

PART III: CONSUMER INFORMATION

CERVARIX™

Human Papillomavirus vaccine Types 16 and 18
(Recombinant, AS04 adjuvanted)

This leaflet is part III of a three-part "Product Monograph" published when CERVARIX™ was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CERVARIX™. Contact your health professional if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is used for:

CERVARIX™ is a vaccine intended to protect females against cervical cancer (cancer of the lower part of the uterus or womb) and abnormal and precancerous cervical lesions (changes in cells of the cervix that have a risk of turning into cancer). These diseases are caused by infection with Human Papillomaviruses (HPV) types 16 and 18 and other cancer causing types.

HPV-16 and HPV-18 are responsible for approximately 70% of cervical cancers cases. Other HPV types can also cause cervical cancer. CERVARIX™ provides protection against HPV-16 and HPV-18, although it will not prevent all cancers or precancerous lesions caused by these or other types of HPV.

What it does:

CERVARIX™ works by stimulating the production of antibodies against HPV types 16 and 18. These antibodies have been shown in clinical trials to protect females aged 15 to 25 years against HPV-16 and HPV-18 related diseases. In 10 to 14 year old girls, the antibodies produced indicate that they will provide just as much protection as in older women.

- CERVARIX™ is not infectious and so, it cannot cause HPV related diseases.
- CERVARIX™ will not treat HPV related diseases already present at time of vaccination.
- If you are currently infected with an HPV-16 or HPV-18 infection, CERVARIX™ may protect you against the other vaccine type.
- CERVARIX™ will not protect against diseases that are caused by other infections, including other types of HPV.

As with all vaccines, CERVARIX™ may not fully protect all people who are vaccinated. It is not a substitute for regular cervical screening and you should continue to consult your health professional for regular cervical cancer screening (i.e. Pap tests).

What is the Adjuvant

An adjuvant is a component added to a vaccine to improve the immune response by providing stronger and longer protection.

Adjuvants have been used in vaccines for almost 80 years. Nearly all vaccines are made with adjuvants. Most common vaccines are designed with traditional adjuvants such as aluminum salts (alum).

The adjuvant system in CERVARIX™ is AS04 which is made up of 1) a natural compound which comes from a type of organism which most people have been exposed to and 2) alum.

Long-Term Protection

In clinical trials, sustained protection has been observed for up to 6.4 years after the first dose. Long-term studies are ongoing to establish the duration of protection.

What is Human Papillomavirus (HPV)?

HPV is a common virus which affects humans. The virus is generally spread by skin-to-skin contact during sexual activity. In most cases, females infected with HPV will not have any symptoms and their body will clear the virus. However, the body does not develop long term protection against HPV and must continue to clear new and previously encountered HPV types. Up to 80% of sexually active females will be infected with HPV during their lifetime, which in some cases may cause cervical cancer.

What is cervical cancer?

Cervical cancer is a serious and sometimes life threatening disease. Cervical cancer is caused by HPV infection. There are about 15 types of HPV that cause most cases of cervical cancer. These HPV types can cause the normal cells on the cervix to turn into abnormal precancerous cervical lesions. If left untreated, some of these lesions can turn into cancer over time. Cervical cancer affects females of all ages and among females aged 20 to 44, cervical cancer ranks as the second most common cancer after breast cancer. Cervical cancer screening (i.e. Pap tests) can identify abnormal changes in the cervix that may be treated.

When it should not be used:

Please see Warnings and Precautions section.

What the medicinal ingredient is:

CERVARIX™ contains Human Papillomavirus type 16 L1 protein and Human Papillomavirus type 18 L1 protein as active substances and is adjuvanted with AS04 adjuvant system [composed of aluminum hydroxide, hydrated and 3-*O*-desacyl-4'-monophosphoryl lipid A (MPL)]. The adjuvant system is designed to boost the body's response to CERVARIX™ leading to long lasting antibody levels. The duration of protection has not been established.

CERVARIX™ is not infectious and so, it cannot cause HPV related diseases.

What the important nonmedicinal ingredients are:

CERVARIX™ contains the following nonmedicinal ingredients: sodium chloride, sodium dihydrogen phosphate dihydrate, and sterile water for injections.

What dosage forms it comes in:

CERVARIX™ is available as:

- 0.5 mL single-dose pre-filled syringe
- 0.5 mL single-dose vial

WARNINGS AND PRECAUTIONS

CERVARIX™ should not be given if you have previously had any allergic reaction to CERVARIX™, or any ingredient contained in CERVARIX™. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Before you are vaccinated, talk to your health professional if you:

- have a severe infection with a high temperature. It is recommended to delay the vaccination where there is a severe infection or fever until recovery. A minor infection such as a cold should not be a problem, but talk to your health professional first.
- have a bleeding problem or bruise easily

Use in children

CERVARIX™ can be used in children as young as 10 years of age.

Use in pregnancy

Health professionals need to assess the benefits and potential risks of administering the vaccine to pregnant females.

In clinical studies, there was a slightly higher rate of spontaneous abortions in pregnancies which occurred around the time of vaccination in women who were given the CERVARIX™ vaccine compared with those who received a control vaccine. It is not known if this imbalance is due to CERVARIX™.

If pregnancy occurs during the course of vaccination, it is recommended to postpone vaccination until after pregnancy. It is also recommended to take adequate precautions to avoid pregnancy for 2 months following vaccination with CERVARIX™.

Patients and healthcare providers are encouraged to report any exposure to CERVARIX™ vaccine during pregnancy by calling 1-800-387-7374.

Use in breastfeeding

Health professionals need to assess the benefits and potential risks of administering the vaccine to breastfeeding females.

INTERACTIONS WITH THIS VACCINE

If CERVARIX™ is to be given at the same time as another injectable vaccine(s), the vaccines should always be given with separate syringes and at different injection sites.

CERVARIX™ may not have an optimal effect if used with medicines that suppress the immune system.

In clinical trials, oral contraceptives (e.g. the pill) did not reduce the protection obtained by CERVARIX™.

Please tell your health professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or have recently received any other vaccine.

PROPER USE OF THIS VACCINE

Usual dose:

Your health professional will give CERVARIX™ as an injection into the muscle. You or your daughter will receive a total of three injections to be given as follows:

- First injection: at chosen date by you and your health professional
- Second injection: 1 month after first injection
- Third injection: 6 months after first injection

If necessary, the vaccination schedule can be more flexible. Please speak to your health professional for more information.

Missed Dose:

It is important that you follow the instructions of your health professional regarding return visits. If you forget to go back to your health professional at the scheduled time, ask your health professional for advice.

If you do not finish the entire vaccination course of three injections, your protection from developing cervical cancer may be reduced.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CERVARIX™ may cause side effects, although not everybody gets them.

You may feel:

- pain or discomfort at the injection site

or you may see some:

- redness or swelling at the injection site.

However, these effects usually clear up within a few days.

Other side effects that occurred during clinical trials with CERVARIX™ were as follows:

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- headache
- aching muscles, muscle tenderness or weakness, not caused by exercise
- fatigue

Common (these may occur with up to 1 in 10 doses of the vaccine):

- gastrointestinal symptoms including nausea, vomiting, diarrhea and abdominal pain
- itching, red skin rash, hives
- joint pain
- fever ($\geq 38^{\circ}\text{C}$)

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- upper respiratory tract infection
- dizziness
- other injection site reactions such as hard lump, tingling or numbness

Rare (these may occur with up to 1 in 1,000 doses of the vaccine):

- Allergic reactions. These can be recognized by:
 - Itchy rash of the hands and feet
 - Swelling of the eyes and face
 - Difficulty in breathing or swallowing
 - Sudden drop in blood pressure and loss of consciousness

These reactions will usually occur a short time after vaccination. However, if you experience any of these symptoms you should contact a doctor immediately.

This is not a complete list of side effects. For any unexpected effects while taking CERVARIX™, contact your health professional.

HOW TO STORE IT

- Keep out of the reach and sight of children.
- Do not use CERVARIX™ after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a refrigerator ($2^{\circ}\text{C} - 8^{\circ}\text{C}$).
- Do not freeze.
- Store in the original package in order to protect from light.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: 1-866-844-0018

By toll-free fax: 1-866-844-5931

Web Address: <http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

By regular mail:

Vaccine Safety

130 Colonnade Road

Ottawa, Ontario

K1A 0K9 Address Locator 6502A

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 does not provide medical advice.

MORE INFORMATION

Patients can refer to www.cervarix.ca for further information.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca> or by contacting the sponsor,

GlaxoSmithKline Inc.

7333 Mississauga Road

Mississauga, Ontario

L5N 6L4

1-800-387-7374

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