

CERVARIX[®]

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

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use CERVARIX.

This leaflet answers some common questions about CERVARIX. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking CERVARIX against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is CERVARIX used for?

CERVARIX is a vaccine used in females from 10 to 45 years of age to prevent early stage cervical cancers (pre-cancerous lesions), pap smear abnormalities and cervical cancer caused by human papillomaviruses (HPV) types 16 and 18.

HPV is a very common virus which affects humans. More than 100 types of HPV have been identified, most of which are harmless. About 30 types are spread through sexual contact, of which some types can cause visible

genital warts, while others can cause cervical cancer and other genital cancers. HPV 16 and 18 belong to the group of HPVs that cause cervical cancer and other genital cancers.

When a person is given the vaccine, the immune system (the body's natural defence system) will make antibodies against HPV. These antibodies are expected to protect against disease caused by HPV.

As with all vaccines, CERVARIX may not completely protect all people who are vaccinated against the human papillomavirus infections it is intended to prevent.

If you are already infected with HPV at initiation of the vaccination course, CERVARIX is not expected to induce regression of the lesions and may not be able to protect you against the disease progression.

As cervical cancer can be caused by HPV types not included in the vaccine and as CERVARIX is not expected to induce regression of any lesions if you are already infected with HPV types 16 and 18 at the start of the vaccination course, it is important to continue to consult your doctor for regular cervical screening.

Before you take CERVARIX

Do not take if:

You must not take CERVARIX if:

- if you have previously had any allergic reaction to human papillomavirus vaccines, or any

ingredient contained in CERVARIX. The active substances and other ingredients in CERVARIX are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

- if you are already pregnant or trying to become pregnant. If you become pregnant after commencing the course of vaccination then further doses should be postponed until after completion of the pregnancy. Women trying to become pregnant should postpone vaccination until completion of pregnancy.
- if you have a severe infection with a high temperature. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.
- take special care with CERVARIX if you have a bleeding problem or bruise easily.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you have fainted with a previous injection.

Tell your doctor if:

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you are taking any other medicines, including medicines you buy without a prescription.
- you are breastfeeding, pregnant or trying to become pregnant.

How CERVARIX is given

The total number of injections you will receive depends on your age at the time of the first injection. Each injection is given on a separate visit. You will be informed by the doctor or nurse when you should come back for subsequent injections.

If you are between 10 and 14 years old:

CERVARIX can be administered according to the following 2-dose or 3-dose schedule:

2-dose schedule:

Second injection: given between 5 and 13 months after the first injection.

3-dose schedule:

Second injection: 1 month after the first injection.

Third injection: 6 months after the first injection.

If you are 15 to 45 years old:

CERVARIX is administered according to the **3-dose schedule** above.

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

If you do not finish the complete vaccination course you may not get the best response to vaccination.

The doctor will give CERVARIX as an injection into the muscle.

The vaccine should never be given into a vein.

While you are receiving CERVARIX

Things you must do:

Keep your visits with the doctor or clinic. It is important CERVARIX doses are given at the correct times. This will ensure the best effect of the vaccine in protecting you (or your child) against cervical cancer and cervical abnormalities.

Things to be careful of:

Be careful driving or operating machinery until you know how CERVARIX affects you. CERVARIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or lightheadedness. Make sure you know how you react to CERVARIX before you drive a car or operate machinery, or do anything that could be dangerous if you are dizzy or lightheaded.

What are the side-effects?

Check with your doctor as soon as possible if you think you or your child are experiencing any side effects or allergic reactions due to taking CERVARIX, even if the problem is not listed below.

Like other medicines, CERVARIX can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

You or your child may feel:

- pain or discomfort at the injection site

or you or your child 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 (side effects which may occur in more than 1 per 10 doses of vaccine):
 - headache
 - aching muscles, muscle tenderness or weakness, not caused by exercise
 - fatigue
 - Common (side effects which may occur in less than 1 per 10 but more than 1 per 100 doses of vaccine):
 - gastrointestinal including nausea, vomiting, diarrhoea, and abdominal pain
 - itching, red skin rash, hives
 - joint pain
 - fever ($\geq 37.5^{\circ}\text{C}$ - $\leq 38^{\circ}\text{C}$)
 - Uncommon (side effects which may occur in less than 1 per 100 but more than 1 per 1,000 doses of vaccine):
 - upper respiratory tract infection
 - swollen glands in the neck, armpit or groin
 - dizziness
 - other injection site reactions including hard lump, loss of feeling, especially pain, during a medical procedure, itching
 - flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
 - Rare (side effects which may occur in less than 1 per 1,000 but more than 1 per 10,000 doses of vaccine):
 - spinning sensation
 - muscular weakness
 - generally feeling unwell
- Following rare side effects (these may occur with up to 1 in 1,000

doses of the vaccine) have been reported:

- allergic reactions. These can be recognised 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
- fainting sometimes accompanied by shaking or stiffness.

If you or your child gets any of these symptoms you should contact a doctor urgently.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side effects from your medicine which are not mentioned here.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

How do I store CERVARIX?

CERVARIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store CERVARIX always:

- Keep CERVARIX in a refrigerator stored between +2°C and +8°C. Do not store it in the bathroom, or leave it in the car. Avoid exposing the vaccine to sunlight. **HEAT CAN DESTROY THE VACCINE.**
- Keep the vaccine out of the reach of children.

- Keep CERVARIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over CERVARIX that has expired or has not been used.

Product description

What CERVARIX looks like

CERVARIX is a turbid white suspension for injection.

CERVARIX is available in pre-filled syringes with or without needles in packs of 1 and 10.

Not all pack sizes may be marketed.

Ingredients

CERVARIX contains the active ingredients HPV-16 L1 protein and HPV-18 L1 protein.

CERVARIX also contains 3-O-desacyl-4'- monophosphoryl lipid A (MPL), aluminium hydroxide, sodium chloride, sodium phosphate-monobasic and water for injections.

Supplier:

Your CERVARIX is supplied by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria 3067
Australia

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared on 16 July 2015.

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