

**B. PACKAGE LEAFLET
(VIAL)**

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gardasil, suspension for injection

Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)

Read all of this leaflet carefully before you or your child are vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child. 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 Gardasil is and what it is used for
2. Before you use Gardasil
3. How to use Gardasil
4. Possible side effects
5. How to store Gardasil
6. Further information

1. 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 Papillomavirus (HPV) types 6, 11, 16, and 18.

These diseases include cervical cancer; pre-cancerous lesions of the female genitals (cervix, vulva and vagina); and genital warts. HPV types 16 and 18 are responsible for approximately 70% of cervical cancer cases and 70% of HPV-related pre-cancerous lesions of the vulva and vagina. 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 females who already have a persistent infection or disease associated with any of the HPV types in the vaccine. However, in females who are already infected with one or more of the vaccine HPV types, Gardasil can still protect against disease 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 these HPV 6-, 11-, 16-, and 18-related diseases in adult women 16-26 years of age. The vaccine also produces antibodies in 9- to 15-year-old children and adolescents. Whether these type-specific antibodies prevent disease in adult males has not been evaluated.

Gardasil should be used in accordance with official guidelines.

2. BEFORE YOU USE GARDASIL

Do not use Gardasil if:

the person to be vaccinated

- is allergic (hypersensitive) to any of the active substances or any of the other ingredients of

Gardasil (listed under “other ingredients”– see section 6).

- has developed an allergic reaction after receiving a dose of Gardasil.
- suffers 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.

Take special care with Gardasil:

You should tell your doctor if the person to be vaccinated:

- 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 or HIV infection

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 I know about Gardasil?

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

Taking other medicines:

Gardasil can be given with a Hepatitis B vaccine or with a combined booster vaccine containing diphtheria (d) and tetanus (T) with either pertussis [acellular, component] (ap) and/or poliomyelitis [inactivated] (IPV) (dTap, dT-IPV, dTap-IPV vaccines) at a separate injection site (another part of your body, e.g. the other arm or leg) during the same visit.

Gardasil may not have an optimal effect if:

- used with medicines that suppress the immune system.

In clinical trials, oral or other contraceptives (e.g. the pill) did not reduce the protection obtained by Gardasil.

Please tell your doctor or pharmacist if the person for whom the vaccine is intended is taking or has recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding:

Consult your doctor if the person to be vaccinated is pregnant, trying to become pregnant or becomes pregnant during the course of vaccination.

Gardasil may be given to women who are breast-feeding or intend to breast-feed.

Driving and using machines:

There is no information to suggest that Gardasil affects your ability to drive or use machinery.

3. HOW TO USE GARDASIL

Gardasil is given as an injection by your doctor. Gardasil is intended for adolescents from 9 through 15 years of age and females 16 years of age onwards. The person to be vaccinated will receive three doses of the vaccine.

First injection: at chosen date
Second injection: ideally 2 months after first injection
Third injection: ideally 6 months after first injection

If an alternate vaccination schedule is necessary, the second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. Please speak to your doctor for more information.

The person to be vaccinated should complete the three-dose vaccination course; otherwise the person to be vaccinated may not be fully protected.

Gardasil will be given as an injection through the skin into the muscle (preferably the muscle of the upper arm or thigh).

The vaccine should not be mixed in the same syringe with any other vaccines and solutions.

If you forget to take Gardasil:

If you miss a scheduled injection, your doctor will decide when to give the missed dose. It is important that you follow the instructions of your doctor or nurse regarding return visits for the follow-up doses. If you forget or are not able to go back to your doctor at the scheduled time, ask your doctor for advice. When Gardasil is given as your first dose, the following two doses to complete the 3-dose vaccination course should also be Gardasil, and not another HPV vaccine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. 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. Fever was also seen.

Commonly (more than 1 in 100 patients), side effects found at the injection site include: bruising, itching, pain in extremity.

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.

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), Guillain-Barré Syndrome (muscle weakness, abnormal sensations, tingling in the arms, legs and upper body), dizziness and headache, nausea and vomiting, joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell, and bleeding or bruising more easily than normal.

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 GARDASIL

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

The vaccine should not be used after the expiry date which is stated on the vial label and the outer carton (after EXP). The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

6. FURTHER INFORMATION

If you have any further questions on Gardasil after reading this leaflet, please ask your doctor or pharmacist.

What Gardasil contains

The active substances are: highly purified non-infectious protein for each of the Human Papillomavirus types (6, 11, 16, and 18).

1 dose (0.5 ml) contains approximately:

Human Papillomavirus ¹ Type 6 L1 protein ^{2,3}	20 micrograms
Human Papillomavirus ¹ Type 11 L1 protein ^{2,3}	40 micrograms
Human Papillomavirus ¹ Type 16 L1 protein ^{2,3}	40 micrograms
Human Papillomavirus ¹ Type 18 L1 protein ^{2,3}	20 micrograms

¹Human Papillomavirus = HPV

²L1 protein in the form of virus like particles produced in yeast cells (*Saccharomyces cerevisiae* CANADE 3C-5 (Strain 1895)) by recombinant DNA technology.

³adsorbed on amorphous aluminium hydroxyphosphate sulphate adjuvant (225 micrograms Al).

The other ingredients in the vaccine suspension are:

Sodium chloride, L-histidine, polysorbate 80, sodium borate and water for injections.

What Gardasil looks like and contents of the pack

1 dose of Gardasil suspension for injection contains 0.5 ml.

Prior to agitation, Gardasil may appear as a clear liquid with a white precipitate. After thorough agitation, it is a white, cloudy liquid.

Gardasil is available in packs of 1, 10 or 20 vials.

Not all pack sizes are marketed.

Marketing Authorisation Holder: Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, F-69007 Lyon, France

Manufacturer: Merck Sharp and Dohme, B.V., Waarderweg, 39, 2031 BN Haarlem, The Netherlands

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien Sanofi Pasteur MSD Tél/Tel: +32.2.726.95.84	Italia Sanofi Pasteur MSD Spa, Tel: +39.06.664.092.11
България, Česká republika, Eesti, France, Κύπρος, Latvija, Lietuva, Magyarország, Malta, Polska, România, Slovenija, Slovenská republika Sanofi Pasteur MSD SNC, Tél: +33.4.37.28.40.00	Luxembourg/Luxemburg Sanofi Pasteur MSD, Tél: +32.2.726.95.84
Danmark Sanofi Pasteur MSD Tlf: +45 23 32 69 29	Nederland Sanofi Pasteur MSD, Tel: +31.23.567.96.00
Deutschland Sanofi Pasteur MSD GmbH, Tel: +49.6224.5940	Norge Sanofi Pasteur MSD, Tlf: +47. 67.50.50.20
España Sanofi Pasteur MSD S.A., Tel: +34.91.371.78.00	Österreich Sanofi Pasteur MSD GmbH, Tel: +43.1.866.70.22.202
Ελλάδα BIANEΞ A.E., Τηλ: +30.210.8009111	Portugal Sanofi Pasteur MSD, SA, Tel: +351 21 470 45 50
Ireland Sanofi Pasteur MSD Ltd, Tel: +3531.468.5600	Suomi/Finland Sanofi Pasteur MSD, Puh/Tel: +358.9.565.88.30
Ísland Sanofi Pasteur MSD, Sími: +32.2.726.95.84	Sverige Sanofi Pasteur MSD, Tel: +46.8.564.888.60

	United Kingdom Sanofi Pasteur MSD Ltd, Tel: +44 1628 785 291
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This leaflet was last approved in:

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 medical or healthcare professionals only:

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration. Discard the product if particulates are present or if it appears discoloured.