

PART III: CONSUMER INFORMATION**GARDASIL®**

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

This leaflet is part III of a three-part "Product Monograph" published when GARDASIL® 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®. Contact your physician or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE**What the vaccine is used for:**

GARDASIL® 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, and 18:

- Cervical cancer (cancer of the lower end of the uterus or womb) caused by HPV types 16 and 18
- Vulvar (the outside of the female genital area) and vaginal cancers caused by HPV types 16 and 18
- Genital warts 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, and 18
- Abnormal and precancerous vaginal and vulvar lesions (outside of the female genital area) caused by HPV types 6, 11, 16, and 18

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

- Anal cancer caused by HPV types 16 and 18
- Abnormal and precancerous anal lesions caused by HPV types 6, 11, 16, and 18.

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

- Anal cancer caused by HPV types 16 and 18
- Genital warts caused by HPV types 6 and 11
- Abnormal and precancerous anal lesions caused by HPV types 6, 11, 16, and 18.

GARDASIL® helps prevent these diseases—but it will not treat them.

You or your child cannot get HPV or any of the above diseases from GARDASIL®.

What it does:

- As with all vaccines, GARDASIL® may not fully protect everyone who gets the vaccine. Continue to follow your health-care provider's advice on getting Pap tests.
- There are more than 100 HPV types; GARDASIL® will not protect against all types. GARDASIL® helps protect against 4 types (6, 11, 16, and 18). These 4 types have been selected

for GARDASIL® because they cause over 70% of cervical cancers, 90% of genital warts, and 80-90% of HPV-related anal cancers worldwide.

- GARDASIL® also will not protect against other diseases that are not caused by HPV.
- GARDASIL® works best when given before you or your child has any contact with certain types of HPV.

What are cervical cancer, precancerous lesions, and genital warts?

Cancer of the cervix is a serious and sometimes life-threatening disease. It starts when a female catches certain types of HPV. These 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 by a Pap test. If these lesions are not treated, they can turn cancerous. You or your child cannot get cancer of the cervix without first having an HPV infection.

Genital warts are caused by certain types of HPV. They often appear as skin-colored 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.

What are vulvar and vaginal cancers and precancerous lesions?

Approximately 40-50% of vulvar and 65-80% of vaginal cancers are associated with HPV. HPV types 16 and 18 have been associated with 60-95% of all HPV-related vulvar and vaginal cancers. The rates of these cancers have been increasing. There are no routine screening tests for these cancers.

What are anal cancer and anal precancerous lesions?

Human Papillomavirus (HPV) infection is strongly associated with anal cancer and the precancerous anal lesions that precede cancer. The great majority of anal cancers are squamous cell carcinoma (SCC) and 80 to 90% of these cancers are HPV positive. HPV types 16 and 18 are the most commonly associated types. Approximately 100,000 new cases of anal cancer are estimated to occur annually around the world and the rate of anal cancer cases has been increasing. There are no routine screening tests for this cancer in healthy people.

What is Human Papillomavirus (HPV)?

HPV is a common virus. It is estimated that the occurrence of HPV in Canadian women ranges from 20-33%.³⁴ The highest rates of cancer-causing HPV infection (16-24%) were in young women aged 15 to 29 years.³⁵ There are many different types of HPV; some cause no harm. Others can cause diseases of the genital area.

While most people clear the virus, those who don't can develop cervical cancer, precancerous lesions, or genital warts.

Every year, there are an estimated 4 million Pap tests performed in Canada and 350,000 of these are abnormal. The majority of abnormal Pap tests are caused by HPV. A Pap test is a procedure by which cells of the cervix are collected by a healthcare professional and examined.³⁶

Who is at risk for Human Papillomavirus?

In the absence of vaccination, it is estimated that 75% of sexually active Canadians will catch HPV during their lifetime. A person of any age who takes part in any kind of sexual activity that involves genital contact is at risk. The only way to fully protect yourself from HPV is to avoid this kind of sexual activity.

Many people who have HPV may not show any signs or symptoms. This means that they can pass on the virus to others and not know it.

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

GARDASIL® 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® will help protect you against the other three types. Talk to your health-care provider for more information.

When it should not be used:

Anyone who:

- is allergic to any of the ingredients in the vaccine. A list of ingredients can be found below.
- has an allergic reaction after getting a dose of the vaccine.

What the medicinal ingredient is:

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

What the important non-medicinal ingredients are:

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

What dosage forms it comes in:

GARDASIL® is supplied as:

- 0.5 mL single-dose vials

WARNINGS AND PRECAUTIONS

It is very important to tell your 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 a weakened immune system, for example due to a genetic defect or HIV infection, or if you take medicines that affect your immune system
- is pregnant or is planning to get pregnant
- has any illness with a fever more than 37.8°C
- takes or plans to take any medicines, even those you can buy over the counter

Your health-care provider will decide if you or your child should receive the vaccine.

Use in children

GARDASIL® 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. The use of the vaccine is not recommended during pregnancy.

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

Pregnant women exposed to GARDASIL® 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

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

Can I drive or operate machinery following vaccination with GARDASIL®?

There is no information to suggest that GARDASIL® affects your ability to drive or operate machinery.

INTERACTIONS WITH THIS VACCINE**Can other vaccines and medications be given at the same time as GARDASIL®?**

GARDASIL® can be given at the same time as RECOMBIVAX HB® [hepatitis B vaccine (recombinant)], Menactra* [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], and Adacel* [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)]; however the vaccine should not be mixed in the same syringe with any other vaccines or solutions.

Please inform your physician or health-care provider if you or your child are taking or have recently taken any other medicines, even those not prescribed.

PROPER USE OF THIS VACCINE**Usual dose:**

GARDASIL® is given as an injection usually in the arm muscle.

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 health-care provider choose
- Second dose: 2 months after the first dose
- Third dose: 6 months after the first dose

The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. Please speak to your doctor for more information.

Alternatively, individuals 9 through 13 years of age, may receive

2 doses of the vaccine.

First injection: at chosen date

Second injection: ideally 6 months or 12 months after first injection

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

Make sure that you or your child gets all doses. This allows you or your child to get the full benefits of GARDASIL[®].

Missed dose:

If you or your child misses a dose, your health-care provider will decide when to give the missed dose.

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.

feeling unwell, bleeding or bruising more easily than normal, and skin infection.

If you or your child has any unusual or severe symptoms after receiving GARDASIL[®], contact your health-care provider right away.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all vaccines, there may be some side effects with GARDASIL[®]. GARDASIL[®] has been shown to be generally well tolerated in adults and children as young as 9 years of age.

The most commonly reported side effects included:

- pain, swelling, itching, bruising and redness at the injection site
- fever, nausea, dizziness, headache, vomiting, and pain in extremity.

Fainting 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 vaccine.

Allergic reactions that may include difficulty breathing, wheezing (bronchospasm), hives, and rash have been reported. Some of these reactions have been severe.

There was no increase in side effects when GARDASIL[®] was given at the same time as hepatitis B vaccine (recombinant).

There was more injection-site swelling when GARDASIL[®] was given at the same time as Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap).

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

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in **your province/territory**.

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

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

By toll-free telephone: 1-866-844-0018
 By toll-free fax: 1-866-844-5931
 Email: CAEFI@phac-aspc.gc.ca
 Web: <http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

Mail:
 The Public Health Agency of Canada
 Vaccine Safety Section
 130 Colonnade Road, AL 6502A
 Ottawa, ON K1A 0K9

or Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at: 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to: 1-877-428-8675, or
 - Mail to: Merck Canada Inc.
 Medical Information Center
 16750 route Transcanadienne
 Kirkland, QC H9H 4M7

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada or Merck do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.merck.ca or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

Last revised: May 03, 2017

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