

PART III: CONSUMER INFORMATION**GARDASIL[®]9**

[Human Papillomavirus 9-valent Vaccine, Recombinant]

This leaflet is part III of a three-part "Product Monograph" published when GARDASIL[®]9 was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about GARDASIL[®]9. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE**What the vaccine is 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).

Girls and Women

GARDASIL[®]9 is a vaccine (injection/shot) that helps protect girls and women 9 through 45 years of age against the following diseases caused by an infection with Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- 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
- 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 and vulvar lesions (outside of the female genital area) caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58

GARDASIL[®]9 helps protect girls and women 9 through 26 years of age against:

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Abnormal and precancerous anal lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

Boys and Men

GARDASIL[®]9 helps protect boys and men 9 through 26 years of age against infection caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases caused by HPV:

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Genital warts caused by HPV types 6 and 11

- Abnormal and precancerous 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 it does not:GARDASIL[®]9:

- Does not remove the need for cervical cancer screening; 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.

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 75% of HPV-related vulvar, vaginal and anal cancers, and precancers. 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 or the Vaccine Safety Section at Public Health Agency of Canada at 1-866-844-0018 or www.phac-aspc.gc.ca/im/vs-sv/index-eng.php.

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.

When it should not be used:

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 the important non-medicinal ingredients are” section).

What the medicinal ingredient is:

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

What the important non-medicinal ingredients are:

It also contains amorphous aluminum hydroxyphosphate sulfate (AAHS Adjuvant), L-histidine, polysorbate 80, sodium borate, sodium chloride, and water for injection.

What dosage forms it comes in:

GARDASIL[®]9 is supplied as:

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

WARNINGS AND PRECAUTIONS

It is very important to tell your healthcare professional if you or your child (the person getting GARDASIL[®]9):

- 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.

INTERACTIONS WITH THIS VACCINE

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)]

PROPER USE OF THIS VACCINE

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.

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.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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 as Repevax*, or Menactra* and 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, side effects have been reported during general use. The following side effects have been reported with GARDASIL[®] and may also be seen after getting GARDASIL[®]9:

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

This is not a complete list of side effects. For any unexpected effects while taking GARDASIL[®]9, contact your doctor or pharmacist.

HOW TO STORE IT

Store refrigerated at 2°C to 8°C. Do not freeze. Protect from light.

Keep out of reach of children.

Reporting Suspected Vaccine Adverse Events

For the general public:
If you suspect you have had a serious or unexpected event following receipt of a vaccine, please ask your healthcare professional to complete the Adverse Events Following Immunization (AEFI) Form and send it to your local [health unit](#) in your province/territory.

For healthcare professionals:
If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Form and send it to your local [health unit](#) in your province/territory.

If you have any questions or have difficulty contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

Toll-free telephone: 1-866-844-0018
Toll-free fax: 1-866-844-5931
By email: caefi@phac-aspc.gc.ca

NOTE: Should you require information related to the management of the adverse events, please contact your health professional before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION**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 Consumer Information by visiting the [Health Canada website](#) or Merck Canada web site www.merck.ca or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to GARDASIL^{®9}, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

Last revised: December 07, 2016.

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