

VACCINE INFORMATION STATEMENT

HPV Vaccine Cervarix[®] (Human Papillomavirus)

What You Need to Know

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

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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 10,000 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 other types of cancer in both men and women. It 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?

HPV vaccine is important because **it can prevent most cases of cervical cancer** in females, if it is given before a person is exposed to the virus.

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.

The vaccine you are getting is one of **two HPV vaccines that can be given to prevent cervical cancer**. It is given to females only.

The other vaccine may be given to both males and females. It can also prevent most genital warts. It has also been shown to prevent some vaginal, vulvar and anal cancers.

3 Who should get this HPV vaccine and when?

Routine vaccination

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

Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine **before** their first sexual contact—because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

Catch-up vaccination

- The vaccine is also recommended for girls and women **13 through 26 years of age** who did not get all 3 doses when they were younger.

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.

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

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 latex.
- 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.



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

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 888-452-9622. This will help us learn 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 in use around the world for several 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 HPV vaccine. These do not last long and go away on their own.

- Reactions where the shot was given:
 - Pain (about 9 people in 10)
 - Redness or swelling (about 1 person in 2)
- Other mild reactions:
 - Fever of 99.5°F or higher (about 1 person in 8)
 - Headache or fatigue (about 1 person in 2)
 - Nausea, vomiting, diarrhea, or abdominal pain (about 1 person in 4)
 - Muscle or joint pain (up to 1 person in 2)
- 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 serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

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.
- 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)
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