

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

GARDASIL

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Gardasil?

Gardasil is a vaccine. It is a suspension for injection that contains purified L1 proteins for 4 types of the human papillomavirus (types 6, 11, 16 and 18).

What is Gardasil used for?

Gardasil is used to vaccinate against human papillomavirus (HPV) infections caused by types 6, 11, 16 and 18. Gardasil is intended to protect against the high grade dysplasia (pre-cancerous abnormal cell growth) of the cervix or the vulva, cancer of the cervix and genital warts that are caused by these HPV infections.

The effectiveness of Gardasil has been studied in adult women aged 16-26 years of age, and its immunogenicity (its ability to make the immune system respond to the viruses) has been studied in children and adolescents aged 9-15 years of age. Its protective effectiveness has not been studied in males.

Gardasil is given according to official recommendations. The medicine can only be obtained with a prescription.

How is Gardasil used?

Gardasil is given to individuals age 9 or older, as three doses, with 2 months between the first and second dose, and 4 months between the second and third dose. If a different schedule is needed, there should be at least 1 month between the first and the second dose, and at least 3 months between the second and the third, and all doses should be given within one year. The vaccine is given as an intramuscular injection (injection into a muscle), preferably the upper arm or the thigh.

How does Gardasil work?

Papillomaviruses are viruses that cause warts and abnormal tissue growth. There are more than 100 types of papillomaviruses, and some types are associated with genital cancers. HPV types 16 and 18 cause approximately 70% of cervical cancers and HPV types 6 and 11 cause approximately 90% of genital warts.

All papillomaviruses have a shell, or 'capsid', that is made up of proteins (L1 proteins). Gardasil contains the purified L1 proteins for 4 of the types of human papillomaviruses, types 6, 11, 16, and 18. The proteins in Gardasil are produced by a method known as 'recombinant DNA technology'. They are made by a yeast that has received a gene (DNA), which makes it able to produce the L1 proteins. They are assembled in 'virus-like particles' (these are structures that look like the HPV virus, so that

the body easily recognises them).The vaccine also contains an ‘adjuvant’ (a compound containing aluminium) to stimulate a better response.

When a patient is given the vaccine, the immune system (the system that fights diseases) makes antibodies against these proteins. The antibodies help destroy the virus. After vaccination, the immune system is able to produce antibodies quicker when it is again exposed to the viruses. This will help to protect against the diseases caused by these viruses.

How has Gardasil been studied?

The effects of Gardasil were first tested in experimental models before being studied in humans. The four main studies involved more than 20,000 16-26 year-old women. Gardasil was compared to a placebo (dummy vaccine). The studies looked at how many women developed genital warts, genital lesions or abnormal cell growth linked to HPV infections. The women were followed up for 2 to 4 years.

What benefit has Gardasil shown during the studies?

Gardasil was effective against cervical dysplasia and external genital lesions related to HPV types 6, 11, 16 and 18. Looking at the results of all 4 studies together, in women who had never been infected before by HPV types 6, 11, 16 and 18, and who received the full course of vaccination, none of the women vaccinated with Gardasil (8,487 women) developed high grade dysplastic cervical lesions due to HPV 16 or 18, whereas 53 of the 8,460 women who received a placebo vaccine had such lesions. For genital warts due to HPV type 6, 11, 16 or 18, where the results of 3 studies were looked at together, these were seen in 1 woman in the Gardasil-vaccinated group (7,897) and in 91 women in the placebo group (7,899).

What is the risk associated with Gardasil?

In studies, the most common side effects (seen in more than 1 patient in 10) are pyrexia (fever) and reactions at the site of the injection (redness, pain, swelling). For the full list of all side effects reported with Gardasil, see the Package Leaflet.

Gardasil should not be used in people who may be hypersensitive (allergic) to the active substance or any of the other ingredients. If a patient shows signs of an allergy after a dose of Gardasil, they should not receive further doses of the vaccine. Vaccination should be postponed in patients who are ill with a high fever.

Why has Gardasil been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Gardasil’s benefits are greater than its risks as a vaccine to prevent the cervical lesions (CIN 2/3) and cervical cancers, vulvar lesions (VIN 2/3) and external genital warts (condyloma acuminata) caused by HPV types 6, 11, 16 and 18. They recommended that Gardasil be given marketing authorisation.

Other information about Gardasil:

The European Commission granted a marketing authorisation valid throughout the European Union for Gardasil to Sanofi Pasteur MSD SNC on 20 September 2006.

The full EPAR for Gardasil can be found [here](#).

This summary was last updated in 09-2006.