Package leaflet: Information for the user

Gardasil® 9 suspension for injection in a pre-filled syringe
Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)

Read all of this leaflet carefully before you or your child are vaccinated because it contains important information for you or your child.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Gardasil 9 is and what it is used for

Gardasil 9 is a vaccine for children and adolescents from 9 years of age and adults. It is given to protect against diseases caused by Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58.

These diseases include pre-cancerous lesions and cancers of the female genitals (cervix, vulva, and vagina), pre-cancerous lesions and cancers of the anus and genital warts in males and females.

Gardasil 9 has been studied in males 9 to 26 years of age and females 9 to 45 years of age.

Gardasil 9 protects against the HPV types that cause most cases of these diseases.

Gardasil 9 is intended to prevent these diseases. The vaccine is not used to treat HPV related diseases. Gardasil 9 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 9 can still protect against diseases associated with the other HPV types in the vaccine.

Gardasil 9 cannot cause HPV-related diseases.

When an individual is vaccinated with Gardasil 9, the immune system (the body's natural defence system) stimulates production of antibodies against the nine vaccine HPV types, to help protect against the diseases caused by these viruses.

If you or your child receive a first dose of Gardasil 9, you have to complete the full vaccination course with Gardasil 9.

If you or your child already received an HPV vaccine, ask your doctor if Gardasil 9 is right for you.

Gardasil 9 should be used in accordance with official guidelines.

2. What you need to know before you or your child receive Gardasil 9

Do not receive Gardasil 9 if you or your child

- is allergic to any of the active substances or any of the other ingredients of this vaccine (listed under "other ingredients", in section 6).
- developed an allergic reaction after receiving a dose of Gardasil or Silgard (HPV types 6, 11, 16, and 18) or Gardasil 9.

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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;
- suffer from an illness with high fever. However, a mild fever or upper respiratory infection (for example having a cold) itself is not a reason to delay vaccination.

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

As with any vaccine, Gardasil 9 may not fully protect all of those who get the vaccine.

Gardasil 9 will not protect against every type of Human Papillomavirus. Therefore appropriate precautions against sexually transmitted disease should continue to be used.

Vaccination is not a substitute for routine cervical screening. If you are a woman, **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 9

The duration of protection is not yet known. Longer term follow-up studies are ongoing to determine whether a booster dose is needed.

Other medicines and Gardasil 9

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Gardasil 9 can be given 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, for example the other arm or leg) during the same visit.

Gardasil 9 may not have an optimal effect if used with medicines that suppress the immune system.

Hormonal contraceptives (for example the pill) did not reduce the protection obtained by Gardasil 9.

Pregnancy and breast-feeding

If you are pregnant, think that you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Gardasil 9 may be given to women who are breast-feeding or intend to breast-feed.

Driving and using machines

Gardasil 9 may slightly and temporarily affect the ability to drive or use machines (see section 4 "Possible side effects").

Gardasil 9 contains sodium chloride

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Gardasil 9 is given

Gardasil 9 is given as an injection by your doctor. Gardasil 9 is intended for adolescents and adults from 9 years of age onwards.

If you are from 9 to and including 14 years of age at time of first injection
Gardasil 9 can be administered according to a 2-dose schedule:
- First injection: at chosen date
- Second injection: given between 5 and 13 months after first injection

If the second vaccine dose is administered earlier than 5 months after the first dose, a third dose should always be administered.

Gardasil 9 can be administered according to a 3-dose schedule:
- First injection: at chosen date
- Second injection: 2 months after first injection (not earlier than one month after the first dose)
- Third injection: 6 months after first injection (not earlier than 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.

If you are from 15 years of age at time of first injection
Gardasil 9 should be administered according to a 3-dose schedule:
- First injection: at chosen date
- Second injection: 2 months after first injection (not earlier than one month after the first dose)
- Third injection: 6 months after first injection (not earlier than 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.

It is recommended that individuals who receive a first dose of Gardasil 9 complete the vaccination course with Gardasil 9.

Gardasil 9 will be given as an injection through the skin into the muscle (preferably the muscle of the upper arm or thigh).

If you forget one dose of Gardasil 9

If a scheduled injection is missed, your doctor will decide when to give the missed dose.
It is important that you follow your doctor or nurse's instructions 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 9 is given as your first dose, the completion of the vaccination course should be done with Gardasil 9, and not another HPV vaccine.

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

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

The following side effects can be seen after the use of Gardasil 9:

Very common (may affect more than 1 in 10 people): side effects found at the injection site (pain, swelling, and redness) and headache.

Common (may affect up to 1 in 10 people): side effects found at the injection site (bruising, and itching), fever, tiredness, dizziness and nausea.

Uncommon (may affect up to 1 in 100 people): swollen glands (neck, armpit, or groin), hives (urticaria), fainting sometimes accompanied by shaking or stiffening, vomiting; joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell.

Rare (may affect up to 1 in 1,000 people): allergic reactions.

Unknown (frequency cannot be estimated from the available data): serious allergic reactions (anaphylactic reaction).

When Gardasil 9 was given with a combined diphtheria, tetanus, pertussis [acellular, component] and poliomyelitis [inactivated] booster vaccine during the same visit, there was more injection-site swelling.

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.

The following side effects have been reported with GARDASIL or SILGARD and may also be seen after getting GARDASIL 9:

Allergic reactions have been reported. Some of these reactions have been severe. Symptoms may include difficulty breathing and wheezing.

As with other vaccines, side effects that have been reported during general use include: muscle weakness, abnormal sensations, tingling in the arms, legs and upper body, or confusion (Guillain-Barré syndrome, acute disseminated encephalomyelitis); bleeding or bruising more easily than normal and skin infection at the injection site.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Gardasil 9

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

Do not use this vaccine after the expiry date which is stated on the carton and syringe label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 ºC – 8 ºC). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gardasil 9 contains

The active substances are: highly purified non-infectious protein for each of the Human Papillomavirus types (6, 11, 16, 18, 31, 33, 45, 52, and 58).

1 dose (0.5 ml) contains approximately:

Human Papillomavirus[1] Type 6 L1 protein[2,3]	30 micrograms
Human Papillomavirus[1] Type 11 L1 protein[2,3]	40 micrograms
Human Papillomavirus[1] Type 16 L1 protein[2,3]	60 micrograms
Human Papillomavirus[1] Type 18 L1 protein[2,3]	40 micrograms
Human Papillomavirus[1] Type 31 L1 protein[2,3]	20 micrograms
Human Papillomavirus[1] Type 33 L1 protein[2,3]	20 micrograms
Human Papillomavirus[1] Type 45 L1 protein[2,3]	20 micrograms
Human Papillomavirus[1] Type 52 L1 protein[2,3]	20 micrograms
Human Papillomavirus[1] Type 58 L1 protein[2,3]	20 micrograms

[1]Human Papillomavirus = HPV
[2]L1 protein in the form of virus like particles produced in yeast cells (*Saccharomyces cerevisiae* CANADE 3C-5 (Strain 1895)) by recombinant DNA technology.
[3]adsorbed on amorphous aluminium hydroxyphosphate sulfate adjuvant (0.5 milligrams Al).

Amorphous aluminium hydroxyphosphate sulfate is included in the vaccine as an adjuvant. Adjuvants are included to improve the immune response of vaccines.

The other ingredients in the vaccine suspension are: sodium chloride, histidine, polysorbate 80, borax and water for injections.

What Gardasil 9 looks like and contents of the pack

1 dose of Gardasil 9 suspension for injection contains 0.5 ml.

Prior to agitation, Gardasil 9 may appear as a clear liquid with a white precipitate. After thorough agitation, it is a white, cloudy liquid.

Gardasil 9 is available in packs of 1 or 10 pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London EC2M 6UR, United Kingdom.

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The following information is intended for healthcare professionals only:

Gardasil 9 suspension for injection in a pre-filled syringe:

- Gardasil 9 may appear as a clear liquid with a white precipitate prior to agitation.
- Shake the pre-filled syringe well before use, to make a suspension. After thorough agitation, it is a white, cloudy liquid.
- Inspect the suspension visually for particulate matter and discolouration prior to administration. Discard the vaccine if particulates are present and/or if it appears discoloured.
- Choose an appropriate needle to ensure an intramuscular (IM) administration depending on your patient's size and weight.
- In packs with needles, two needles of different lengths are provided per syringe.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe. Administer the entire dose as per standard protocol.
- Inject immediately using the intramuscular (IM) route, preferably in the deltoid area of the upper arm or in the higher anterolateral area of the thigh.
- The vaccine should be used as supplied. The full recommended dose of the vaccine should be used.

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

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