

USPPI

Patient Information about

GARDASIL® (pronounced "gard-Ah-sill")

Generic name: [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]

Read this information with care before you or your child gets GARDASIL*. You or your child will need 3 doses of the vaccine. It is important to read this leaflet when you receive each dose. This leaflet does not take the place of talking with your health care professional about GARDASIL.

What is GARDASIL and what is it used for?

GARDASIL is a vaccine (injection/shot) that helps protect against the following diseases caused by Human Papillomavirus (HPV) Types in the vaccine (6, 11, 16, and 18):

- Cervical cancer (cancer of the lower end of the uterus or womb).
- Abnormal and precancerous cervical lesions.
- Abnormal and precancerous vaginal lesions.
- Abnormal and precancerous vulvar lesions.
- Genital warts.

GARDASIL helps prevent these diseases – but it will not treat them.

You or your child cannot get these diseases from GARDASIL.

What other key information about GARDASIL should I know?

- Vaccination does not substitute for routine cervical cancer screening. Females who receive GARDASIL should continue cervical cancer screening.
- As with all vaccines, GARDASIL may not fully protect everyone who gets the vaccine.
- Gardasil will not protect against diseases due to non-vaccine HPV types. There are more than 100 HPV types; GARDASIL helps protect against 4 types (6, 11, 16, and 18). These 4 types have been selected for GARDASIL because they cause approximately 70% of cervical cancers and 90% of genital warts.
- This vaccine will not protect you against HPV types to which you may have already been exposed.
- GARDASIL also will not protect against other diseases that are not caused by HPV.
- GARDASIL works best when given before you or your child has any contact with certain types of HPV (i.e., HPV types 6, 11, 16, and 18).

Who can receive GARDASIL?

GARDASIL is for girls and women 9 through 26 years of age.

See "Who should not receive GARDASIL?" below.

Who should not receive GARDASIL?

Anyone who:

- is allergic to any of the ingredients in the vaccine. A list of ingredients can be found at the end of this leaflet.
- has an allergic reaction after getting a dose of the vaccine.

What should I tell my health care professional before I am vaccinated or my child is vaccinated with GARDASIL?

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It is very important to tell your health care professional if you or your child:

- has had an allergic reaction to the vaccine.
- has a bleeding disorder and cannot receive injections in the arm.
- has a weakened immune system, for example, due to a genetic defect or HIV infection.
- is pregnant or is planning to get pregnant. GARDASIL is not recommended for use in pregnant women.
- has any illness with a fever more than 100°F (37.8°C).
- takes or plans to take any medicines, even those you can buy over the counter.

Your health care professional will decide if you or your child should receive the vaccine.

How is GARDASIL given?

GARDASIL is given as an injection.

You or your child will receive 3 doses of the vaccine. Ideally the doses are given as:

- First dose: at a date you and your health care professional choose.
- Second dose: 2 months after the first dose.
- Third dose: 6 months after the first dose.

Make sure that you or your child gets all 3 doses. This allows you or your child to get the full benefits of GARDASIL. If you or your child misses a dose, your health care professional will decide when to give the missed dose.

What are the possible side effects of GARDASIL?

As with all vaccines, there may be some side effects with GARDASIL. GARDASIL has been shown to be generally well tolerated in women and girls as young as 9 years of age.

The most commonly reported side effects included:

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

Fainting can occur after vaccination, most commonly among adolescents and young adults. Although fainting episodes are uncommon, patients should be observed for 15 minutes after they receive HPV vaccine.

Allergic reactions that may include difficulty breathing, wheezing (bronchospasm), hives, and rash have been reported. Some of these reactions have been severe.

Additional side effects reported include swollen glands (neck, armpit, or groin), Guillain-Barré syndrome, headache, joint pain, aching muscles, unusual tiredness or weakness, and generally feeling unwell.

If you or your child has any unusual or severe symptoms after receiving GARDASIL, contact your health care professional right away.

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

What are the ingredients in GARDASIL?

The main ingredients are purified inactive proteins that come from HPV Types 6, 11, 16, and 18.

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It also contains amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, and water for injection.

What are cervical cancer, precancerous lesions, and genital warts?

Cancer of the cervix is a serious disease that can be life-threatening. This disease is caused by certain HPV types that can cause the cells in the lining of the cervix to change from normal to precancerous lesions. If these are not treated, they can turn cancerous.

Genital warts are caused by certain types of HPV. They often appear as skin-colored growths. They are found on the inside or outside of the genitals. They can hurt, itch, bleed, and cause discomfort. These lesions are usually not precancerous. Sometimes, it takes multiple treatments to eliminate these lesions.

What is Human Papillomavirus (HPV)?

HPV is a common virus. In 2005, the Centers for Disease Control and Prevention (CDC) estimated that 20 million people in the United States had this virus. There are many different types of HPV; some cause no harm. Others can cause diseases of the genital area. For most people the virus goes away on its own. When the virus does not go away it can develop into cervical cancer, precancerous lesions, or genital warts, depending on the HPV type. See "What other key information about GARDASIL should I know?"

Who is at risk for Human Papillomavirus?

In 2005, the CDC estimated that at least 50% of sexually active people catch HPV during their lifetime. A male or female of any age who takes part in any kind of sexual activity that involves genital contact is at risk.

Many people who have HPV may not show any signs or symptoms. This means that they can pass on the virus to others and not know it.

Will GARDASIL help me if I already have Human Papillomavirus?

You may benefit from GARDASIL if you already have HPV. This is because most people are not infected with all four types of HPV contained in the vaccine. In clinical trials, individuals with current or past infection with one or more vaccine-related HPV types prior to vaccination were protected from disease caused by the remaining vaccine HPV types. GARDASIL is not intended to be used for treatment for the above mentioned diseases. Talk to your health care professional for more information.

This leaflet is a summary of information about GARDASIL. If you would like more information, please talk to your health care professional or visit www.gardasil.com.

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