

What Gardasil is and what it is used for ?

Gardasil is a vaccine. Vaccination with Gardasil is intended to protect against diseases caused by Human Papilloma virus (HPV) types 6, 11, 16, and 18.

These diseases include pre-cancerous lesions of the female genitals (cervix, vulva, and vagina); pre-cancerous lesions of the anus and genital warts in males and females; cervical and anal cancers. HPV types 16 and 18 are responsible for approximately 70% of cervical cancer cases, 75-80% of anal cancer cases; 70% of HPV-related pre-cancerous lesions of the vulva and vagina, 75% of HPV related precancerous lesions of the anus. HPV types 6 and 11 are responsible for approximately 90% of genital wart cases.

Gardasil is intended to prevent these diseases. The vaccine is not used to treat HPV related diseases. Gardasil does not have any effect in individuals who already have a persistent infection or disease associated with any of the HPV types in the vaccine. However, in individuals who are already infected with one or more of the vaccine HPV types, Gardasil can still protect against diseases associated with the other HPV types in the vaccine.

Gardasil cannot cause the diseases it protects against.

Gardasil produces type-specific antibodies and has been shown in clinical trials to prevent HPV 6, 11, 16, and 18-related diseases in women 16-45 years of age and in men 16-26 years of age. The vaccine also produces type-specific antibodies in 9-15-year-old children and adolescents.



What you need to know before you receive Gardasil Do not receive Gardasil if:

- You or your child is allergic (hypersensitive) to any of the active substances or any of the other ingredients of Gardasil (listed under “other ingredients” – see section 6).
- You or your child developed an allergic reaction after receiving a dose of Gardasil.
- You or your child suffer from an illness with high fever. However, a mild fever or upper respiratory infection (for example cold) itself is not a reason to delay vaccination.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before vaccination if you or your child

- has a bleeding disorder (a disease that makes you bleed more than normal), for example haemophilia.
- has a weakened immune system, for example due to a genetic defect, HIV infection or medicines that affect the immune system.

Fainting, sometimes accompanied by falling, can occur (mostly in adolescents) following any needle injection. Therefore tell the doctor or nurse if you fainted with a previous injection.

As with any vaccine, Gardasil may not fully protect 100% of those who get the vaccine.

Gardasil will not protect against every type of Human Papillomavirus. Therefore appropriate precautions against sexually transmitted disease should continue to be used.

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

Vaccination is not a substitute for routine cervical screening. You should continue to follow your doctor’s advice on cervical smear/Pap tests and preventative and protective measures.

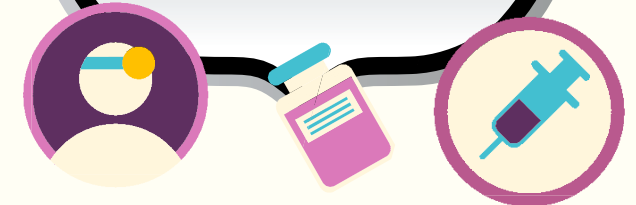
What other important information should you or your child know about Gardasil



The duration of protection is currently unknown. Longer term follow-up studies are on-going to determine whether a booster dose is needed.

IMPORTANT What You Need To Know Before You Receive The HPV Vaccine GARDASIL

**INFORM
PARENT'S
HPV VACCINE
INFORMATION**



**Email: informparents@gmail.com
www: informparents.wordpress.com**

f [informparentsIRL](https://www.facebook.com/informparentsIRL)

Contacts

**Aengus: 087 25 12272
Don: 085 8005400**

POSSIBLE SIDE EFFECTS



Like all vaccines and medicines, Gardasil can cause side effects, although not everybody gets them.

The following side effects can be seen after the use of Gardasil:

Very commonly (more than 1 in 10 patients), side effects found at the injection site include: pain, swelling and redness. Headache was also seen.

Commonly (more than 1 in 100 patients), side effects found at the injection site include: bruising, itching, pain in extremity. Fever and nausea have also been reported.

Rarely (less than 1 in 1000 patients): hives (urticaria). Very rarely (less than 1 in 10,000 patients), difficulty breathing (bronchospasm) has been reported.

When Gardasil was given with a combined diphtheria, tetanus, pertussis [acellular, component] and poliomyelitis [inactivated] booster vaccine during the same visit, there was more headache and injection-site swelling.

Information is as per manufacturers PIL
- revised in: January 2017

<http://www.hpra.ie/docs/default-source/vaccine-pils/gardasil-pil.pdf?sfvrsn=2>

MESSAGE FROM INFORMED PARENTS Vaccination is not compulsory

Parents / Guardians have a right to decide if they wish to vaccinate or if they wish not to vaccinate their daughters. The Patient Information Leaflet (PIL) contains very important information which should be read by all parents / guardians.

What are the possible side effects of GARDASIL?

The most common side effects with GARDASIL are:

- Pain, swelling, itching, bruising, and redness at the injection site
- Headache
- Fever
- Nausea
- Dizziness
- Vomiting
- Fainting

Tell your health care provider if you have any of the following problems because these may be signs of an allergic reaction:

- Difficulty breathing
- Wheezing (bronchospasm)
- Hives
- Rash

Tell your health care provider if you have:

- Swollen glands (neck, armpit, or groin)
- Joint pain
- Unusual tiredness, weakness, or confusion
- Chills
- Generally feeling unwell
- Leg pain
- Shortness of breath
- Chest pain
- Aching muscles
- Muscle weakness
- Seizure
- Skin infection
- Bad stomach ache
- Bleeding or bruising more easily than normal

Contact your health care provider right away if you get any symptoms that concern you, even several months after getting the vaccine.

For a more complete list of side effects, ask your health care provider.

https://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_ppi.pdf

Side effects that have been reported during marketed use include:

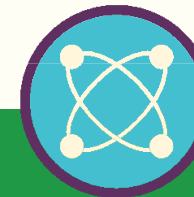
Fainting, sometimes accompanied by shaking or stiffening, has been reported. Although fainting episodes are uncommon, patients should be observed for 15 minutes after they receive HPV vaccine.

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); muscle weakness, abnormal sensations, tingling in the arms, legs and upper body, or confusion (Guillain-Barré Syndrome, Acute disseminated encephalomyelitis); dizziness, vomiting, joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell, bleeding or bruising more easily than normal and skin infection at the injection site.

Reporting of side effects

Talk to your doctor or pharmacist.
You can also report side effects directly to the:
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971 Fax: +353 1 6762517.
Website: www.hpra.ie; e-mail: medsafety@hpra.ie



All information in this leaflet is collated from the PILs