

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Gardasil, suspension for injection in a pre-filled syringe** 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 (including cervix, and vulva), and genital warts. HPV types 16 and 18 are responsible for ~70% of cervical cancer cases and HPV types 6, 11, for approximately 90% of genital wart cases.

Gardasil cannot cause the diseases it protects against.

Gardasil produces type-specific antibodies and have in clinical trials been shown 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.

The most benefit from Gardasil is expected before infection with any of the Human Papillomavirus types covered by the vaccine. However, in individuals who are already infected by one or more of the vaccine HPV types, the vaccine will protect against the remaining vaccine related HPV types.

### **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 all types 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 Hepatitis B vaccine at a separate injection site (another part of your body, e.g. the other arm or leg) at 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. 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

The dosing schedule can be more flexible, 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.

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 are 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: bleeding, itching.

Very rarely (less than 1 in 10,000 patients), difficulty breathing (bronchospasm) has been reported.

Rarely (less than 1 in 1000 patients), hives (urticaria).

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 syringe 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 syringe 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 <sup>1</sup> Type 6 L1 protein <sup>2,3</sup>	20 micrograms
Human Papillomavirus <sup>1</sup> Type 11 L1 protein <sup>2,3</sup>	40 micrograms
Human Papillomavirus <sup>1</sup> Type 16 L1 protein <sup>2,3</sup>	40 micrograms
Human Papillomavirus <sup>1</sup> Type 18 L1 protein <sup>2,3</sup>	20 micrograms.

<sup>1</sup>Human Papillomavirus = HPV

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

<sup>3</sup>adsorbed 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 pre-filled syringes with or without a needle guard (safety) device.

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.

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**This leaflet was last approved in:**

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**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 discoloration prior to administration. Discard the product if particulates are present or if it appears discoloured.

*Pre-filled syringe use*

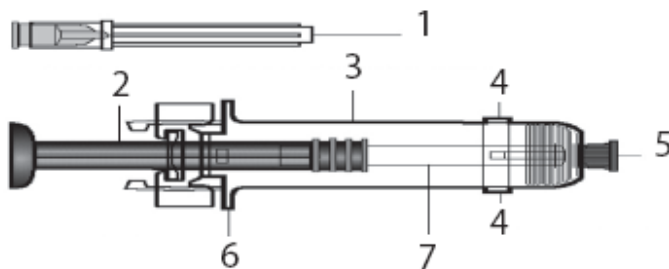
NOTE: Please use one of the enclosed needles for administration. Two detachable labels containing details of the batch number, expiry date and product name are provided.

Disposal

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

Instructions for using the pre-filled single dose syringes pre-assembled with needle guard (safety) device

The needle guard (safety) device is designed to cover the needle after release of the plunger.



1. Luer needle with sheath; 2. Plunger; 3. Needle guard device; 4. Anti-rotation tab; 5. Syringe tip cap; 6. Finger flange; 7. Syringe.

**Attach the needle**

Remove syringe tip cap. Attach Luer needle. Depress both Anti-Rotation Tabs to secure syringe and attach Luer needle by twisting in clockwise direction, until the needle fits securely on the syringe. Remove needle sheath.

If a different needle is chosen to those enclosed, it should fit securely on the syringe and be no longer than 25mm to ensure proper functioning of the needle guard (safety) device.

**Administer the vaccine**

Administer injection per standard protocol as stated above and in section 3 (How to use Gardasil). Depress the plunger while grasping the finger flange until the entire dose has been given. The needle guard (safety) device will NOT activate unless the ENTIRE dose has been given. Remove needle from the vaccine recipient. Release the plunger to allow the syringe to move up until the entire needle is guarded. The labels can only be removed after the needle is guarded.

Instructions for using the pre-filled single dose syringes pre-assembled without needle guard (safety device)

Hold the syringe barrel and attach the needle by twisting in clockwise direction, until the needle fits securely on the syringe.