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.
- 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. Do not pass it on to others.
- 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.

In this leaflet:

1. WHAT CERVARIX IS AND WHAT IT IS USED FOR

Cervarix is a vaccine intended to protect females 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),
- precancerous cervical lesions (changes in cells of the cervix 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 cancer cases. Other HPV types can also cause cervical cancer. Cervarix does not protect against all HPV types.

When a female is vaccinated with Cervarix, the immune system (the body's natural defence system) will make antibodies against HPV types 16 and 18. In clinical trials Cervarix has been shown to prevent HPV related diseases in women 15-25 years of age. Cervarix also stimulates production of antibodies in females 10-14 years of age.

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. BEFORE YOU RECEIVE CERVARIX

Cervarix should not be given if
the person to be vaccinated:
- is allergic (hypersensitive) to any of the active substances or any of the other ingredients of Cervarix. The active substances and other ingredients of Cervarix are listed at the end of the leaflet (see section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- has 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.

Take special care with Cervarix
You should tell the doctor if the person to be vaccinated:

- has a bleeding problem or bruises easily.
- has any disease which reduces her resistance to infection such as HIV infection

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.

The duration of protection after vaccination is currently unknown. In clinical trials, sustained protection has been observed in females aged 15 to 25 years for up to 6.4 years after the first dose. The need for booster dose(s) has not been investigated.

Using other medicines
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), or with a combined hepatitis A and hepatitis B vaccine (Twinrix) or a hepatitis B vaccine (Engerix B), 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.

Please tell the doctor if the person to be vaccinated is taking or has recently taken any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.

Pregnancy and breast-feeding
There are insufficient data concerning the use of Cervarix during pregnancy. If pregnancy occurs during the course of vaccination your doctor should be consulted. It is recommended to postpone vaccination until after completion of the pregnancy.

Ask your doctor for advice about breast-feeding before receiving Cervarix.

Driving and using machines
There is no information on the effect of Cervarix on your ability to drive or use machinery.

3. HOW CERVARIX IS GIVEN

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

Cervarix is intended for females from 10 years of age onwards. A total of three injections will be administered by your doctor or nurse according to the following schedule:

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 3-dose vaccination course.

The vaccine should never be given into a vein.

If you forget a return visit for Cervarix:
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 of three injections, you may not get the best response and protection from the vaccination.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cervarix 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.

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.

5. HOW TO STORE CERVARIX

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 with or without needles in packs of 1 and 10.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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