

# GARDASIL® 9

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this vaccine, speak to your doctor, nurse or pharmacist.

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### 1. Why am I or my child being given GARDASIL 9?

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.

For more information, see Section [1. Why am I or my child being given GARDASIL 9?](#) in the full CMI.

### 2. What should I know before my child or I are given GARDASIL 9?

Do not get GARDASIL 9 if you or your child have had an allergy to a previous dose of GARDASIL or GARDASIL 9 or to any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before my child or I are given GARDASIL 9?](#) in the full CMI.

### **3. What if my child or I are taking other medicines?**

Some medicines may interfere with GARDASIL 9 and affect how it works. Tell your doctor, nurse or pharmacist if you or your child are taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

A list of these medicines is in Section [3. What if my child or I are taking other medicines?](#) in the full CMI.

### **4. How is GARDASIL 9 given?**

- A doctor or nurse will give you or your child this vaccine as an injection into the muscle in the arm or leg.

More instructions can be found in Section [4. How is GARDASIL 9 given?](#) in the full CMI.

## 5. What should I know after my child or I are given GARDASIL 9?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Call your doctor straight away if you or your child have symptoms of an allergic reaction, which may 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.</li><li>• Remind any doctor, nurse or pharmacist you or your child visit that you or your child have been given GARDASIL 9</li></ul>
<b>Looking after your vaccine</b>	<ul style="list-style-type: none"><li>• It is unlikely that you will be asked to store GARDASIL 9. If you are, keep this vaccine in the refrigerator between 2°C and 8°C. Do not freeze this vaccine. Keep this vaccine in the original</li></ul>

	pack until it is time to be given.
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For more information, see Section [5. What should I know after my child or I are given GARDASIL 9?](#) in the full CMI.

## **6. Are there any side effects?**

Side effects of allergic reaction may include: wheezing, shortness of breath or difficulty breathing; pinkish, itchy swellings on the skin, also called hives; 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

The most common side effects are: pain, swelling, redness, itching and bruising at or around the injection site; headache; fever or high temperature; nausea; dizziness; fatigue

For more information, including what to do if you or your child have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# GARDASIL 9

*Human Papillomavirus 9-valent Vaccine, Recombinant*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about being given GARDASIL 9. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about you or your child being given GARDASIL 9.**

**Where to find information in this leaflet:**

- [1. Why am I or my child being given GARDASIL 9?](#)
- [2. What should I know before my child or I are given GARDASIL 9?](#)
- [3. What if my child or I are taking other medicines?](#)
- [4. How is GARDASIL 9 given?](#)
- [5. What should I know after my child or I are given GARDASIL 9?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

# **1. Why am I or my child being given GARDASIL 9?**

**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 to 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 to 45 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 or your child 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 certain cancers and other diseases. While most people clear the virus, those who do not can develop disease, including cervical, some vaginal, vulvar, and anal cancer 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 precancerous 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, nurse or pharmacist for more information.

The GARDASIL 9 vaccine:

- does not remove the need for screening for cervical, vulvar, vaginal and anal cancers, as recommended by your doctor; 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 (vulvar, vaginal and anal cancers) 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 instructions on regular cervical cancer screening tests.

## **2. What should I know before my child or I are given GARDASIL 9?**

### **Warnings**

#### **Do not get GARDASIL 9 if:**

- You or your child have had an allergy to a previous dose of GARDASIL or GARDASIL 9
- You or your child are allergic to any of the ingredients 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.

#### **Check with your doctor 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.
- have any other medical conditions.
- take any medicines for any other condition.

During treatment, you or your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Tell the doctor or health care professional if you or your child (the person getting GARDASIL 9), is pregnant or is planning to get pregnant. You should not get GARDASIL 9 during pregnancy. If you plan to get pregnant or get pregnant, you should wait until you are no longer pregnant to complete your vaccine series.

In more than 1000 pregnancies, women who were pregnant or became pregnant after getting GARDASIL 9 did not have a higher chance for miscarriages or babies with birth defects. These data are considered insufficient to recommend use of Gardasil 9 during pregnancy.

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

## **Use in the elderly**

- GARDASIL 9 has not been studied in the elderly.

### **3. What if my child or I are taking other medicines?**

Tell your doctor, nurse or pharmacist if you or your child are taking any other vaccines or medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

#### **Use with other vaccines**

Tell your doctor if you or your child 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, nurse or 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]

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

If you have already received GARDASIL, talk to your doctor nurse, 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).

**Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GARDASIL 9.**

## **4. How is GARDASIL 9 given?**

### **How much is given**

- A doctor or nurse will give you GARDASIL 9 as an injection into the muscle in the arm or leg.
- Each dose of GARDASIL 9 is 0.5mL.

### **When is it 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 nurse or pharmacist chooses
- 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 to 14 years of age may receive 2 doses of the vaccine.

- Dose 1: at a date you and your doctor or nurse or pharmacist chooses
- 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 miss a dose**

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

It is important that you follow the instructions of your doctor or nurse regarding return visits for the follow-up dose.

## **5. What should I know after my child or I are given GARDASIL 9?**

### **Things you should do**

- Keep follow-up appointments with your doctor or clinic
- Keep a record of the vaccinations and update this after each injection

Remind any doctor, nurse or pharmacist you visit that you or your child have been given GARDASIL 9.

### **Looking after your vaccine**

It is unlikely that you will be asked to store GARDASIL 9. However, if you need to store GARDASIL 9:

- Keep it in the fridge where the temperature is between 2°C and 8°C
- Do not freeze this vaccine. Freezing destroys the vaccine
- Protect it from light by keeping it in the original pack until it is time to be given

GARDASIL 9 should be administered as soon as possible after being removed from refrigeration.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted vaccine

It is unlikely that you will be asked to dispose of GARDASIL 9. However, if you no longer need to take this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this vaccine after the expiry date.

## 6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• pain, swelling, redness, itching and bruising at or around the injection site.</li><li>• headache</li><li>• fever or high temperature</li><li>• nausea</li><li>• dizziness</li></ul>	<b>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</b>



<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● fatigue</li> </ul> <p>Studies show that there was more swelling where the shot was given when GARDASIL 9 was given at the same time with other vaccines such as Repevax*, Menactra and/or Adacel.</p> <p>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.</p> <p>As with other vaccines, additional side effects that have been reported during general use for GARDASIL 9 are shown below. Side effects reported during the general use of GARDASIL are also shown below. GARDASIL side effects are reported as they may be relevant to GARDASIL</p>	

<b>Less serious side effects</b>	<b>What to do</b>
<p>9 since the vaccines are similar in composition.</p> <p><b>GARDASIL 9</b></p> <ul style="list-style-type: none"> <li>● fainting sometimes accompanied with seizure-like movements</li> <li>● vomiting</li> <li>● lump where you got the shot</li> </ul> <p>Additionally, the following side effects have been seen with the general use of GARDASIL:</p> <ul style="list-style-type: none"> <li>● skin infection (may appear as hot, tender and red skin)</li> <li>● bleeding or bruising more easily than normal (may appear as purple or red spots visible through the skin)</li> <li>● swollen glands in the neck, armpit or groin</li> <li>● muscle weakness, abnormal sensations, tingling in the arms, legs and upper</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p>body (Guillain-Barre syndrome)</p> <ul style="list-style-type: none"> <li>● confusion</li> <li>● dizziness</li> <li>● headache</li> <li>● nausea</li> <li>● joint pain or painful, swollen joint</li> <li>● aching muscles (may appear as muscle weakness or weakness that is not caused by exercise)</li> <li>● unusual tiredness, weakness</li> <li>● chills</li> <li>● generally feeling unwell</li> </ul>	

## **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.

## Serious side effects

Serious side effects	What to do
<p>As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.</p> <ul style="list-style-type: none"><li>• wheezing, shortness of breath or difficulty breathing</li><li>• pinkish, itchy swellings on the skin, also called hives</li><li>• skin rash, itchiness</li><li>• swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing, or swelling of other parts of the body</li></ul> <p>All of these side effects are rare.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p>These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.</p>

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this vaccine.

## 7. Product details

This vaccine is only available with a doctor's prescription.

### What GARDASIL 9 contains

<b>Active ingredient (main ingredient)</b>	Highly purified inactive proteins from HPV Types 6, 11, 16, 18, 31, 33, 45, 52 and 58
<b>Other ingredients (inactive ingredients)</b>	Aluminium (as amorphous aluminium hydroxyphosphate sulfate adjuvant)  Sodium chloride  Histidine  Polysorbate 80  Borax

	Residual traces of yeast protein Water
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**Do not take this vaccine if you are allergic to any of these ingredients.**

## **What Gardasil 9 looks like**

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

GARDASIL 9 syringe (AUST R 224092)

GARDASIL 9 vial (AUST R 224093) #

# Not currently available in Australia

\* Not currently registered in Australia

The tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.

The vial stopper is not made with natural rubber latex.

## **Who sponsors Gardasil 9**

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

## **Who distributes Gardasil 9**

Seqirus (Australia) Pty Ltd

Melbourne, Victoria

Australia

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