Package leaflet: Information for the user

Cervarix suspension for injection in pre-filled syringe
Human Papillomavirus vaccine [Types 16, 18] (Recombinant, adjuvanted, adsorbed)

Read all of this leaflet carefully before you start receiving this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cervarix is and what it is used for

Cervarix is a vaccine intended to protect from the age of 9 years against the diseases caused by infection with Human Papillomaviruses (HPV).

These diseases include:
- cervical cancer (cancer of the cervix i.e. lower part of the uterus or womb) and anal cancer,
- precancerous cervical, vulvar, vaginal and anal lesions (changes in genital or anal cells that have a risk of turning into cancer).

The Human Papillomavirus (HPV) types contained in the vaccine (HPV types 16 and 18) are responsible for approximately 70% of cervical cancers, 90% of anal cancers, 70% of HPV-related pre-cancerous lesions of the vulva and vagina and 78% of HPV-related pre-cancerous lesions of the anus. Other HPV types can also cause ano-genital cancers. Cervarix does not protect against all HPV types.

When a female or a male individual is vaccinated with Cervarix, the immune system (the body's natural defence system) will make antibodies against HPV types 16 and 18.

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

Cervarix is not used to treat HPV related diseases already present at the time of vaccination.

Cervarix should be used in accordance with official guidelines.

2. What you need to know before you receive Cervarix

Cervarix should not be given:

- if you are allergic to any of the active substances or any of the other ingredients of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before you are given Cervarix

- if you have a bleeding problem or bruise easily.
- if you have any disease which reduces your resistance to infection such as HIV infection.
- 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 the doctor first.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you or your child fainted with a previous injection.

As with all vaccines, Cervarix may not fully protect all people who are vaccinated.

Cervarix does not protect people from diseases caused by infection with HPV types 16 or 18 if they are already infected with Human Papillomavirus type 16 or 18 at the time of vaccination.

Although vaccination may protect you against cervical cancer, it is not a substitute for regular cervical screening. You should continue to follow your doctor's advice on cervical smear/Pap test (test to screen for changes in cells of the cervix caused by an HPV infection) and preventative and protective measures.

As Cervarix will not protect against all types of Human Papillomavirus, appropriate precautions against exposure to HPV and sexually transmitted diseases should continue to be used.

Cervarix will not protect against other diseases that are not caused by Human Papillomavirus.

Other medicines and Cervarix
Cervarix can be given with a combined booster vaccine containing diphtheria (d), tetanus (T) and pertussis [acellular] (pa) with or without inactivated poliomyelitis (IPV), (dTpa, dTpa -IPV vaccines), with a combined hepatitis A and hepatitis B vaccine (Twinrix) or a hepatitis B vaccine (Engerix B), or with a meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine (MenACWY-TT), at a separate injection site (another part of your body, e.g. the other arm) during the same visit.

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.

Tell your doctor if you are taking, have recently taken, might take any other medicines, or have recently received any other vaccine.

Pregnancy, breast-feeding and fertility
If you are pregnant, if pregnancy occurs during the course of vaccination or if you are trying to become pregnant it is recommended to postpone or interrupt vaccination until after completion of the pregnancy.

If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this vaccine.

Driving and using machines
Cervarix is not likely to affect your ability to drive or use machines. However, do not drive or use any machines if you are feeling unwell.

Cervarix contains sodium chloride.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".

3. How Cervarix is given

How the vaccine is given
The doctor or nurse will give Cervarix as an injection into the muscle of the upper arm.

How much is given
Cervarix is intended for use from 9 years of age onwards.

The total number of injections you will receive depends on your age at the time of the first injection.

If you are between 9 and 14 years old

You will receive 2 injections:

First injection: at chosen date
Second injection: given between 5 and 13 months after first injection

If you are 15 years old or above

You will receive 3 injections:

First injection: at chosen date
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 doctor for more information.

When Cervarix is given for the first dose, it is recommended that Cervarix (and not another vaccine against HPV) be given for the complete vaccination course.

The vaccine should never be given into a vein.

Cervarix is not recommended for use below 9 years of age.

If you miss a dose
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 (two or three injections depending on your age at vaccination), you may not get the best response and protection from the vaccination.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

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):
  - pain or discomfort at the injection site
  - redness or swelling at the injection site
  - headache
  - aching muscles, muscle tenderness or weakness (not caused by exercise)
  - tiredness

- Common (side effects which may occur in less than 1 per 10 but more than 1 per 100 doses of vaccine):
  - gastrointestinal symptoms including nausea, vomiting, diarrhoea and abdominal pain
  - itching, red skin rash, hives (urticaria)
  - joint pain
  - fever (≥38°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 (infection of the nose, throat or trachea)
  - dizziness
  - other injection site reactions such as hard lump, tingling or numbness.

Side effects that have been reported during marketed use of Cervarix include:

- 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.
  These reactions will usually occur before leaving the doctor's surgery. However, if your child gets any of these symptoms you should contact a doctor urgently.
- swollen glands in the neck, armpit or groin
- fainting sometimes accompanied by shaking or stiffness.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cervarix

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine 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°C – 8°C).
Do not freeze.
Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cervarix contains

- The active substances are:

Human Papillomavirus[1] type 16 L1 protein[2,3,4]	20 micrograms
Human Papillomavirus[1] type 18 L1 protein[2,3,4]	20 micrograms

[1]Human Papillomavirus = HPV

[2]adjuvanted by AS04 containing:

3-*O*-desacyl-4'- monophosphoryl lipid A (MPL)[3]	50 micrograms
[3]adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$)	0.5 milligrams Al^{3+} in total

[4]L1 protein in the form of non-infectious virus-like particles (VLPs) produced by recombinant DNA technology using a Baculovirus expression system which uses Hi-5 Rix4446 cells derived from the insect *Trichoplusia ni*.

- The other ingredients are sodium chloride (NaCl), sodium dihydrogen phosphate dihydrate ($NaH_2PO_4.2\ H_2O$) and water for injections.

What Cervarix looks like and contents of the pack

Suspension for injection in pre-filled syringe.

Cervarix is a turbid white suspension.

Cervarix is available in pre-filled syringes (0,5 ml) with or without needles in packs of 1 and 10.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

GlaxoSmithKline Biologicals s.a.
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in April 2019
Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

The following information is intended for healthcare professionals only:

Cervarix should be administered as soon as possible after being removed from the refrigerator. However, stability has been demonstrated when stored outside the refrigerator for up to 3 days at temperatures between 8°C and 25°C or for up to 1 day at temperatures between 25°C and 37°C. If not used at the end of this period the vaccine should be discarded.

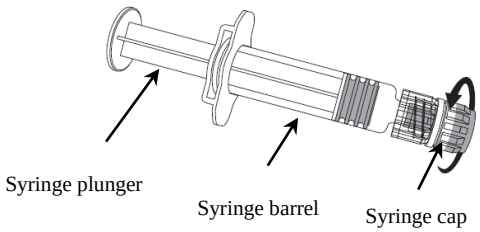
A fine white deposit with a clear colourless supernatant may be observed upon storage of the syringe. This does not constitute a sign of deterioration.

The content of the syringe should be inspected visually both before and after shaking for any foreign particulate matter and/or abnormal physical appearance prior to administration.
In the event of either being observed, discard the vaccine.

The vaccine should be well shaken before use.

Instructions for administration of the vaccine presented in pre-filled syringe

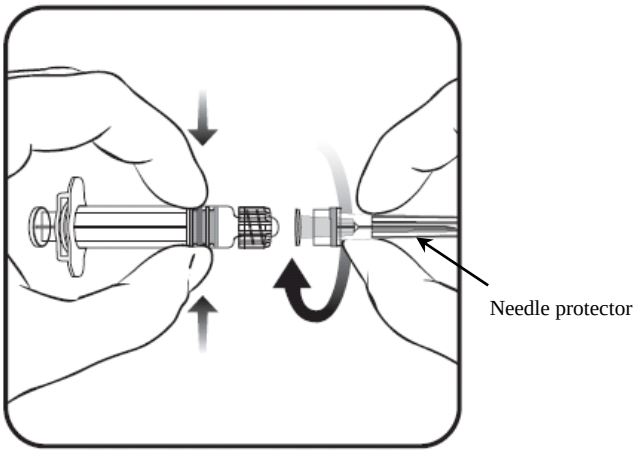
1. Holding the syringe **barrel** in one hand
(avoid holding the syringe plunger),
unscrew the syringe cap by twisting it anticlockwise.



2. To attach the needle to the syringe,
twist the needle clockwise into the syringe
until you feel it lock.

3. Remove the needle protector, which on occasion can be a little stiff.

4. Administer the vaccine.



Any unused medicinal product or waste material should be disposed of in accordance with local requirements.