



## **GARDASIL<sup>®</sup>** **[Human Papillomavirus Quadrivalent** **(Types 6, 11, 16, and 18) Vaccine, Recombinant]**

**Patient Information about GARDASIL<sup>®</sup>** (pronounced "gard-Ah-sill")  
Generic name: [Human Papillomavirus Quadrivalent  
(Types 6, 11, 16, and 18) Vaccine, Recombinant]

Read this information with care before getting GARDASIL<sup>1</sup>. You (the person getting GARDASIL) will need 3 doses of the vaccine. It is important to read this leaflet when you get each dose. This leaflet does not take the place of talking with your health care provider about GARDASIL.

### **What is GARDASIL?**

GARDASIL is a vaccine (injection/shot) that is used for girls and women 9 through 26 years of age to help protect against the following diseases caused by Human Papillomavirus (HPV):

- ▶ Cervical cancer
- ▶ Vulvar and vaginal cancers
- ▶ Genital warts
- ▶ Abnormal and precancerous cervical, vaginal, and vulvar lesions
  - The diseases listed above have many causes, and GARDASIL only protects against diseases caused by certain kinds of HPV (called Type 6, Type 11, Type 16, and Type 18). Most of the time, these 4 types of HPV are responsible for the diseases listed above.
  - GARDASIL cannot protect you from a disease that is caused by other types of HPV, other viruses, or bacteria.
  - GARDASIL does not treat HPV infection.
  - You cannot get HPV or any of the above diseases from GARDASIL.

GARDASIL is used for boys and men 9 through 26 years of age to help protect against genital warts.

### **What important information about GARDASIL should I know?**

- ▶ You should continue to get routine cervical cancer screening.
- ▶ GARDASIL may not fully protect everyone who gets the vaccine.
- ▶ GARDASIL will not protect against HPV types that you already have.

### **Who should not get GARDASIL?**

You should not get GARDASIL if you have, or have had:

- ▶ an allergic reaction after getting a dose of GARDASIL.
- ▶ a severe allergic reaction to yeast, amorphous aluminum hydroxyphosphate sulfate, polysorbate 80.

### **What should I tell my health care provider before getting GARDASIL?**

Tell your health care provider if you:

- ▶ are pregnant or planning to get pregnant. GARDASIL is not recommended for use in pregnant women.
- ▶ have immune problems, like HIV infection, cancer, or you take medicines that affect your immune system.
- ▶ have a fever over 100°F (37.8°C).
- ▶ had an allergic reaction to another dose of GARDASIL.
- ▶ take any medicines, even those you can buy over the counter.

Your health care provider will help decide if you should get the vaccine.

### **How is GARDASIL given?**

GARDASIL is a shot that is usually given in the arm muscle. You will need 3 shots given on the following schedule:

- ▶ Dose 1: at a date you and your health care provider choose.
- ▶ Dose 2: 2 months after Dose 1.
- ▶ Dose 3: 6 months after Dose 1.

Fainting can happen after getting GARDASIL. Sometimes people who faint can fall and hurt themselves. For this reason, your health care provider may ask you to sit or lie down for 15 minutes after you get GARDASIL. Some people who faint might shake or become stiff. This may require evaluation or treatment by your health care provider.

Make sure that you get all 3 doses on time so that you get the best protection. If you miss a dose, talk to your health care provider.

### **What are the possible side effects of GARDASIL?**

The most common side effects with GARDASIL are:

- ▶ pain, swelling, itching, bruising, and redness at the injection site
- ▶ headache
- ▶ fever
- ▶ nausea
- ▶ dizziness
- ▶ vomiting
- ▶ fainting

Tell your health care provider if you have any of the following problems because these may be signs of an allergic reaction:

- ▶ difficulty breathing
- ▶ wheezing (bronchospasm)
- ▶ hives
- ▶ rash

Tell your health care provider if you have:

- ▶ swollen glands (neck, armpit, or groin)
- ▶ joint pain
- ▶ unusual tiredness, weakness, or confusion
- ▶ chills
- ▶ generally feeling unwell
- ▶ leg pain
- ▶ shortness of breath
- ▶ chest pain
- ▶ aching muscles
- ▶ muscle weakness
- ▶ seizure
- ▶ bad stomach ache
- ▶ bleeding or bruising more easily than normal

Contact your health care provider right away if you get any symptoms that concern you, even several months after getting the vaccine.

For a more complete list of side effects, ask your health care provider.

### **What are the ingredients in GARDASIL?**

The ingredients are proteins of HPV Types 6, 11, 16, and 18, amorphous aluminum hydroxyphosphate sulfate, yeast protein, sodium chloride, L-histidine, polysorbate 80, sodium borate, and water for injection.

This leaflet is a summary of information about GARDASIL. If you would like more information, please talk to your health care provider or visit [www.gardasil.com](http://www.gardasil.com).

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# WHAT YOU SHOULD KNOW ABOUT HPV, CERVICAL CANCER, AND GENITAL WARTS.

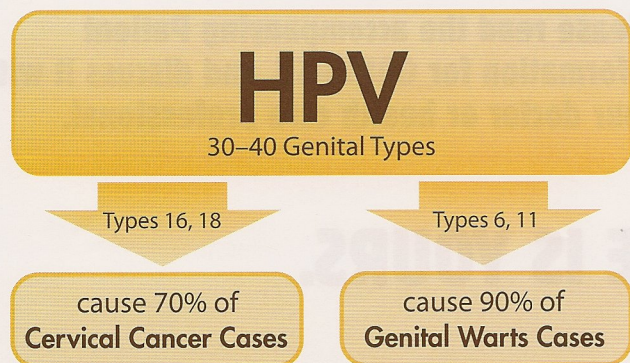
## CERVICAL CANCER IS CAUSED BY CERTAIN TYPES OF A VIRUS.

Cervical cancer is cancer of the cervix (the lower part of the uterus that connects to the vagina). Unlike other cancers, cervical cancer is not hereditary. It's caused by certain types of a virus, human papillomavirus (HPV). When a woman becomes infected with one of these types of HPV, and the virus doesn't go away on its own, abnormal cells can develop in the lining of the cervix. If these cells are not found early, precancers and then cancer can develop.

## CERVICAL CANCER: IT'S NOT TOO EARLY TO THINK ABOUT IT.

Based on American Cancer Society (ACS) estimates, about 30 women a day were diagnosed with cervical cancer in the United States in 2008. While half of all women diagnosed with cervical cancer are between 35 and 55 years old, many of these women could have been initially exposed to cancer-causing HPV types in their teens and 20s.

## THERE ARE MORE THAN 30 TYPES OF GENITAL HPV.



The types of HPV that cause cervical cancer are different from the types that cause genital warts. All HPV types that affect the genital area can cause abnormal Pap tests.

## 80% OF WOMEN WILL HAVE HAD HPV IN THEIR LIFETIME.

Both men and women can have HPV, and it is easily spread. Any type of genital contact with someone who has HPV can put you at risk — intercourse isn't necessary. And since there are often no signs or symptoms, many people don't know they are passing it on. There are about 6 million new cases of genital HPV in the United States each year.

There are more than 30 types of genital HPV, and most will clear on their own. But for some women who don't clear certain types of the virus, cervical cancer can develop. And there's no way to predict who will or won't clear the virus.

## GENITAL WARTS: ANOTHER DISEASE CAUSED BY HPV.

While certain types of HPV can cause cervical cancer, other types can cause genital warts. Genital warts are usually soft, flesh-colored growths that can be raised or flat, small or large, alone or in clusters. There are an estimated 1 million new cases of genital warts each year in the United States.\* While genital warts are not life threatening, they can be life altering. There are a number of ways to treat genital warts, including creams, removal by burning, freezing, or laser, and surgery. However, even after treatment, genital warts can return. In fact, 25% of cases return within 3 months.

\*This estimate includes both men and women.



## PROTECTION WITH GARDASIL.

GARDASIL is the only cervical cancer vaccine that helps protect against 4 types of HPV: 2 types that cause 70% of cervical cancer cases, and 2 more types that cause 90% of genital warts cases. GARDASIL is for girls and young women ages 9 to 26.

GARDASIL is given as 3 injections over 6 months (0, 2 months, 6 months). Getting all 3 doses will allow you or your daughter to get the full benefits of GARDASIL.

## GARDASIL WORKS TO HELP PREVENT ILLNESS.

Like other vaccines, GARDASIL works to help prevent illness. That's why it's recommended that girls 11 to 12 years of age (and as young as 9) get vaccinated. HPV vaccination is a part of the recommended vaccination schedule defined by the Centers for Disease Control and Prevention (CDC).

Leading medical organizations recommend HPV vaccination including the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG).

## IT'S NOT TOO LATE TO GET VACCINATED.

Only a doctor or health care professional can tell you if GARDASIL is right for you. But, if you're already sexually active, you may still benefit from GARDASIL. That's because even if you have been exposed to HPV, it's unlikely that you have been infected with all 4 types of the virus covered by GARDASIL.

## CERVICAL CANCER SCREENINGS ARE IMPORTANT.

Vaccination with GARDASIL is important, but it does not replace routine cervical cancer screenings. Pap tests look for abnormal cervical cells in the lining of the cervix before they have a chance to become precancers and then cervical cancer. Most often this change takes a number of years. But in rare cases it can happen within a year.

## IMPORTANT INFORMATION ABOUT GARDASIL

GARDASIL may not fully protect everyone, and does not prevent all types of cervical cancer, so it's important to continue routine cervical cancer screenings. GARDASIL does not treat cervical cancer or genital warts. GARDASIL will not protect against diseases caused by other HPV types or against diseases not caused by HPV.

## SELECT SAFETY INFORMATION

Anyone who is allergic to the ingredients of GARDASIL, including those severely allergic to yeast, should not receive the vaccine. GARDASIL is not for women who are pregnant.

The side effects include pain, swelling, itching, bruising, and redness at the injection site, headache, fever, nausea, dizziness, vomiting, and fainting. Sometimes fainting is accompanied by falling with injury, as well as shaking or stiffening and other seizure-like activity.


Only a doctor or health care professional can decide if GARDASIL is right for you or your daughter.

**Please read the accompanying Patient Information for **GARDASIL** and discuss it with your doctor or health care professional.**

# NOW THE CHOICE IS YOURS.



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