

# VAERS Line List Report

Report run on: 15 MAY 2009 10:16

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**Vax Type: HPV4    Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND**

**Vaers Id:** 320598-1 (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>
19.0	F	11-May-2007	22-May-2007	11	29-Jul-2008	01-Aug-2008	NM		04-Nov-2008

<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.	0384U	0	Left arm	Intramuscular	

**Seriousness:** ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

**MedDRA PT** Aggression, Arthralgia, Complex partial seizures, Confusional state, Convulsion, Crying, Dizziness, Epilepsy, Fatigue, Feeling abnormal, Grand mal convulsion, Immediate post-injection reaction, Irritability, Myalgia, Nausea, Pain, Postictal state, Somnolence, Syncope, Tremor, Unresponsive to stimuli

**Symptom Text:** SYNCOPE, NAUSE, DIZZINESS AT TIME OF INJECTION. FATIGUE, "BRAIN FOG", IRRITABILITY AND MUSCLE ACHES AND SORENESS IN JOINTS WITHIN HOURS OF INJECTION AND CONTINUING TO DATE. SEIZURES, WITH NO PREVIOUS HISTORY, WITHIN MONTHS OF VACCINE, NO EXPLANATION AND CONTINUE TO DATE. PATIENT IS ON MEDICATIONS TO CONTROL SEIZURES AT THIS TIME. PATIENT REQUIRED TO EMERGENCY ROOM VISITS AT TIME OF BOTH GRAND MAL SEIZURES. 9/22/2008 Office records received from Neuro consult beginning 11/27/07. Pt presented after 1st generalized seizure on 11/24/07. Seizure lasted ~45 minutes with post ictal sleepines, then confusion, combativeness and tearfulness. Seen 12/7/07 following 2nd similar seizure, again during sleep. Placed on lamictal. Pt continued to have brief complex partial seizures. Report from 2nd neurologist also included. Seen 1/2/2008. DX: New onset epilepsy. 10/29/2008 MR received for ER visit 12/2/2007 with DX: seizure. Pt presented after 2nd seizure. Found unresponsive, shaking all over. Pain 4-10/10. D/C on Cerebyx.

**Other Meds:**

**Lab Data:** CBC, CT SCAN, MRI SCAN, TOXICOLOGY SCREEN, MULTIPLE EEGS. CONTINUED BLOOD WORK TO DATE. Labs and Diagnostics: EEG WNL initially then slightly abnormal. 24 hr ambulatory EEG unremarkable. MRI brain WNL.

**History:** PMH: none. Family hx of seizure. On oral contraceptives for acne

**Prex Illness:**

**Prex Vax Illns:**

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Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

**Vaers Id:** 330671-1

<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>
17.0	F	23-Apr-2008	Unknown		17-Oct-2008	11-Feb-2009	AR	WAES0809USA04924	12-Feb-2009

<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	2	Unknown	Unknown	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Biopsy skin, Skin papilloma

**Symptom Text:** Information has been received from a physician concerning a 17 year old female who on 23-APR-2008 was vaccinated with the third dose of GARDASIL. The physician reported that after the patient's last dose of GARDASIL the patient experienced skin warts that were all over her body cleared up. Biopsy of skin warts were performed. The patient sought unspecified medical attention. Additional information has been requested.

**Other Meds:** Unknown

**Lab Data:** Unknown

**History:** Unknown

**Prex Illness:**

**Prex Vax Illns:**

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**Vax Type: HPV4    Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND**

**Vaers Id:** 319836-1 (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-Jun-2006	01-Feb-2008	610	21-Jul-2008	28-Jul-2008	--		30-Jul-2008

<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	2	Unknown	Unknown	

**Seriousness:** LIFE THREATENING, SERIOUS

**MedDRA PT** Biopsy cervix abnormal, Cervix carcinoma, Smear cervix abnormal, Surgery

**Symptom Text:** I was diagnosis with Cervical Cancer in April 2008. I have gotten a routine thin pap test each year for the last 8 years. February 2008 was my first abnormal pap smear in my lifetime. I received the GARDASIL shot in June of 2006 after hearing and reading about its approval by the FDA. I was the first patient my doctor ever gave the HPV vaccination to. I received all three of the shots and completed the HPV vaccination in November of 2006; each given by my doctor. I had my annual pap smear in February of 2007, and like each pap smear before, it came back negative. When my February 2008 pap smear came back positive my doctor then did a biopsy which came back with high-grade cells and warranted a LEEP procedure. The LEEP was performed at a local hospital on March 14, 2008. The pathology results from the LEEP came back and showed that within a year of my last normal pap smear and 15 months from the completion of the GARDASIL HPV vaccination, I had full blown cervical cancer. On May 6th of 2008 I had my second surgery, a Cone Biopsy of my cervix by Dr., an oncologist at Cancer Center. My second surgery was performed at another hospital. I will now have to see my Oncologist every three months and wait to see, not 'if', but 'when', my cervical cancer returns. My oncologist would like to do a hysterectomy at this time, but as a 26-year-old who has always wanted children, I have chosen to wait as long as possible before removing my reproductive organs. As a very health conscious and responsible person, I have always researched health care issues and been good to my body. Thinking it was in my best interest of my health and well being, I received the GARDASIL shot in June 2006. It was discovered in March of 2008, followed by my first abnormal pap smear, that I have two of the four HPV strains, 16 and 18, that the shot is suppose to prevent, as well as prevent the onset of HPV symptoms. I now have cervical cancer and I am left wondering what role the GARDASIL HPV vaccination played in the hasty onset of my onset. I wish I ha

**Other Meds:**

**Lab Data:** 7/28/08-records received-5/6/08-Cold knife conization of cervix-squamous metaplasia and acute and chronic cervicitis, no dysplasia or malignancy identified. 5/22/08-Stage 1 depth of invasion less than 1mm with margin involvement dysplasia.

**History:**

**Prex Illness:**

**Prex Vax Illns:**

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Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

**Vaers Id:** 318052-1 (S) **Related reports:** 318052-2; 318052-3; 318052-4

<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>
21.0	F	24-Aug-2007	01-Sep-2007	8	01-Jul-2008	03-Jul-2008	OH		06-May-2009

<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.	0930U	1	Left arm	Intramuscular	

**Seriousness:** ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

**MedDRA PT** Abasia, Asthenia, Conversion disorder, Dermatitis acneiform, Dizziness, Eating disorder, Facial palsy, Fall, Headache, Hyperaesthesia, Hyperhidrosis, Hypoaesthesia, Hyporeflexia, Local swelling, Loss of control of legs, Myalgia, Myositis, Nausea, Pain, Pain of skin, Paraesthesia, Photosensitivity reaction, Red blood cell sedimentation rate increased, Skin burning sensation, Sleep disorder, Swelling face, Syncope, Vertigo, Vomiting

**Symptom Text:** Aug.24, second Gardasil injection received. Sept.3, pressure in jaw and head began, followed by weakness, severe pain and loss of use of legs; nausea, dizziness, fainting, swelling and drooping of face and neck. Oct.2007, lost ability to walk, burning prickles in scalp, hands, legs. Seen by several specialists including hospital neurological teams- no diagnosis given. Seen by multiple specilists Jan. 2008 - June 2008. Unable to eat solid foods, placed on liquid diet. Finally diagnosed by D.O. as having an adverse reaction to Gardasil. Special diet and pain medication given which seem to be helping in small degrees. We were told it would be a long time recovering. 2nd report 320256. 07/23/2008 MR received for DOS 10/19-24/2007 which include 2 Rheumatology consults, neuro consult, psych consult and inpt admission. Pt presented for Rheum eval 10/19/07 with c/o 6 week hx of pain and sensitivity in her face, jaw neck and thoracic region (burning & tingling) and progressive weakness in her limbs. Unable to walk without assistance. Pt reports dizziness, vertigo, syncope and photosensitivity. Sleep is disturbed. Several falls. Has sweats. Presents in sunglasses for photophobia and in a w/c. This followed a viral and /or sinus infection 6 weeks prior. PE (+) for anceiform rash on the back, scalp, face, jaw, and neck tenderness, DTRs 1+ arms, unobtainable in legs, decreased strength in arms and legs, unable to walk. Concern for neurological illness resulted in emergent admission to hospital for further eval. DOS 10/19-24/2007 with DX: weakness. other dx: fibromyalgia, migraines, asthma and chronic pain syndrome. Neuro consult as above but able to elicit patellar reflexes. Psych eval to r/o conversion d/o. Requested further eval. 2nd Rheum consult for increased sed rate. Additional sx of touch sensitivity and lower extremity numbness. Impression: Elevated Sed rate. Myalgia and myositis NOS, Headache, Difficulty in walking. Pt had some nausea and vomiting while admitted. Treated for pain and pt was ambulati

**Other Meds:** Topomax 50 mg 1 per day

**Lab Data:** MRI, CTscan, LP, Multiple Blood tests, Sed rate checked multiple times, DNA tests, Urine analysis, EEG, EMG. Hair analysis. Labs and Diagnostics: CXR WNL. Lumbar MRI Unremarkable. Cervical MRI Unremarkable. Thoracis MRI Unremarkable. Bra

**History:** Fibromyalgia, chemical sensitivity, migraines. PMH: fibromyalgia, migraines, asthma, hernia surgery, abd surg.

**Prex Illness:** None

**Prex Vax Illns:** None~ ()~0~Patient

# VAERS Line List Report

**Vax Type: HPV4    Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND**

**Vaers Id:** 314769-1

<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	02-Jun-2008	02-Jun-2008	0	03-Jun-2008	04-Jun-2008	MI		04-Jun-2008

<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>
	MNQ	SANOFI PASTEUR	U2562AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2688AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB114AH	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	

**Seriousness:** NO CONDITIONS, NOT SERIOUS

**MedDRA PT** Heart rate, Loss of consciousness, Pallor, Respiratory rate, Syncope

**Symptom Text:** Administered Tdap, Hep A, and then HPV4. Within 5-10 seconds following the HPV4 client fainted, was unconscious for approx 15-20 seconds, woke up with ammonia inhalants. Color pale but pulse at approx 60/min and resp from 12-14/minute. Assisted to exam table, remained in clinic for 30 minutes under observation. Grandmother with client--states has hx of being "woozy". Menactra given after recovery.

**Other Meds:** None

**Lab Data:** none

**History:** None, no allergies noted.

**Prex Illness:** None

**Prex Vax Illns:**