

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

GARDASIL®9

[Human Papillomavirus 9-valent Vaccine, Recombinant]

Read this carefully before you are given **GARDASIL®9** and each time you get a shot. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **GARDASIL®9**.

What is **GARDASIL®9** used for?

GARDASIL®9 is a vaccine (injection/shot) that helps protect against some diseases caused by some types of Human Papillomavirus (HPV). **GARDASIL®9** contains the same 4 HPV types (6, 11, 16, 18) as in **GARDASIL®** with 5 additional HPV types (31, 33, 45, 52, 58).

For the following indication **GARDASIL®9** has been approved **with conditions** (Notice of Compliance with conditions (NOC/c)). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the vaccine works the way it should. For more information, talk to your healthcare professional.

GARDASIL®9, a vaccine (injection/shot) indicated for:

- Individuals 9 through 45 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine:
 - Certain head and neck cancers, such as throat and back of mouth cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58

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- Individuals 9 through 45 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine:
 - Cervical cancer (cancer of the lower end of the uterus or womb) caused by HPV types 16, 18, 31, 33, 45, 52, and 58
 - Vulvar (the outside of the female genital area) and vaginal cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58
 - Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58
 - Genital warts (condyloma acuminata) caused by HPV types 6 and 11
 - Abnormal and precancerous cervical lesions (changes in cells of the cervix that have a risk of turning into cancer) as found in a Pap test caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58
 - Abnormal and precancerous vaginal, vulvar (outside of the female genital area) and anal lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58

These diseases have many causes. Most of the time, these diseases are caused by nine types of HPV: HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL®9 only protects against diseases caused by these nine types of HPV.

People cannot get HPV or any of these diseases from GARDASIL®9.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a vaccine in Canada.

Health Canada only gives an NOC/c to a vaccine that treats, prevents, or helps identify a serious or life-threatening illness. The vaccine must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the vaccine must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Vaccine makers must agree in writing to clearly state on the label that the vaccine was given an NOC/c, to complete more testing to make sure the vaccine works the way it should, to actively monitor the vaccine's performance after it has been sold, and to report their findings to Health Canada.

How does GARDASIL®9 work?

When an individual receives the GARDASIL®9 vaccine, his/her immune system produces antibodies against the 9 HPV types contained in the vaccine. If that individual is exposed to one of these types, the antibodies may help defend against developing infection and related diseases.

About HPV

Human Papillomavirus (HPV) is a common virus. Without vaccination, the majority of sexually active people will catch HPV during their lifetime. While most infected people clear the virus, those who do not can develop HPV-related cancers and precancers, or genital warts. Many 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.

HPV causes nearly 100% of cervical cancers. HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 specifically cause approximately 90% of cervical cancers and 75-85% of cervical precancers. These 9 types of HPV also cause at least 25% of HPV-related vulvar, 74% vaginal, 80 – 90% of anal cancers and precancers and 70% of certain head and neck cancers, such as throat and back of mouth cancers. Over 90% of genital warts are caused by HPV types 6 and 11.

Will GARDASIL®9 help me if I already have Human Papillomavirus?

GARDASIL®9 helps prevent the diseases caused by some types of papillomavirus but will not treat them. If you are already infected with one type of HPV contained in the vaccine, GARDASIL®9 will help protect you against the other eight types. Talk to your health-care provider for more information.

Use in children

GARDASIL®9 can be used in children as young as 9 years of age.

Use in pregnancy

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.

Pregnant women exposed to GARDASIL®9 are encouraged to report their exposure or suspected adverse reactions by contacting Merck Canada Inc., at 1-800-567-2594.

Use in breast-feeding

It is not known whether GARDASIL®9 is excreted in human milk. If you are breast-feeding, talk to your doctor or health care professional to see if you should be vaccinated with GARDASIL®9.

Use in geriatrics

GARDASIL®9 has not been studied in the elderly.

What are the ingredients in GARDASIL®9?

Medicinal ingredients: The main ingredients are highly purified inactive proteins (L1) that come from HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

Non-medicinal ingredients: Amorphous aluminum hydroxyphosphate sulfate (AAHS Adjuvant), L-histidine, polysorbate 80, sodium borate, sodium chloride, and water for injection. GARDASIL®9 does not contain any preservatives.

GARDASIL®9 comes in the following dosage forms:

- 0.5 mL single-dose vials
- 0.5 mL single-dose prefilled syringes

Do not use GARDASIL®9 if:

Anyone with an allergic reaction to:

- A previous dose of GARDASIL®9
- A previous dose of GARDASIL®
- Any of the ingredients in the vaccine (listed in “What are the ingredients in GARDASIL®9” section).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child get GARDASIL®9. Talk about any health conditions or problems you may have, including if you:

- Are pregnant or planning to get pregnant. GARDASIL®9 is not recommended for use in pregnant women.
- Have immune problems, like HIV or cancer.
- Take medicines that affect the immune system.
- Have any illness with a fever over 37.8°C.
- Had an allergic reaction to a previous dose of GARDASIL®9 or GARDASIL®.
- Have a bleeding disorder and cannot receive injections in the arm.
- Take any medicines, even those you can buy over the counter.

The healthcare professional will help decide if you or your child should get the vaccine.

Other warnings you should know about:

GARDASIL®9:

- Does not remove the need for screening for cervical, vulvar, vaginal, anal, and certain head and neck cancers, such as throat and back of mouth cancers as recommended by a health care professional; women should still get routine cervical cancer screening.
- Does not protect the person getting GARDASIL®9 from a disease that is caused by other types of HPV, other viruses or bacteria.
- Does not treat HPV infection.
- Does not protect the person getting GARDASIL®9 from HPV types that he/she may already have; but most people do not have all types contained in the vaccine.

GARDASIL®9 may not fully protect each person who gets it.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Can you get GARDASIL®9 if you have already gotten GARDASIL®?

Talk to your health care professional to see if GARDASIL®9 is right for you.

Can you get GARDASIL®9 with other vaccines?

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

- Menactra* [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine]
- Adacel* [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)]
- Repevax* [Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content) (Tdap-IPV)]

How to take GARDASIL®9:

Usual dose:

GARDASIL®9 is a shot that is usually given in the arm muscle.

You or your child (the person getting GARDASIL®9) will receive 3 doses of the vaccine. Ideally the doses are given as:

- First dose: at a date you and your health-care provider choose
- Second dose: 2 months after the first dose (not earlier than one month after the first dose)
- Third dose: 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.

Overdose:

If you think you, or a person you are caring for, have received too much GARDASIL®9, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Make sure the person getting GARDASIL®9 gets the complete vaccine series. This allows you or your child to get the full benefits of GARDASIL®9. If the person getting GARDASIL®9 misses a dose, tell the doctor or health care professional. Your doctor or health care professional will decide when to give the missed dose.

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

What are possible side effects from using GARDASIL®9?

These are not all the possible side effects you may have when taking GARDASIL®9. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects seen with GARDASIL®9 are:

- pain, swelling, redness, itching, bruising, bleeding and a lump where you got the shot
- headache, fever, nausea, dizziness, tiredness, diarrhea, abdominal pain, sore throat

Fainting can happen after getting a HPV vaccine. Sometimes people who faint can fall and hurt themselves. For this reason, the health care professional may ask the person getting GARDASIL®9 to sit or lie down for 15 minutes after getting the vaccine. Some people who faint might shake or become stiff. The health care professional may need to treat the person getting GARDASIL®9.

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*, or Menactra* and/or Adacel*.

Tell the doctor or health care professional if you or your child has these problems because these may be signs of an allergic reaction:

- difficulty breathing
- wheezing (bronchospasm)
- hives
- rash

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®9 since the vaccines are similar in composition.

GARDASIL®9

- fainting sometimes accompanied with seizure-like movements
- vomiting

Additionally, the following side effects have been seen with the general use of GARDASIL®.

- swollen glands (neck, armpit, or groin), Guillain-Barré syndrome, joint pain, aching muscles, unusual tiredness, weakness, or confusion, chills, bad stomach ache, muscle weakness, leg pain, shortness of breath, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store refrigerated at 2°C to 8°C. Do not freeze. Protect from light.
Keep out of reach and sight of children.

If you want more information about GARDASIL®9:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the Merck Canada website www.merck.ca, or by calling 1-800-567-2594.

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Last Revised Apr-06-2022

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