

VAERS Line List Report

Report run on: 07 SEP 2007 12:15

Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND

Vaers Id: 283893-1

| <u>Age</u> | <u>Gender</u> | <u>Vaccine Date</u> | <u>Onset Date</u> | <u>Days</u> | <u>Received Date</u> | <u>Status Date</u> | <u>State</u> | <u>Mfr Report Id</u> | <u>Last Edit Date</u> |
|------------|---------------|---------------------|-------------------|-------------|----------------------|--------------------|--------------|----------------------|-----------------------|
| 18.0 | F | 14-Jun-2007 | 15-Jun-2007 | 1 | 05-Jul-2007 | 08-Jul-2007 | NC | | 09-Jul-2007 |

| <u>VAX Detail:</u> | <u>Type</u> | <u>Manufacturer</u> | <u>Lot</u> | <u>Prev Doses</u> | <u>Site</u> | <u>Route</u> | <u>Other Vaccine</u> |
|--------------------|-------------|---------------------|------------|-------------------|-------------|---------------|----------------------|
| | HPV4 | MERCK & CO, INC. | 0387U | 2 | Right arm | Intramuscular | |

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Facial palsy, Fatigue, Gait disturbance, Guillain-Barre syndrome, Headache, Heart rate increased, Muscular weakness, Myalgia, Paraesthesia

Symptom Text: Guillain-Barre Syndrome. Within 24 hours of receiving HPV shot, patient experienced headache and extreme fatigue and weakness. Muscle weakness began in legs and progressed to arms, head and neck. Tingling in hands and feet. Intense muscle pain in thighs, hips, and arms. By ninth day, patient's facial muscles were drooping, experiencing rapid heartbeat and dragging right foot when trying to walk. By end of week 2 muscle function had returned and patient was recovering. Extreme fatigue still remains.

Other Meds: Cymbalta

Lab Data: EMS, 1 abnormal nerve response in right leg.

History: none

Prex Illness: none

Prex Vax Illns:

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Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND

Vaers Id: 280233-1 (S)

| <u>Age</u> | <u>Gender</u> | <u>Vaccine Date</u> | <u>Onset Date</u> | <u>Days</u> | <u>Received Date</u> | <u>Status Date</u> | <u>State</u> | <u>Mfr Report Id</u> | <u>Last Edit Date</u> |
|------------|---------------|---------------------|-------------------|-------------|----------------------|--------------------|--------------|----------------------|-----------------------|
| 20.0 | F | 19-Apr-2007 | 26-Apr-2007 | 7 | 04-Jun-2007 | 05-Jun-2007 | IN | WAES0705USA04014 | 07-Jun-2007 |

| <u>VAX Detail:</u> | <u>Type</u> | <u>Manufacturer</u> | <u>Lot</u> | <u>Prev Doses</u> | <u>Site</u> | <u>Route</u> | <u>Other Vaccine</u> |
|--------------------|-------------|---------------------|------------|-------------------|-------------|---------------|----------------------|
| | HPV4 | MERCK & CO. INC. | NULL | 0 | Unknown | Intramuscular | |

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Headache, VIth nerve paralysis, Vision blurred

Symptom Text: Information has been received from a physician and a 20 year old female consumer with Ceclor and sulfonamide allergy who on 19-APR-2007 was vaccinated with the first dose of Gardasil, IM. Concomitant medication was not reported. On approximately 26-APR-2007 ("within a week of receiving the vaccination), the patient reported that she had continued blurred vision "MS type symptoms" and had a 3 day hospital stay. A physician reported that on 29-APR-2007, the patient developed double vision which became progressively worse. The patient was diagnosed with sixth cranial nerve palsy. The patient had numerous diagnostic tests performed which included MRI's, an angiogram, lumbar puncture, visual tests and blood tests including a complete blood count, metabolic profile, antinuclear antibody (ANA) test, anticardiolipin antibody, sedimentation rate and blood test to rule out syphilis, Myasthenia Gravis, Sarcoidosis and Lyme disease. All of these test results were within normal limits. The patient was treated with steroids and was improving. Additional information has been requested. 06/06/07-records received from facility for DOS 5/1-5/2/07-DC DX: Left cranial nerve VI palsey on left. Mild hypertension. On 4/29/07 while watching TV noticed double vision on looking to left. Gradual onset. On 4/30/07 woke with double vision when looking in all directions. Double vision is with one image side by side to the other image. MRI brain showed right hemispheric lesion. Ophthalmologist noted optic nerve lesion. Headache come on after having double vision. No eye pain no numbness or weakness.

Other Meds: Unknown

Lab Data: angiography 04/29?/07 - within normal limits, diagnostic laboratory 04/29?/07 - within normal limits, diagnostic laboratory 04/29?/07 - Sarcoidosis: within normal limits, magnetic resonance 04/29?/07 - within normal limits, visual acuity te

History: records received 6/6/07-HX:possible hypertension, seasonal allergies, dysmenorrhea and possible diabetes. Prescribed metformin but does not take it.

Prex Illness: Allergic reaction to antibiotics; Sulfonamide allergy

Prex Vax Illns:

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Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) **Reported Date:** 10-MAY-07 - 07-SEP-07 **All comb. w/AND**

Vaers Id: 289027-1 (S)

| <u>Age</u> | <u>Gender</u> | <u>Vaccine Date</u> | <u>Onset Date</u> | <u>Days</u> | <u>Received Date</u> | <u>Status Date</u> | <u>State</u> | <u>Mfr Report Id</u> | <u>Last Edit Date</u> |
|------------|---------------|---------------------|-------------------|-------------|----------------------|--------------------|--------------|----------------------|-----------------------|
| 13.0 | F | Unknown | Unknown | | 27-Aug-2007 | 28-Aug-2007 | KY | WAES0708USA02942 | 28-Aug-2007 |

| <u>VAX Detail:</u> | <u>Type</u> | <u>Manufacturer</u> | <u>Lot</u> | <u>Prev Doses</u> | <u>Site</u> | <u>Route</u> | <u>Other Vaccine</u> |
|--------------------|-------------|---------------------|------------|-------------------|-------------|--------------|----------------------|
| | HPV4 | MERCK & CO. INC. | NULL | 0 | Unknown | Unknown | |

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Myelitis transverse, Neuromyelitis optica, Paralysis

Symptom Text: Initial and follow-up information has been received from a physician concerning an "otherwise healthy" 13 year old female who was vaccinated with her first and second doses of Gardasil. Subsequently the patient experienced what was thought to be transverse myelitis and was hospitalized. She experienced paralysis from the chest down, lesions of the optic nerve, and was diagnosed with "Neuromyelitis Optica (NMO)". The patient was treated with high dose corticosteroids (unspecified) and did not respond. A course of Cytoxan was planned. Duration of hospitalization was not reported. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

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Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND

Vaers Id: 280230-1 (S)

| <u>Age</u> | <u>Gender</u> | <u>Vaccine Date</u> | <u>Onset Date</u> | <u>Days</u> | <u>Received Date</u> | <u>Status Date</u> | <u>State</u> | <u>Mfr Report Id</u> | <u>Last Edit Date</u> |
|--------------------|---------------|---------------------|---------------------|-------------|----------------------|--------------------|--------------|----------------------|-----------------------|
| 16.0 | F | 22-May-2007 | 22-May-2007 | 0 | 04-Jun-2007 | 05-Jun-2007 | FR | WAES0705AUS00191 | 05-Jun-2007 |
| <u>VAX Detail:</u> | | <u>Type</u> | <u>Manufacturer</u> | <u>Lot</u> | <u>Prev Doses</u> | <u>Site</u> | <u>Route</u> | <u>Other Vaccine</u> | |
| | | HPV4 | MERCK & CO. INC. | NULL | 0 | Unknown | Unknown | | |

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Brachial plexopathy, Hypokinesia, Injected limb mobility decreased, Injection site anaesthesia, Mobility decreased, Muscular weakness, Neck pain, Paraesthesia, Paralysis, Pharyngeal hypoaesthesia

Symptom Text: Information has been received from a physician at an infectious diseases unit, who was notified of the following adverse event by a consultant neurologist who was the treating physician. This information was reported to us via a agency, as part of a business agreement (manufacturer's case number: GARD 2007 05 28 003). The patient is a 16 year old female who on 22-MAY-2007 was vaccinated with Gardasil as prophylaxis. On 22-MAY-2007, following vaccination with Gardasil, the patient experienced numbness at injection site which increased over the next five days. She was also unable to move her left leg but this resolved on 27-MAY-2007, five days post-vaccination. On 27-MAY-2007 the patient developed paralysis of injected limb and was unable to move her left arm. She had some left neck pain and paraesthesia and some throat numbness. She also experienced weakness in her left arm. The patient was hospitalised and at the time of reporting on 28-MAY-2007 was awaiting investigation. The consultant neurologist (treating physician) made a clinical diagnosis of "probable post-vaccine brachial plexopathy" but at the time of reporting a magnetic resonance imaging (MRI) and nerve conduction studies had not been performed. The patient's numbness at injection site; inability to move left arm; weakness in left arm; left neck pain and paraesthesia, and throat numbness persisted. The reporter felt that paralysis of injected limb; inability to move left arm and left leg; numbness at injection site; weakness in left arm; left neck pain and paresthesia, and throat numbness were related to therapy with Gardasil. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

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Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND

Vaers Id: 287369-1 (S)

| <u>Age</u> | <u>Gender</u> | <u>Vaccine Date</u> | <u>Onset Date</u> | <u>Days</u> | <u>Received Date</u> | <u>Status Date</u> | <u>State</u> | <u>Mfr Report Id</u> | <u>Last Edit Date</u> |
|------------|---------------|---------------------|-------------------|-------------|----------------------|--------------------|--------------|----------------------|-----------------------|
| 23.0 | F | 27-Apr-2007 | 01-Jun-2007 | 35 | 08-Aug-2007 | 09-Aug-2007 | VA | WAES0707USA04986 | 09-Aug-2007 |

| <u>VAX Detail:</u> | <u>Type</u> | <u>Manufacturer</u> | <u>Lot</u> | <u>Prev Doses</u> | <u>Site</u> | <u>Route</u> | <u>Other Vaccine</u> |
|--------------------|-------------|---------------------|------------|-------------------|-------------|---------------|----------------------|
| | HPV4 | MERCK & CO. INC. | NULL | 0 | Unknown | Intramuscular | |

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Contusion, Epistaxis, Idiopathic thrombocytopenic purpura, Immunoglobulins

Symptom Text: Information has been received from a physician concerning a 23 year old female patient who during the last week of April 2007 was vaccinated IM with a first dose of Gardasil. Concomitant therapy included tetanus toxoid, tetracycline and hormonal contraceptives (unspecified brand). In June 2007, the patient developed nose bleed and bruising of her body. The patient's platelet count reached 2000 and was hospitalized for ITP (Idiopathic Thrombocytopenic Purpura). The patient was treated with intravenous immunoglobulin and high dose corticosteroids (unspecified). The patient responded to the corticosteroids (unspecified) but became intolerant to the side effects. There have been more than one attempts to taper the patient off the corticosteroid but the platelets decreased each time. As of 26-JUL-2007, the patient's platelet count was 8000. No other details were provided. Physician did not provide specifics on corticosteroid side effects that the patient developed. The patient had not recovered. The events nose bleeds, bruising of patient's body, and Idiopathic Thrombocytopenic Purpura (ITP) were considered to be life-threatening. Additional information has been requested.

Other Meds: Hormonal contraceptives; Tetracycline

Lab Data: Platelet count 06/??/07 - 2000; Platelet count 07/26/07 - 8000

History: Unknown

Prex Illness:

Prex Vax Illns:

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Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND

Vaers Id: 281653-1 (S)

| <u>Age</u> | <u>Gender</u> | <u>Vaccine Date</u> | <u>Onset Date</u> | <u>Days</u> | <u>Received Date</u> | <u>Status Date</u> | <u>State</u> | <u>Mfr Report Id</u> | <u>Last Edit Date</u> |
|--------------------|---------------|---------------------|---------------------|-------------|----------------------|--------------------|---------------|----------------------|-----------------------|
| 24.0 | F | 01-Apr-2007 | 01-Apr-2007 | 0 | 14-Jun-2007 | 15-Jun-2007 | NY | WAES0706USA00814 | 15-Jun-2007 |
| <u>VAX Detail:</u> | | <u>Type</u> | <u>Manufacturer</u> | <u>Lot</u> | <u>Prev Doses</u> | <u>Site</u> | <u>Route</u> | <u>Other Vaccine</u> | |
| | | HPV4 | MERCK & CO. INC. | NULL | 0 | Unknown | Intramuscular | | |

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Heart rate irregular, Nausea, Throat tightness

Symptom Text: Information has been received from a nurse concerning a 24 year old female patient who in April 2007, "about two months ago" was vaccinated IM with a first dose of Gardasil. Within about a half an hour, the patient experienced chest pains, nausea, tightening of the throat, and an irregular heartbeat. The nurse reported that the patient has been hospitalized twice for the irregular heartbeat since receiving Gardasil. The nurse also reported that the patient has no prior history of heartbeat irregularities. Laboratory diagnostic studies included blood pressure and monitoring. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: medical observation 04/??/07 - Blood Pressure Monitoring

History: Unknown

Prex Illness:

Prex Vax Illns: