atopic	0	0	73	0	73	0
Eczema	0	0	45	0	45	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	1	0	1	0
<i>Erythemas</i>						
Erythema	0	0	24	0	24	0
Generalised erythema	0	0	1	0	1	0
Plantar erythema	0	0	1	0	1	0
Rash erythematous	0	0	1	0	1	0
<i>Exfoliative conditions</i>						
Exfoliative rash	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 Skin disorders cont'd						
SOC						
<i>HLT</i>						
<i>PT</i>						
Skin exfoliation	0	0	2	0	2	0
Hyperkeratoses						
Keratosis pilaris	0	0	1	0	1	0
Hyperpigmentation disorders						
Skin hyperpigmentation	0	0	2	0	2	0
Hypopigmentation disorders						
Skin hypopigmentation	0	0	1	0	1	0
Nail and nail bed conditions (excl infections and infestations)						
Nail disorder	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 papular	0	0	4	0	4	0
Rash papulosquamous	0	0	1	0	1	0
Photosensitivity and photodermatosis conditions						
Photosensitivity reaction	0	0	2	0	2	0
Solar dermatitis	0	0	1	0	1	0
Pilar disorders NEC						
Hair disorder	0	0	1	0	1	0
Hair growth abnormal	0	0	1	0	1	0
Pruritus NEC						
Pruritus	0	0	29	0	29	0
Pruritus generalised	0	0	2	0	2	0
Rash pruritic	0	0	26	0	26	0
Psoriatic conditions						
Psoriasis	0	0	4	0	4	0
Purpura and related conditions						
Chronic pigmented purpura	0	0	1	0	1	0
Ecchymosis	0	0	1	0	1	0
Henoch-Schonlein purpura	0	0	3	0	3	0
Petechiae	0	0	2	0	2	0
Rashes, eruptions and exanthems NEC						
Rash	0	0	42	0	42	0
Rash generalised	0	0	9	0	9	0
Rash macular	0	0	2	0	2	0
Rash maculo-papular	0	0	3	0	3	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

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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						
HLT						
PT						
<i>Skin and subcutaneous tissue ulcerations</i>						
Skin ulcer	0	0	1	0	1	0
<i>Skin dystrophies</i>						
Skin wrinkling	0	0	1	0	1	0
<i>Skin vasculitides</i>						
Leukocytoclastic vasculitis	0	0	1	0	1	0
<i>Urticarias</i>						
Urticaria	0	0	69	0	69	0
Urticaria chronic	0	0	1	0	1	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	0	0	465	0	465	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						
Bedridden	0	0	1	0	1	0
Impaired driving ability	0	0	1	0	1	0
Learning disability	0	0	1	0	1	0
Social circumstances SOC TOTAL	0	0	3	0	3	0

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Earliest reaction date:	01-Jan-2005	Reaction:	ALL
MedDRA version:	MedDRA 16.0	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						
Haematological therapeutic procedures NEC						
Bone marrow transplant	0	0	1	0	1	0
Lymphoid tissue therapeutic procedures						
Thymectomy	0	0	1	0	1	0
Obstetric therapeutic procedures						
Caesarean section	0	0	1	0	1	0
Therapeutic procedures NEC						
Off label use	0	0	2	0	2	0
Surgical & medical procedures SOC TOTAL	0	0	5	0	5	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.

Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

Drug name:	HUMAN PAPILLOMA VIRUS	Report type:	Spontaneous
Report run date:	31-Oct-2013	Report origin:	DENMARK
Data lock date:	30-Oct-2013 23:33:49	Route of admin:	ALL
Period covered:	01-Jan-1968 to 30-Oct-2013	Reporter type:	ALL
Earliest reaction date:	01-Jan-2005	Reaction:	ALL
MedDRA version:	MedDRA 16.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Vascular disorders						
<i>Blood pressure disorders NEC</i>						
Labile blood pressure	0	0	1	0	1	0
<i>Circulatory collapse and shock</i>						
Peripheral circulatory failure	0	0	1	0	1	0
<i>Haemorrhages NEC</i>						
Haematoma	0	0	1	0	1	0
Haemorrhage	0	0	1	0	1	0
<i>Non-site specific vascular disorders NEC</i>						
Arterial disorder	0	0	1	0	1	0
<i>Peripheral vascular disorders NEC</i>						
Flushing	0	0	1	0	1	0
Hot flush	0	0	11	0	11	0
<i>Site specific vascular disorders NEC</i>						
Pallor	0	0	9	0	9	0
<i>Vascular hypotensive disorders</i>						
Hypotension	1	0	10	0	11	0
Orthostatic hypotension	0	0	1	0	1	0
<i>Vasculitides NEC</i>						
Vasculitis	0	0	1	0	1	0
Vascular disorders SOC TOTAL	1	0	38	0	39	0
TOTAL NUMBER OF REACTIONS	45	0	3079	1	3124	1
TOTAL NUMBER OF FATAL ADR REPORTS*		0		1		1*
TOTAL NUMBER OF ADR REPORTS*	4		967		971*	

*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.