

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 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)
- Vulvar (the outside of the female genital area) and vaginal cancers
- 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
- Abnormal and precancerous vaginal and vulvar lesions (outside of the female genital area)
- Genital warts

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

You or your child cannot get these diseases from GARDASIL®.

GARDASIL® is for girls and women aged 9 through 26 years.

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 and 90% of genital warts 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 is Human Papillomavirus (HPV)?

HPV is a common virus. It is estimated that the occurrence of HPV in Canadian women ranges from 20-33%.²⁹ The highest rates of cancer-causing HPV infection (16-24%) were in young women aged 15 to 29 years.³⁰ 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.³¹

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 male or female 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
- 0.5 mL single-dose prefilled syringes
-

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
- 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.

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

GARDASIL® can be given at the same time as hepatitis B vaccine (recombinant); 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.

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

Make sure that you or your child gets all 3 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.

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 in girls and women included:

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

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.

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 or weakness, chills, bad stomach ache, muscle weakness, shortness of breath and generally feeling unwell.

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.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected effects of vaccines. If you suspect you have had a serious or unexpected reaction to this vaccine you should contact your physician or pharmacist. You may also notify

The Public Health Agency of Canada
Vaccine Safety Unit
100 Promenade Eglantine Driveway
A/L 0602C
Ottawa, ON K1A 0L2 CANADA

Telephone: 1-613-952-6339
Fax: 1-613-998-6413
Email: CAEFI@phac-aspc.gc.ca

or Merck Frosst Canada Ltd. by:

Toll-free telephone: 1-800-567-2594
Toll-free fax: 1-877-428-8675
By regular mail:
Merck Frosst Canada Ltd.
P.O. Box 1005
Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Before contacting Health Canada or Merck Frosst, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merckfrosst.com> or by contacting the sponsor, Merck Frosst Canada Ltd., at: 1-800-567-2594.

This leaflet was prepared by Merck Frosst Canada Ltd.

Last revised: April 16, 2009
09,04-a,128745

www.merckfrosst.com



MERCK FROSST CANADA LTD.
KIRKLAND, QUEBEC, CANADA