

VAERS Line List Report

Report run on: 30 MAR 2010 09:46

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Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 339375-2 (S) **Related reports:** 339375-1

<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>
10.0	F	15-Jan-2009	28-Jan-2009	13	10-Dec-2009	11-Dec-2009	--	WAES0903USA04975	05-Jan-2010

<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.	0719X	0	Right arm	Intramuscular	

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

MedDRA PT Areflexia, Asthenia, Ataxia, Blood product transfusion, Dizziness, Guillain-Barre syndrome, Headache, Vertigo, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 15-JAN-2009, a 10 year old female with allergy to AMPICILLIN SULBACTAM was vaccinated IM into the right arm with the first dose of GARDASIL (lot # 0719X). There was no concomitant therapy. There was no preexisting illness. Thirteen days later on 28-JAN-2009 and for 3 days the patient had vomit, dizziness and cephalgia, later vertiginous sensation. On 31-JAN-2009, the patient presented a frank ataxia gait and progressive loss of strength in lower and upper extremities almost totally in the following 3 days with loss of osteotendinous reflexes. They had taken a normal brain computed axial tomography (CT) scan, a normal magnetic resonance imaging (MRI) and nerve conduction studies compatible with GBS. She started treatment with immunoglobulin with a response in 72 hours and almost total recovery of the motor function. Vertiginous felling and cephalgia still persisted. The listing indicated that one or more of the events required hospitalization, was considered to be immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS ID # is 339375. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released.

Other Meds: None

Lab Data: nerve conduction study, compatible with GUILLAIN-BARRE Syndrome; head computed axial, normal; magnetic resonance, normal

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns: