

GARDASIL®

[Quadrivalent HPV (Types 6, 11, 16, 18) Recombinant Vaccine]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GARDASIL. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of your child or you being given GARDASIL against the benefits they expect it will have for your child or you.

If you have any concerns about being given this vaccine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What GARDASIL is used for

GARDASIL is a vaccine that helps prevent the following diseases in girls and women 9 through 45 years of age caused by Human Papillomavirus (HPV) Types 6, 11, 16 or 18.

- cervical (the lower end of the uterus or womb), vulvar (the outside of the female genitals), vaginal, and anal cancer
- abnormal and precancerous (changes in cells which have a risk of turning into cancer) cervical, vaginal, vulvar and anal lesions
- genital warts
- HPV infection

GARDASIL helps protect against anal cancer, precancerous anal lesions, external genital lesions

(including genital warts) and infection caused by HPV types 6, 11, 16 and 18 in boys and men 9 through 26 years of age

GARDASIL helps prevent, but does not treat these diseases. You cannot get HPV or any of the above diseases from GARDASIL.

GARDASIL can be given to females aged 9 to 45 years and males aged 9 to 26 years.

HPV is a common virus. Of the many different types of HPV, some are harmless and others can cause diseases of the genital areas. While most people clear the virus, those who do not can develop cervical cancer, precancerous lesions, or genital warts.

In the absence of vaccination, it is estimated that the majority of people who have ever had sex will become infected with HPV during their lifetime. A male or female of any age who has taken part in any kind of sexual activity that involved genital contact is at risk.

Most people who have HPV may not show any signs or symptoms. This means that they can transmit (pass on) the virus to others without knowing it.

Cancer of the cervix is a serious and sometimes life-threatening disease. It begins when a female is infected with certain types of HPV. These types of HPV can cause the cells in the lining of the cervix to change from normal to abnormal or precancerous lesions. These lesions are usually detected by a Pap Test. If these lesions are not treated, they can turn cancerous. You or your child cannot get cervical cancer

without first having a HPV infection.

Genital warts are caused by certain types of HPV. They commonly appear as skin-colored, irregular growths. They are found on the inside or outside of the genitals in both males and females. They can hurt, itch, bleed, and cause discomfort. Sometimes they can come back after treatment.

GARDASIL works best when given before a person has become infected with certain types of HPV, but may also be of benefit if you or your child have had a previous infection. Therefore, you should talk with your doctor or health care provider to find out if GARDASIL is right for you or your child.

How it works

GARDASIL works by causing the body to produce its own protection against HPV types 6, 11, 16 and 18 that cause disease.

There are more than 100 HPV types, GARDASIL will not protect against all types. HPV Types 6, 11, 16 and 18 have been included in GARDASIL because they cause over 70% of cervical cancers and 90% of genital warts worldwide. HPV Types 16 and 18 are also associated with some vulvar and vaginal cancers, and strongly associated with a significant proportion of anal cancers.

GARDASIL provides some protection against HPV types 31, 33, 52, 56, 58, and 59. These types cause approximately 12% of cervical cancers.

As with any vaccine, GARDASIL may not fully protect everyone who

gets the vaccine. Continue to follow your doctor or health care provider's instructions on regular Pap tests.

GARDASIL will not protect against diseases that are not caused by HPV.

Before GARDASIL is given

When you or your child must not be given GARDASIL

Do not, or do not let your child have GARDASIL if you or your child have had an allergy to any of the ingredients listed at the end of this leaflet or if you or your child have had an allergic reaction after receiving a dose of the vaccine.

Symptoms of allergic reaction include swelling of the face, lips, tongue, throat, difficulty in breathing or hives.

If you are not sure whether you or your child should be given GARDASIL, talk to your doctor or health care provider.

Before you or your child is given GARDASIL:

Tell your doctor or health care provider 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 any illness with a fever higher than 100°F (37.8°C)
- is pregnant or is planning to get pregnant
- takes or plans to take any medicines, including over the counter medicines
- has a weakened immune system, for example due to a genetic defect or Human Immunodeficiency Virus (HIV) infection or if you take medicines that affect your immune system.

If you have not told your doctor about any of the above, tell them before you or your child is given GARDASIL.

Taking other medicines

Tell your doctor if you or your child is taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Use with other vaccines

GARDASIL can be given at the same time as hepatitis B vaccine (recombinant). The vaccine should not be mixed in the same syringe with any other vaccines or solutions.

How GARDASIL is given

How much is given

Each dose of GARDASIL is 0.5mL. The entire amount, 0.5mL, of the vial or syringe should be injected.

A complete course consists of three 0.5mL doses.

How GARDASIL is given

GARDASIL is given as an injection into the muscle in your arm or leg (intramuscularly).

Vaccination Schedule

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 doctor or health care provider 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

If you miss a scheduled dose, talk to your doctor or health care provider. See your doctor or health care provider who will decide when to give the missed dose.

It is important that you follow the instructions of your doctor or health care provider regarding return visits for the follow-up doses.

Women who become pregnant before the completion of the 3-dose schedule should complete their vaccination schedule after childbirth.

After you or your child has been given GARDASIL

Things you must do

Keep a record of the vaccinations and update this after each injection.

Side Effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well during or after having had an injection of GARDASIL.

GARDASIL helps protect from disease and infection due to HPV Types 6, 11, 16 and 18, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if they get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you or your child have any of the following and they are troublesome or ongoing:

- pain, itching, bruising, tenderness, or soreness at the injection site
- headache
- local reaction around the injection site such as soreness, redness, or swelling
- fever
- dizziness, nausea and vomiting
- pain in the extremities

These are the more common side effects of GARDASIL. For the most part these have been mild. They usually improve or disappear within a few days.

Fainting

Fainting, sometimes accompanied by shaking or stiffening, has been reported. 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 vaccination.

As with other vaccines, side effects that have been reported during general use include:

- Swollen glands in the neck, armpit and groin
- Joint pain
- Aching muscles
- Unusual tiredness, weakness or confusion
- Chills
- Generally feeling unwell
- Allergic reactions (see below)
- Bleeding or bruising more easily than normal
- Skin infection (with hot, tender and red skin)

Very rarely, tingling, numbness or muscle weakness in limbs (Guillain-Barre syndrome)

If any of the above symptoms worsen or you or your child has any unusual or severe symptoms after receiving GARDASIL, contact your doctor or health care provider right away.

Your doctor or health care provider has a more complete list of side effects for GARDASIL.

Allergic Reaction:

As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.

Tell your doctor immediately or go to accident and emergency if you notice any of the following:

- wheezing or shortness of breath
- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing
- swelling of the hands, feet, or ankles
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- skin rash, itchiness

If you or your child has these, you or your child may have had a serious allergic reaction to GARDASIL. You or your child may need urgent medical attention or hospitalisation. Most of these side effects occur within 15-30 minutes of vaccination, before you or your child leaves the doctor's surgery or clinic.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

Storage

GARDASIL is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store GARDASIL:

- **Keep it where children cannot reach it.**
- **Keep it in the fridge where the temperature is 2-8°C.**
- **Do not freeze the vaccine.**
- **Protect the injection from light by keeping it in the original pack until it is time for it to be given.**

- **Do not use GARDASIL after the expiry date on the label.**

GARDASIL should be administered as soon as possible after being removed from refrigeration. When out of refrigeration at room temperature, or below 25°C, administration may be delayed for up to 3 days.

Product description

What it looks like

GARDASIL is a cloudy white liquid in a glass syringe or vial.

Ingredients

The active ingredients of GARDASIL are highly purified inactive proteins from HPV Types 6, 11, 16 and 18.

Inactive ingredients:

- Aluminium (as amorphous aluminium hydroxyphosphate sulfate adjuvant)
- Sodium chloride
- L-histidine
- Polysorbate 80
- Borax
- Residual traces of yeast protein
- Water for injection

Supplier

GARDASIL is supplied:

In Australia by:
 bioCSL Pty Ltd
 63 Poplar Road
 PARKVILLE VIC 3052

In New Zealand by:
 bioCSL (NZ) Ltd
 PO Box 62 590
 Greenlane
 AUCKLAND 1546

This leaflet was prepared February 2016

Australian Register Numbers:
 AUST R 124408 and 124410
 WPPI-V501-I-022015