VAERS – Cases of Pancreatitis and Pancreatitis Acute

Life Threatening
Reporter considered symptoms were possibly related to therapy with Gardasil
Details relating to symptoms

VAERS ID: 307886  Vaccinated: 2007-09-03
Age: 15.0  Onset: 2008-03-06, Days after vaccination: 185
Gender: Female  Submitted: 2008-03-21, Days after onset: 14
Location: Entered: 2008-03-24, Days after submission: 3
Life Threatening Illness? Yes
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Current Illness:
Diagnostic Lab Data: Unknown
Previous Vaccinations:
Other Medications: THYRONAJOD, Unk - Unk
Preexisting Conditions: No reaction on previous exposure to vaccine
CDC 'Split Type': WAES0803USA02574

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td>0575</td>
<td>0</td>
<td>UN</td>
<td>UN</td>
</tr>
</tbody>
</table>

Administered by: Unknown  Purchased by: Unknown

Symptoms: Pancreatitis acute
Write-up: Information has been received from a physician concerning a 15 year old female, who on 03-SEP-2007 was vaccinated with a first dose of Gardasil (Lot# 655127/0575F; Batch# NF23310). On 08-SEP-2007 was vaccinated with a second dose of Gardasil (Lot# 1358F; Batch# NG01520). The first and second doses were well tolerated. On 07-FEB-2008 the patient was vaccinated IM in the upper arm with a third dose of Gardasil (Lot# 0467U; Batch# NG14290). Concomitant therapy included THYRONAJOD. On 06-MAR-2008 the patient experienced acute pancreatitis. At the time of the report, the outcome of the patient was unknown. The physician considered acute pancreatitis to be life threatening. Additional information was not available.

VAERS ID: 311857  Vaccinated: 2007-09-27
Age: 26.0  Onset: 2007-09-29, Days after vaccination: 2
Gender: Female  Submitted: 2008-05-07, Days after onset: 221
Location: Entered: 2008-05-08, Days after submission: 1
Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
   Extended hospital stay? No
Current Illness:
Diagnostic Lab Data: abdominal X-ray, 03Oct07, abnormal; computed axial tomography, 03Oct07, grossly; computed axial tomography, pancreatitis; Epstein-Barr virus antibodies, 03Oct07, negative; WBC count, 03Oct07, 10.3; adenovirus PCR, 03Oct07, negative; arteria

Previous Vaccinations:
Other Medications: doxycycline hyclate, Unk - Unk; promethazine HCl, Unk - Unk; ranitidine HCl, Unk - Unk
Preexisting Conditions: Unknown

CDC 'Split Type': WAES0805AUS00050

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td>0</td>
<td>IM</td>
<td>UN</td>
<td></td>
</tr>
</tbody>
</table>

Administered by: Unknown  Purchased by: Unknown

Symptoms: Abdominal X-ray, Abdominal pain upper, Acidosis, Alanine aminotransferase normal, Antibody test negative, Ascites, Aspartate aminotransferase increased, Bacterial culture negative, Blood calcium decreased, Blood culture negative, Blood pH increased, Computerised tomogram abnormal, Culture urine negative, Cytomegalovirus antibody negative, Enterovirus serology test negative, Epstein-Barr virus antibody negative, Gamma-glutamyltransferase increased, Haemoglobin, Herpes simplex serology negative, Hypocalcaemia, Laboratory test normal, Mumps antibody test negative, Pancreatitis, Pyrexia, Rash generalised, Toxoplasma serology negative, Viral DNA test negative, Virus serology test, White blood cell count increased, X-ray abnormal

Write-up: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 26 year old female who on 27-SEP-2007 was vaccinated with GARDASIL. Concomitant therapy included doxycycline hyclate, PHENERGAN TABLETS/SUPPOSITORIES) and ZANTAC. On 29-SEP-2007 the patient experienced rash generalised, abdominal pain upper (described as right upper quadrant epigastric pain), blood amylase increased, lipase increased, pancreatitis and pyrexia and was hospitalized, CT scan revealed pancreatitis and intraabdominal fluid. On 03-OCT-2007, the patient’s calcium was low (hypocalcemia) while pH was 7.25 (acidosis). Abdominal x-ray was abnormal. CT scan of the abdomen revealed a grossly oedematous pancreas and ascites. Blood and urine culture were negative. The patient’s GGT was 49, ALT (SGPT) was 27 and the AST (SGOT) was 45. White blood cell count was 10.3 while the haemoglobin was 91%. Other laboratory investigations such as VRE, adenovirus CMV, EBV, HSV, mumps, varicella zoster and toxoplasma screens were all negative. At the time of reporting on 19-OCT-2007 the patient’s rash generalised and abdominal pain upper and blood amylase increased and lipase increased and pancreatitis and pyrexia persisted. The agency considered that rash generalised, abdominal pain upper, blood amylase increased, lipase increased, pancreatitis and pyrexia were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient’s experience was reported in an article, 25-JAN-2008. Additional information is not expected.

VAERS ID: 312075  Vaccinated: 2007-07-15
Age: 24.0  Onset: 2007-09-18, Days after vaccination: 65
Gender: Female  Submitted: 2008-05-09, Days after onset: 234
Location: Entered: 2008-05-12, Days after submission: 3

Life Threatening Illness? No
Died? No

Copyright 2010 S.A.N.E. Vax Inc.
sanevax.org
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
Extended hospital stay? No

Current Illness:
Diagnostic Lab Data: Serum calcium 18Sep07 2.63 H mmol/L Normal Range: 2.10 - 2.60; serum lipase test 18Sep07 711 H U/L Normal Range: 13 - 60

Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown
CDC 'Split Type': WAES0805AUS00064

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td>0734U</td>
<td>1</td>
<td>IM</td>
<td>UN</td>
</tr>
</tbody>
</table>

Administered by: Unknown Purchased by: Unknown

Symptoms: Blood calcium increased, Lipase increased, Pancreatitis

Write-up: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 24 year old female who on 15-JUL-2007 was vaccinated with GARDASIL. On 18-SEP-2007 the patient developed pancreatitis and was hospitalized. Laboratory investigations included calcium which was 2.63 H mmol/L (normal range: 2.10-2.60) and lipase which was 711H U/L (normal range: 13-60). At the time of reporting on 19-OCT-2007, the patient's pancreatitis persisted. The agency considered that pancreatitis was possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient’s experience was reported in an article, 25-JAN-2008. Additional information is not expected. A copy of the published article is attached as further documentation of the patient’s experience.

VAERS ID: 324446 Vaccinated: 2007-10-11
Age: 20.0 Onset: 2007-10-11, Days after vaccination: 0
Gender: Female Submitted: 2008-09-05, Days after onset: 330
Location: Entered: 2008-09-08, Days after submission: 3

Life Threatening Illness? No
Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
Extended hospital stay? No

Current Illness:
Diagnostic Lab Data: diagnostic laboratory test, 25?Aug 08, all bloods returned to normal; serum lipase test, 04Aug08, 2025, abnormal; serum amylase test, ??08, increased

Previous Vaccinations:
Other Medications: ethinyl estradiol (+) levonorgestrel, Unk - Unk
Preexisting Conditions: Unknown
CDC 'Split Type': WAES0808AUS00325

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td>0734U</td>
<td>1</td>
<td>IM</td>
<td>UN</td>
</tr>
</tbody>
</table>

Copyright 2010 S.A.N.E. Vax Inc.
sanevax.org
Administered by: Unknown        Purchased by: Unknown

Symptoms: Blood amylase increased, Inappropriate schedule of drug administration, Lipase increased, Pancreatitis

Write-up: Information has been received from a physician as part of a business agreement (manufacturer control number GARD 2008 08 28 001) concerning a 20 year old female who on 11-APR-2007 was vaccinated with her first dose of GARDASIL (Lot No. 657874/0582U, Batch No. J2299, Expiry date 26-FEB-2010). Subsequently, on 11-OCT-2007, the patient received her second dose of GARDASIL (Lot No. 658214/0734U, Batch No. J2926, Expiry date 13-MAR-2010) (considered as inappropriate schedule of vaccine) and on 25-FEB-2008 she received her third dose of GARDASIL (Lot No. 658214/0734U, Batch No. J2926, Expiry date 13-MAR-2010). Concomitant therapy included LEVLEN. On 04-AUG-2008 the patient experienced pancreatitis (also reported as sudden onset of acute pancreatitis) and was hospitalized. On 4-AUG-2008, the patient's lipase result was 2025 (units not specified) and was reported as abnormal. It was also reported that the patient's lipase and amylase increased. The patient was treated with IV rehydration and "settled quickly." No cause for the pancreatitis was identified. Subsequently, the patient was "well" since discharge. The patient was reviewed by her physician 3 weeks later at which time all bloods had returned to normal. Additional information has been requested.

---

VAERS ID: 330901        Vaccinated: 2008-04-09
Age: 13.0        Onset: 2008-04-10, Days after vaccination: 1
Gender: Female        Submitted: 2008-10-30, Days after onset: 203
Location: Entered: 2008-10-31, Days after submission: 1

Life Threatening Illness? No
Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
Extended hospital stay? No

Current Illness:
Diagnostic Lab Data: Abdominal ultrasound, ??Apr08, normal; Diagnostic pathological examination, ??May?08, all investigations for cause of pancreatitis were normal; Hepatic function tests, ??Apr08, normal; Serum lipase test, 24?Apr08, 1272 U/L, elevated; Serum

Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown

CDC 'Split Type': WAES0810AUS00154

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td>2</td>
<td>UN</td>
<td>UN</td>
<td></td>
</tr>
</tbody>
</table>

Administered by: Unknown        Purchased by: Unknown

Symptoms: Abdominal pain upper, Lipase increased, Liver function test normal, Pancreatitis, Pathology test, Ultrasound abdomen normal

Write-up: Information was obtained on request by the Company from the agency, via a tabulation and Public Case Details Form, concerning a 13 year old female who on 09-APR-2008 was vaccinated with her third dose of GARDASIL as prophylactic vaccination. On 10-APR-2008, one day post-vaccination, the patient experienced persistent epigastric pain without vomiting, anorexia or fevers. Epigastric pain worsened after two weeks at which time the patient's serum lipase level was found to be elevated at 1272 U/L, later peaking at 5920 U/L. The patient's liver function tests were normal and an abdominal ultrasound was normal. Subsequently, in April 2008 the patient was hospitalised for 10 days and treated with nil by mouth and nasojejunal feeding. The patient was discharged on oral fluids and NJ feeds. In May 2008, three weeks later, the patient was readmitted to hospital with 3 to 4 days of...
worsening abdominal pain. Her serum lipase level was elevated at 7944 U/L. A diagnosis of acute-on-chronic pancreatitis was made and the patient was hospitalised for eight weeks. Treatment was NJ feeding and then a low-fat diet. On 14-JUL-2008 the patient recovered from upper abdominal pain and pancreatitis. All investigations for the cause of the patient's pancreatitis have been normal. The agency considered that upper abdominal pain and pancreatitis were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

VAERS ID: 330902  Vaccinated: 2008-07-15
Age: 19.0  Onset: 2008-07-15, Days after vaccination: 0
Gender: Female  Submitted: 2008-10-30, Days after onset: 107
Location: Entered: 2008-10-31, Days after submission: 1

Life Threatening Illness? No
Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
Extended hospital stay? No

Current Illness:
Diagnostic Lab Data: Computed axial tomography, 15-Jul08, no organic cause found for pancreatitis
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown

CDC 'Split Type': WAES0810AUS00156

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td>1</td>
<td>IM</td>
<td>UN</td>
<td></td>
</tr>
</tbody>
</table>

Administered by: Unknown  Purchased by: Unknown

Symptoms: Abdominal pain, Back pain, Computerised tomogram normal, Hyperhidrosis, Pancreatitis, Pyrexia

Write-up: Information was obtained on request by the Company from the agency via a tabulation and a Public Case Details Form, concerning a 19 year old female, with normal alcohol use, who in May 2008, was vaccinated with her first dose of GARDASIL as prophylactic vaccination. On 15-JUL-2008 the patient was vaccinated with her second dose of GARDASIL, intramuscularly. Subsequently, in July 2008 "after injection" with GARDASIL, the patient developed a fever and sweating, followed a week later by back and abdominal pain. Subsequently, the patient was hospitalised for four days, with a final diagnosis of pancreatitis. In July 2008 a computed tomography (CT) scan showed no organic cause for the patient's pancreatitis. On 07-AUG-2008 the patient recovered from pancreatitis. The agency considered that pancreatitis was possibly related to therapy with GARDASIL. Vaccination with GARDASIL was discontinued. The original reporting source was not provided. Additional information is not expected.
VAERS ID: 351442  Vaccinated: 0000-00-00
Age:          Onset: 0000-00-00
Gender: Female Submitted: 2009-07-14
Location:     Entered: 2009-07-15, Days after submission: 1
Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Current Illness:
Diagnostic Lab Data: Unknown
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown

VAERS ID: WAES0907AUS00004
Vaccination
Manufacturer Lot  Dose Route Site
HPV4 MERCK & CO. INC. UN UN

Administered by: Unknown  Purchased by: Unknown

Symptoms: Pancreatitis
Write-up: Information has been received from an online media article via CSL as part of a business agreement concerning a female patient who was vaccinated with GARDASIL. Subsequently the patient developed pancreatitis. It was reported that the patient continues to suffer from pancreatitis. Upon internal medical review, pancreatitis was considered another important medical event. This is one of several reports from the same source. Additional information is not expected.

VAERS ID: 387694  Vaccinated: 2010-02-17
Age: 12.0 Onset: 2010-03-10, Days after vaccination: 21
Gender: Female Submitted: 2010-05-17, Days after onset: 67
Location: Entered: 2010-05-18, Days after submission: 1
Life Threatening Illness? No
Died? No
Disability? No
Recovered? Yes
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
Extended hospital stay? No

Current Illness:
Diagnostic Lab Data: Ultrasound, ??Mar? 10, No bilary sludge/pathology; EPSTEIN-BARR virus antibodies, ??Mar? 10, Negative; Mycoplasma PCR, ??Mar? 10, Negative; WBC count, ??Mar? 10, normal, scan (?IBD); serum mumps Ab, ??Mar?10, Negative; serum rubella IgG antibod
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown
CDC 'Split Type': WAES1005USA01112

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td></td>
<td></td>
<td>IM</td>
<td>UN</td>
</tr>
</tbody>
</table>

Administered by: Unknown  Purchased by: Unknown

**Symptoms:**
Blood immunoglobulin G normal, Enterovirus infection, Enterovirus serology test positive, Epstein-Barr virus antibody negative, Mumps antibody test negative, Mycoplasma test, Pancreatitis, Polymerase chain reaction, Rubella antibody negative, Sweat test normal, Ultrasound scan normal, White blood cell count normal

**Write-up:** Information was obtained on request by the company from the agency via public case details form concerning a 12 year old female patient who on 17-FEB-2010 was vaccinated IM with a dose of GARDASIL (lot number not reported). On 10-MAR-2010, the patient experienced pancreatitis and was hospitalized; treatment included: gut rest and investigation. The following laboratories were performed: rubella/mumps/ Mycoplasma/EBV were negative; enterovirus serology was positive and could be the cause of pancreatitis; WCC scan (?IBD) was normal; sweat test (?CF) was normal and an repeat ultrasound showed no bilary sludge/pathology. ON an unspecified date, the patient recovered from the event. The reporting agency considered that pancreatitis was possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

VAERS ID: 397704  Vaccinated: 2010-08-05

Age: 13.0  Onset: 2010-08-06, Days after vaccination: 1

Gender: Female  Submitted: 2010-09-07, Days after onset: 32

Location: Entered: 2010-09-08, Days after submission: 1

Life Threatening Illness? No

Died? No

Disability? No

Recovered? No

ER or Doctor Visit? No

Hospitalized? Yes, 0 days

Extended hospital stay? No

Current Illness:
Diagnostic Lab Data: serum amylase test, 458 U/L; serum lipase test, 1500 U/L

Previous Vaccinations:

Other Medications: Unknown

Preexisting Conditions: Unknown

CDC 'Split Type': WAES1008USA04190

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td>NJ53440</td>
<td>2</td>
<td>IM</td>
<td>UN</td>
</tr>
</tbody>
</table>

Administered by: Unknown  Purchased by: Unknown

**Symptoms:**
Blood amylase increased, Diarrhoea, Dyspepsia, Hyperhidrosis, Lipase increased, Malaise, Nausea, Pancreatitis

**Write-up:** Information has been received from a Health Authority (HA) case n. 122578, local case n. IT368/10 concerning a 13 year old female patient who was vaccinated with the third dose of GARDASIL (batch number NM06870, lot number NJ53440) (site of administration not reported) via intramuscular route on 05-AUG-2010. On 06-AUG-2010, the patient experienced nausea, dyspepsia, diarrhea and profuse sweating. On 09-JUL-2010, there was an improvement. On 11-AUG-2010, new episodes of diarrhea, nausea and malaise were reported. The patient was hospitalized from pancreatitis. Laboratory results showed amylase at 458 and lipase at 1500. Outcome was not reported. HA coded event pancreatitis. The case was medically confirmed. Case is closed. Other business partner numbers include: E2010-
VAERS ID: 397902  Vaccinated: 2009-01-13
Age: Onset: 0000-00-00
Gender: Female  Submitted: 2010-09-09
Location: Entered: 2010-09-10, Days after submission: 1

Life Threatening Illness? No
Died? No
Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? Yes, 0 days
    Extended hospital stay? No

Current Illness:
Diagnostic Lab Data: Unknown
Previous Vaccinations:
Other Medications: Unknown
Preexisting Conditions: Unknown

CDC 'Split Type': WAES1009USA00253

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Manufacturer</th>
<th>Lot</th>
<th>Dose</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV4</td>
<td>MERCK &amp; CO. INC.</td>
<td></td>
<td></td>
<td>IM</td>
<td>UN</td>
</tr>
</tbody>
</table>

Administered by: Unknown  Purchased by: Unknown

Symptoms: Asthenia, Dyspnoea, Fatigue, Headache, Immediate post-injection reaction, Impaired work ability, Kidney infection, Migraine, Muscle spasms, Myalgia, Pancreatitis, Urinary tract infection

Write-up: Information was obtained on request by the company from the agency via a public case details form concerning a female patient who on 13-JAN-2009 was vaccinated with a dose of GARDASIL (lot number not reported) intramuscularly. After the first vaccination the patient experienced immediate loss her energy, lack of endurance and had breathing difficulties, she had to have a few days off work. After the second dose of GARDASIL (lot number not reported) she had increased symptoms of fatigue, recurrent UTI, renal infection, one episode of pancreatitis (July 2010), myalgia, spasm in lower limbs, headaches (migraines); none of these symptoms were present prior immunizations. The patient was treated with unspecified antibiotics. The event caused or prolonged inpatient hospitalization. At the time of the report the patient had not recovered from fatigue, myalgia, dyspnoea, migraine, urinary tract infection and pancreatitis. The agency considered that of fatigue, myalgia, breathing difficulties, headaches (migraines), one episode of pancreatitis and recurrent UTI were "possible" related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.