

Drug Analysis Print
Drug name: HUMAN PAPILLOMA VIRUS

[Jump to first report page](#)

| | | | |
|--------------------------------|----------------------------|------------------------|-------------|
| 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): | SILGARD |
| CERVARIX | |
| GARDASIL | |

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

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 |

| 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 |
|----------------------------------|-----------|----------|-------------|----------|-------------|----------|

| | | | | | | |
|---|----------|----------|------------|----------|-------------|-----------|
| 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.

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 |

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

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 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.

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 | | | | | | |
| 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.

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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 |

*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 PAPILOMA VIRUS

| | | | |
|--------------------------------|----------------------------|------------------------|-------------|
| Drug name: | HUMAN PAPILOMA 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 | | | | | | |
| <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 |

*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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 |

*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 |
| 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 |

*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 | | | | | | |
| <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 |

^{*}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 PAPILOMA VIRUS

| | | | |
|--------------------------------|----------------------------|------------------------|-------------|
| Drug name: | HUMAN PAPILOMA 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 |
| Reaction Name 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 | | | | | | |

^{*}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 |
| 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 |

*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 ^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 |

^aThis 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 | | | | | | |
| Immune system disorders | | | | | | |
| <i>Allergic conditions NEC</i> | | | | | | |
| 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 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | | | | | |
| Food allergy | 0 | 0 | 2 | 0 | 2 | 0 |
| <i>Anaphylactic responses</i> | | | | | | |
| Anaphylactic reaction | 0 | 0 | 2 | 0 | 2 | 0 |
| Anaphylactic shock | 0 | 0 | 5 | 0 | 5 | 0 |
| <i>Atopic disorders</i> | | | | | | |
| House dust allergy | 0 | 0 | 1 | 0 | 1 | 0 |
| Seasonal allergy | 0 | 0 | 2 | 0 | 2 | 0 |
| <i>Immune and associated conditions NEC</i> | | | | | | |
| Immune system disorder | 0 | 0 | 1 | 0 | 1 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | | | | | |
| Immunosuppression | 0 | 0 | 1 | 0 | 1 | 0 |
| Immune system disorders SOC TOTAL | 0 | 0 | 35 | 0 | 35 | 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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 |

*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 |
| 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 |

*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 ^a | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------------------|----------|
| | 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 |

^aThis 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 | | | | | | |
| <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 |

*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 |
| 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 | | | | | | |

*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 ^a | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| Reaction Name Nervous system disorders cont'd | | | | | | |
| SOC | | | | | | |
| HLT | | | | | | |
| 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 |

^aThis 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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 | | | | | | |

*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 |
| 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 |

*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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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 |

*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 | | | | | | |
| <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 |

*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 | | | | | | |
| <i>HLT</i> | | | | | | |
| <i>PT</i> | | | | | | |
| Skin disorders | | | | | | |
| Acnes | | | | | | |
| Acne | 0 | 0 | 5 | 0 | 5 | 0 |
| Acne conglobata | 0 | 0 | 1 | 0 | 1 | 0 |
| Alopecias | | | | | | |
| Alopecia | 0 | 0 | 6 | 0 | 6 | 0 |
| Alopecia areata | 0 | 0 | 2 | 0 | 2 | 0 |
| Angioedemas | | | | | | |
| Angioedema | 0 | 0 | 3 | 0 | 3 | 0 |
| Swelling face | 0 | 0 | 9 | 0 | 9 | 0 |
| Apocrine and eccrine gland disorders | | | | | | |
| Cold sweat | 0 | 0 | 10 | 0 | 10 | 0 |
| Hyperhidrosis | 0 | 0 | 14 | 0 | 14 | 0 |
| Night sweats | 0 | 0 | 2 | 0 | 2 | 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 |
| Dermal and epidermal conditions NEC | | | | | | |
| 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 |
| Dermatitis and eczema | | | | | | |
| 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 |
| Erythemas | | | | | | |
| 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 |
| Exfoliative conditions | | | | | | |
| Exfoliative rash | 0 | 0 | 1 | 0 | 1 | 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 |
| 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 |

*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 |
| Reaction Name Skin disorders cont'd | | | | | | |
| SOC | | | | | | |
| <i>HLT</i> | | | | | | |
| <i>PT</i> | | | | | | |
| <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 |

*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 | | | | | | |
| 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 |

*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 | | | | | | |
| 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.