

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 getting GARDASIL. 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
- Anal cancer
- Genital warts
- Precancerous cervical, vaginal, vulvar, and anal lesions

GARDASIL is used for boys and men 9 through 26 years of age to help protect against the following diseases caused by HPV:

- Anal cancer
- Genital warts
- Precancerous anal 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.

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.

Can other vaccines and medications be given at the same time as GARDASIL?

GARDASIL can be given at the same time as RECOMBIVAX HB^{®1} [hepatitis B vaccine (recombinant)] or Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] and Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)].

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

There was no increase in side effects when GARDASIL was given at the same time as RECOMBIVAX HB [hepatitis B vaccine (recombinant)].

There was more injection-site swelling at the injection site for GARDASIL when GARDASIL was given at the same time as Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] and Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)].

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
- skin infection

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.

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