

GARDASIL[®] 9

[Human Papillomavirus 9-valent Vaccine, Recombinant]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GARDASIL 9. 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 9 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 9 is used for

GARDASIL 9 is a vaccine that helps protect against disease caused by the following types of Human Papillomavirus (HPV): 6,11,16,18,31,33,45,52 and 58.

In girls and women 9 through 45 years of age, it helps prevent:

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

- genital warts and
- HPV infection

In boys and men 9 through 26 years of age, GARDASIL 9 helps prevent

- Anal cancer and precancerous anal lesions
- External genital lesions, including genital warts and
- HPV infection

GARDASIL 9, helps prevent, but does not treat these diseases. You cannot get HPV or any of these diseases from GARDASIL 9.

What is Human Papillomavirus?

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 disease, including cervical cancer, some vaginal, vulvar and anal cancers and genital warts.

Who is at risk for HPV and why is vaccination with GARDASIL 9 important?

Without 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 involves genital contact is at risk.

Most people who have HPV may not show any signs or symptoms. This means that they can pass on

the virus to others without knowing it.

What are cervical cancer and precancerous lesions?

Cancer of the cervix is a serious and sometimes life-threatening disease. It begins when a female catches certain types of HPV. These HPV types can cause the cells in the lining of the cervix to change from normal to abnormal or precancerous lesions. These lesions are usually detected through the cervical screening program. If these lesions are not treated, they can turn cancerous. You or your child cannot get cervical cancer without first having a HPV infection.

What are vulvar and vaginal cancers?

Many vulvar and vaginal cancers are caused by HPV. There are no routine screening tests for these cancers.

What are anal cancer and precancerous lesions? HPV infection is strongly linked to anal cancer and pre-cancerous anal lesions. There are no routine screening tests for anal cancer.

What are genital warts?

Genital warts are caused by certain types of HPV. They commonly appear as skin-coloured, 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 9 only protects against diseases caused by the nine types covered by the vaccine. GARDASIL 9 works best when given before you or your child has become infected with HPV, but may also be of benefit if you or your child have had a previous infection. Talk with your doctor or pharmacist for more information.

The GARDASIL 9 vaccine:

- does not remove the need for cervical cancer screening; women should still get routine cervical cancer screening
- does not protect against disease that is caused by other types of HPV, other viruses or bacteria
- does not protect you or your child from HPV types that you may already have (but most people do not have all types contained in the vaccine).

How it works

GARDASIL 9 works by causing the body to produce its own protection against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 that cause disease. It does this by making substances called antibodies in the blood which fight HPV. If a vaccinated person comes into contact with HPV, the body is usually ready to destroy it.

It usually takes several weeks after vaccination to develop protection against HPV.

Protection requires completion of the vaccine series.

Most people will produce enough antibodies against HPV.

However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give you or your child HPV or any of the disease listed above.

The chance of a severe reaction from GARDASIL 9 is very small, but the risks from not being

vaccinated against cervical cancer and other cancers (vaginal, vulvar, anal) and diseases caused by HPV may be very serious.

As with any vaccine, GARDASIL 9 may not fully protect everyone who gets the vaccine. Continue to follow your doctor or pharmacist's instructions on regular cervical cancer screening tests.

Before GARDASIL 9 is given

When you or your child must not be given GARDASIL 9

Do not have or let your child have GARDASIL 9 if you or your child have had an allergy to:

- a previous dose of GARDASIL or GARDASIL 9
- any of the ingredients in the vaccine listed at the end of this leaflet

Symptoms of allergic reaction include swelling of the face, lips, tongue, throat, or other parts of the body, shortness of breath, wheezing or difficulty in breathing, skin rash, itching or hives.

Do not use GARDASIL 9 after the expiry date printed on the pack.

Do not use GARDASIL 9 if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should be given GARDASIL 9, talk to your doctor or pharmacist.

Before you or your child is given GARDASIL 9:

Tell your doctor or health care provider if you or your child:

- had an allergic reaction to a previous dose of GARDASIL or GARDASIL 9
- has a bleeding disorder and cannot receive injections in the arm
- has any illness with a fever higher than 37.8°C. Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.
- has a weakened immune system, for example due to a genetic defect or Human Immunodeficiency Virus (HIV) infection
- take medicines that affect the immune system
- takes or plans to take any medicines, including over the counter medicines.
- is pregnant or is planning to get pregnant.

Your doctor or pharmacist will help decide if you or your child should get the vaccine.

GARDASIL 9 may be given to women who are breast –feeding or intend to breast-feed.

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

Tell your doctor if you have had any vaccines in the last four weeks. Your doctor will advise you if GARDASIL 9 is to be given with another vaccine. Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with GARDASIL 9.

GARDASIL 9 can be given at the same time as GARDASIL 9 can be given at the same time as:

- Menactra [Meningococcal (Groups A, C, Y and W-135) Vaccine]
- Adacel [Tetanus, Diphtheria and Acellular Pertussis Vaccine]
- Repevax [Diphtheria, Tetanus, Pertussis (acellular component) and Poliomyelitis (inactivated) Vaccine]

Studies have shown there was more swelling where the shot was given at the same time as these vaccines.

Should I receive GARDASIL 9 if I have already received GARDASIL?

If you have already received GARDASIL, talk to your doctor or pharmacist to see if GARDASIL 9 is right for you.

GARDASIL 9 contains the same four HPV types (6, 11, 16, 18) that are in GARDASIL and five additional HPV types (31, 33, 45, 52, 58).

How GARDASIL 9 is given

GARDASIL 9 is given as an injection into the muscle in your arm or leg.

How much is given

Each dose of GARDASIL 9 is 0.5mL.

When it is given

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

- Dose 1: at a date you and your doctor or health care provider choose

- Dose 2: 2 months after the first dose (not earlier than one month after the first dose)
- Dose 3: 6 months after the first dose (not earlier than 3 months after the second dose)

All three doses should be given within a 1-year period. Talk to your doctor for more information.

Alternatively, individuals 9 through 14 years of age may receive 2 doses of the vaccine.

- Dose 1: at a date you and your doctor or health care professional choose

- Dose 2: given between 5 and 13 months after first dose.

If the second vaccine dose is given earlier than 5 months after the first dose, a third dose should always be given.

It is recommended that individuals who receive a first dose of GARDASIL 9 complete the vaccination course with GARDASIL 9.

Make sure that you or your child gets the complete vaccine series. This allows you or your child to get the full benefits of GARDASIL 9.

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.

It is not known whether the vaccine is harmful to an unborn

baby when administered to a pregnant woman. If you are pregnant, you should be vaccinated with GARDASIL 9 only if your doctor or health care professional decides it is clearly needed.

Women who become pregnant before completion of the vaccine series should complete their vaccination schedule after childbirth.

GARDASIL 9 has not been studied in the elderly.

After you or your child has been given GARDASIL 9

Things you must do

Keep follow-up appointments with your doctor or clinic.

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 9.

GARDASIL 9 may have unwanted side effects in a few people. All medicines including 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 worry you:

- pain, swelling, redness, itching, bruising, bleeding, and a lump at or around the injection site
- headache
- fever or high temperature
- nausea
- dizziness
- tiredness
- diarrhoea
- sore throat
- stomach pain or discomfort

These are the most common side effects seen with GARDASIL 9. These side effects are usually mild and usually improve or disappear within a few days.

The following side effects have been reported with GARDASIL and may also be seen after getting GARDASIL 9:

- skin infection (may appear as hot, tender and red skin)
- bleeding or bruising more easily than normal (may appear as purple or red spots visible through the skin)
- swollen glands in the neck, armpit or groin
- confusion
- vomiting
- joint pain or painful, swollen joint
- aching muscles (may appear as muscle weakness or weakness that is not caused by exercise)
- unusual tiredness, weakness
- chills
- generally feeling unwell

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

If any of the above symptoms worsen or you or your child has any unusual or severe symptoms after receiving GARDASIL 9, contact your doctor or healthcare provider.

Fainting

Fainting can happen after getting a vaccine. Sometimes people who faint can fall and hurt themselves. For this reason, you or your child may be asked to sit or lie down for 15 minutes after getting GARDASIL 9. Some people who faint might shake or become stiff and may need to be treated by the doctor.

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 at your nearest hospital if you notice any of the following:

- wheezing, shortness of breath or difficulty breathing
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- skin rash, itchiness
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing, or swelling of other parts of the body

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are rare.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice anything that is making you or your child unwell.

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

Your doctor or pharmacist has a more complete list of side effects for GARDASIL 9.

Storage

GARDASIL 9 is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store GARDASIL 9:

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

GARDASIL should be administered as soon as possible after being removed from refrigeration.

Product description

What it looks like

GARDASIL 9 is a cloudy white liquid in a glass syringe or vial.

Ingredients

The active ingredients of GARDASIL 9 are highly purified inactive proteins from HPV Types 6, 11, 16, 18, 31, 33, 45, 52 and 58.

Inactive ingredients:

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

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This leaflet was prepared in
30 October 2017

CCPPI-V503-I-022016a