

VACCINE INFORMATION STATEMENT

HPV (Human Papillomavirus) Vaccine Gardasil®

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages.
See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

1 What is HPV?

Genital **human papillomavirus (HPV)** is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 12,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women, and anal and oropharyngeal (back of the throat, including base of tongue and tonsils) cancers in both men and women. HPV can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

2 HPV vaccine: Why get vaccinated?

The HPV vaccine you are getting is one of two vaccines that can be given to prevent HPV. It may be given to both males and females.

This vaccine can prevent most cases of cervical cancer in females, if it is given before exposure to the virus. In addition, it can prevent vaginal and vulvar cancer in females, and genital warts and anal cancer in both males and females.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

3 Who should get this HPV vaccine and when?

HPV vaccine is given as a 3-dose series

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

Routine Vaccination

- This HPV vaccine is recommended for girls and boys **11 or 12 years of age**. It *may* be given starting at age 9.

Why is HPV vaccine recommended at 11 or 12 years of age?

HPV infection is easily acquired, even with only one sex partner. That is why it is important to get HPV vaccine before any sexual contact takes place. Also, response to the vaccine is better at this age than at older ages.

Catch-Up Vaccination

This vaccine is recommended for the following people who have not completed the 3-dose series:

- Females 13 through 26 years of age.
- Males 13 through 21 years of age.

This vaccine *may* be given to men 22 through 26 years of age who have not completed the 3-dose series.

It is *recommended* for men through age 26 who have sex with men or whose immune system is weakened because of HIV infection, other illness, or medications.

HPV vaccine may be given at the same time as other vaccines.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

4**Some people should not get HPV vaccine or should wait.**

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.
- HPV vaccine is not recommended for pregnant women. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's HPV-in-pregnancy registry at 800-986-8999. This will help us learn more about how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a moderate or severe illness should wait until they are better.

5**What are the risks from this vaccine?**

This HPV vaccine has been used in the U.S. and around the world for about six years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild** to **moderate** problems are known to occur with this HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
 - Pain (about 8 people in 10)
 - Redness or swelling (about 1 person in 4)
- Fever:
 - Mild (100° F) (about 1 person in 10)
 - Moderate (102° F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)
- Fainting: Brief fainting spells and related symptoms

(such as jerking movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls. Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears. Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

6**What if there is a moderate or severe reaction?****What should I look for?**

- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7**The National Vaccine Injury Compensation Program**

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8**How can I learn more?**

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)

HPV Vaccine (Gardasil)

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