PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) 1986

This medicine is marketed upon physician's prescription only

GARDASIL® 9
Suspension for Injection

1 dose (0.5 ml) contains:
Protein L1 (HPV type 6)* 30 mcg
Protein L1 (HPV type 11) 40 mcg
Protein L1 (HPV type 16) 60 mcg
Protein L1 (HPV type 18) 40 mcg
Protein L1 (HPV type 31) 20 mcg
Protein L1 (HPV type 33) 20 mcg
Protein L1 (HPV type 45) 20 mcg
Protein L1 (HPV type 52) 20 mcg
Protein L1 (HPV type 58) 20 mcg

For the list of the inactive ingredients see section 6 "FURTHER INFORMATION". See also section 2.6 “Important information about some of the ingredients of the medicine”.
***HPV = Human Papillomavirus**

Read the entire leaflet carefully before you or your child are vaccinated
- This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor, pharmacist or nurse.
- This vaccine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
- The medicine is intended for children, adolescents and adults from 9 through 45 years.

1. WHAT GARDASIL 9 IS AND WHAT IS IT INTENDED FOR?

GARDASIL 9 is a vaccine intended to prevent diseases caused by Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 in children, adolescents and adults from 9 through 45 years of age.

These diseases caused by Human Papillomavirus (HPV) 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 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.

Vaccination with **GARDASIL 9**, causes the immune system (the body’s natural defense system) to produce 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 cannot cause HPV-related diseases.

Therapeutic group: Vaccines, Human Papillomavirus vaccines.

GARDASIL 9 should be used in accordance with official guidelines.

2. BEFORE YOU OR YOUR CHILD RECEIVE GARDASIL 9

2.1 Do not receive GARDASIL 9 if you or your child:

- is sensitive (allergic) to any of the active substances or any of the other ingredients of **GARDASIL 9** (For a list of inactive ingredients see section 6 "FURTHER INFORMATION").
- developed an allergic reaction after receiving a dose of **GARDASIL** (HPV types 6, 11, 16, and 18) or **GARDASIL 9**.

2.2 Special warnings regarding use of GARDASIL 9

Before receiving GARDASIL 9 tell your doctor:

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

2.3 Interactions with other medicines
Tell your doctor or pharmacist if you or your child are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements.

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**.

2.4 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. Information from pregnant women vaccinated with **GARDASIL 9** does not show a higher risk for miscarriages or babies with birth defects.

However, if you are pregnant or if you become pregnant during the course of vaccination, it is recommended to postpone or interrupt vaccination until you are no longer pregnant.

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

2.5 Driving and using machines
GARDASIL 9 may slightly and temporarily affect the ability to drive or use machines (see section 4 “Side effects”).

2.6 Important information about some of the ingredients of the medication
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 should always be used as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.
GARDASIL 9 is given as an injection by a doctor or a nurse. **GARDASIL 9** is intended for children, adolescents and adults from 9 through 45 years of age.

The usual dosage is:
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.

If you are from 15 to 45 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.

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).

Do not exceed the recommended dose.

If you or your child have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you or your child 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 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 medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS
Like all vaccines, this vaccine can cause side effects, in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

The following side effects can occur 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, lump (nodule) at the injection site.

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 and may also be seen after getting GARDASIL 9:

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

As with other vaccines, side effects that have been reported 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.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link:
https://sideeffects.health.gov.il

5. HOW TO STORE GARDASIL 9?

- Avoid Poisoning! This vaccine, and any other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this vaccine after the expiry date (exp. date) which is stated on the carton and vial/syringe label. The expiry date refers to the last day of the indicated month.
- **Storage conditions:**
  - Store in a refrigerator (2ºC - 8ºC)
  - Do not freeze
  - Keep the vial/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 to protect the environment.

6. FURTHER INFORMATION

6.1 What GARDASIL 9 contains

The active substances are: highly purified non-infectious protein for each of the HPV 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).

In addition to the active ingredients the medicine also contains:
Sodium chloride, L-histidine, Amorphous aluminum hydroxy-phosphate sulfate adjuvant, Polysorbate 80 (E433), Sodium borate (E285), Water for injection.

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

6.2 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.

Pack sizes:
1 or 10 pre-filled syringes with 2 needles.
Single dose vial, pack of 1.
Not all pack sizes may be marketed.

License holder and importer:
Merck Sharp & Dohme (Israel-1996) Company Ltd., 34 Ha'charash St., Hod-Hasharon.

Revised in November 2024.

Drug registration no. listed in the official Registry of the Ministry of Health:
157.58.34548

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

Gardasil 9 suspension for injection in a vial presentation:

- Gardasil 9 may appear as a clear liquid with a white precipitate prior to agitation.

- Shake 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.
- Withdraw the 0.5 ml dose of vaccine from the vial using a sterile needle and syringe.
- 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.

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.
- Two needles of different lengths are provided in the pack; choose the appropriate needle to ensure an intramuscular (IM) administration depending on your patient's size and weight.
- 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.