Applicant: MSD (Pty) Ltd
APPROVED PATIENT INFORMATION LEAFLET
GARDASIL 9 INJECTION

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

GARDASIL® 9 Injection

[Human Papillomavirus 9-valent Vaccine, Recombinant]

Read all of this leaflet carefully because it contains important information before you or your child is vaccinated.

GARDASIL 9 is available without a doctor's prescription. Nevertheless you still need to use GARDASIL 9 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GARDASIL 9 with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What GARDASIL 9 is and what it is used for
2. What you need to know before GARDASIL 9 given
3. How GARDASIL 9 is given
4. Possible side effects
5. How to store GARDASIL 9
6. Contents of the pack and other information

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

GARDASIL 9 is a vaccine (injection/shot) that helps protect against some diseases caused by some types of Human Papillomavirus (HPV). GARDASIL 9 contains the same 4 HPV types (6, 11, 16, 18) as in GARDASIL with 5 additional HPV types (31, 33, 45, 52, 58).

In girls and women 9 years of age onward, GARDASIL 9 helps protect against:

- Cervical (the lower end of the uterus or womb), vulvar (the outside of the female genitals), vaginal and anal cancer.
- Pre-cancerous (changes in cells which have a risk of turning into cancer) cervical, vulvar (the outside of the female genitals), vaginal and anal lesions.
- Genital warts.
- HPV persistent infection.

In boys and men 9 years of age onward, GARDASIL 9 helps protect against:

- Anal cancer.
- Pre-cancerous anal lesions.
- Genital warts.
- HPV persistent infection.

These diseases have many causes. Most of the time, these diseases are caused by 9 types of HPV: HPV Types 6, 11, 16, 18, 31, 33, 45, 52 and 58. GARDASIL 9 only protects against diseases caused by these nine types of HPV.

You or your child cannot get HPV or any of the above diseases from GARDASIL 9.

GARDASIL 9 helps prevent, but does not treat these diseases.

Why is vaccination with GARDASIL 9 important?

In the absence of vaccination, it is estimated that the majority of sexually active people will catch Human Papillomavirus during their lifetime. A person of any age who takes part in any kind of sexual activity that involves genital contact is at risk. The only way to fully protect yourself from Human Papillomavirus is to avoid this kind of sexual activity.

Many people who have Human Papillomavirus may not show any signs or symptoms. This means that they can transmit (pass on) the virus to others without knowing it.

2. What you need to know before you are given GARDASIL 9

Who should receive GARDASIL 9?

Persons from 9 years of age onward can receive GARDASIL 9.

GARDASIL 9 works best when given before you or your child (the person getting GARDASIL 9) has any contact with HPV. The person getting GARDASIL 9 can still receive benefit if not previously or currently infected with all the HPV types covered by the vaccine.

Therefore, you should talk with your doctor or healthcare professional to find out if GARDASIL 9 is right for you or your child.

Who should not receive GARDASIL 9?

Anyone who:

- is allergic to any of the ingredients in the vaccine (including any of the ingredients listed under inactive ingredients).
- has an allergic reaction after receiving a previous dose of GARDASIL 9.
- has an allergic reaction after receiving a previous dose of GARDASIL.

What should I tell my doctor or healthcare provider before I or my child is vaccinated with GARDASIL 9?

Your doctor or healthcare provider will decide if you or your child should receive GARDASIL 9.

Warnings and precautions

You should tell your doctor or healthcare provider if you or your child:

- has had an allergic reaction to GARDASIL or GARDASIL 9.
- has a bleeding disorder and cannot receive injections in the arm.
- has any illness with a fever higher than 37,8 °C.
- is pregnant or is planning to get pregnant.
- takes or plans to take any medicines, including over-the-counter medicines.
- has a weakened immune system e.g. due to Human Immunodeficiency Virus (HIV) infection or a genetic defect, or if you take medicines that affect your immune system.

What are cervical cancer, pre-cancerous lesions and genital warts?

Cancer of the cervix is a serious and sometimes life-threatening disease. Nearly 100 % of cervical cancer is caused by HPV. Cervical cancer begins when a female catches certain types of Human Papillomavirus. These HPV types can cause the cells in the lining of the cervix to change from normal to abnormal or pre-cancerous lesions. These lesions are usually detected by a Pap test. If these lesions are not treated, they can turn cancerous. HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 cause approximately 90 % of cervical cancers and 75 to 85 % of advanced cervical pre-cancers. You or your child cannot get cervical cancer without first having a Human Papillomavirus infection. Cervical cancer is a leading cause of cancer among women worldwide.

Genital warts are caused by certain types of Human Papillomavirus. HPV types 6 and 11 cause over 90 % of genital warts. They commonly appear as skin-coloured, irregular growths. They are found on the inside or outside of the genitals in both males and females. They can hurt, itch, bleed and cause discomfort.

Sometimes they can come back after treatment.

What are vulvar and vaginal cancers and pre-cancerous lesions?

Approximately 25 % of vulvar and 70 % of vaginal cancers are caused by HPV. HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 cause 85 to 90 % of HPV-related vulvar cancers, 80 to 85 % of HPV-related vaginal cancers, 90 to 95 % of HPV-related advanced vulvar pre-cancers, and 75 to 85 % of HPV-related advanced vaginal pre-cancers. There are no routine screening tests for these cancers.

What are anal cancer and anal pre-cancerous lesions?

HPV infection is strongly associated with anal cancer and the pre-cancerous anal lesions that precede cancer. The great majority of anal cancers are squamous cell carcinoma (SCC) and 90 % of these cancers are HPV positive. HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 cause 90 to 95 % of HPV-related anal cancers and 85 to 90 % of HPV-related advanced anal pre-cancers. There are no routine screening tests for this cancer in healthy people.

What is Human Papillomavirus?

Human Papillomavirus is a common virus. Of the many different types of Human Papillomavirus, some are harmless, and others can cause diseases of the genital areas. While most people clear the virus, those who do not can develop cervical cancer, pre-cancerous lesions or genital warts.

Will I receive any benefit from GARDASIL 9 if I am already infected with Human Papillomavirus?

GARDASIL 9 helps prevent the diseases caused by some types of papillomavirus but will not treat them. If you are already infected with one type of HPV contained in the vaccine, GARDASIL 9 will help protect you against the other eight types. Talk to your healthcare provider for more information.

Children

GARDASIL 9 can be used in children as young as 9 years of age.

Other medicines and GARDASIL 9

GARDASIL 9 should not be used interchangeably with other Human Papillomavirus (HPV) vaccines (as such use has not been studied).

GARDASIL 9 can be given at the same time as

- Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine]
- Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)]
- Repevax [Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content) (dTap-IPV)]

however GARDASIL 9 should not be mixed in the same syringe with any other vaccines or solutions.

Please inform your doctor or healthcare provider if you or your child are taking or have recently taken any other medicines, even those not prescribed.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Pregnancy, breastfeeding and fertility

Tell the doctor or healthcare professional if you or your child (the person getting GARDASIL 9), is pregnant or is planning to get pregnant.

You should not get GARDASIL 9 during pregnancy. If you plan to get pregnant or get pregnant, you should wait until you are no longer pregnant to complete your vaccine series.

In more than 1 000 pregnancies, women who were pregnant or became pregnant after getting GARDASIL 9 did not have a higher chance for miscarriages or babies with birth defects.

Use in breastfeeding

GARDASIL 9 may be given to women who are breastfeeding or intend to breastfeed.

Driving and using machines

GARDASIL 9 may slightly and temporarily affect the ability to drive or use machines (see **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 administered

GARDASIL 9 is given as an injection usually in the arm muscle.

GARDASIL 9 should be administered as soon as possible after being removed from refrigeration.

You or your child will receive 3 doses of the vaccine. Ideally the doses are given as:

- **First dose:** at a date you and your doctor or healthcare provider choose.
- **Second dose:** 2 months after the first dose.
- **Third dose:** 6 months after the first dose.

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 3 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.

Make sure that you or your child gets all doses. This allows you or your child to get the full benefits of GARDASIL 9. If you or your child misses a dose, your doctor or healthcare provider will decide when to give the missed dose.

What should I do if my child or I miss a dose?

Your doctor or healthcare provider will decide when to give the missed dose.

It is important that you follow the instructions of your doctor or healthcare provider regarding return visits for the follow-up doses.

What other important information about GARDASIL 9 should I know?

GARDASIL 9:

- Does not remove the need for cervical cancer screening; women should still get routine cervical cancer screening.
- Does not protect the person getting GARDASIL 9 from a disease that is caused by other types of HPV, other viruses or bacteria.
- Does not treat HPV infection.
- Does not protect the person getting GARDASIL 9 from HPV types that he/she may already have; but most people do not have all types contained in the vaccine.

GARDASIL 9 may not fully protect each person who gets it.

If you have any further questions on the use of GARDASIL 9, ask your doctor or pharmacist

4. Possible side effects

GARDASIL 9 can have side effects.

Any medicine may have unintended or undesirable effects, so-called side effects.

The most frequent side effects seen with GARDASIL 9 are:

- pain, swelling, redness, itching and bruising, where you got the shot
- headache
- fever
- nausea
- dizziness
- fatigue.

Studies show that there was more swelling where the shot was given when GARDASIL 9 was given at the same time as Repevax or Menactra and/or Adacel.

Tell the doctor or healthcare professional if you have any of these problems because these may be signs of an allergic reaction:

- difficulty breathing
- wheezing (bronchospasm)
- hives
- rash.

As with other vaccines, additional side effects that have been reported during general use for GARDASIL 9 are shown below. Side effects reported during the general use of GARDASIL are also shown below. GARDASIL side effects are reported as they may be relevant to GARDASIL 9 since the vaccines are similar in composition.

GARDASIL 9

- fainting sometimes accompanied with seizure-like movements
- vomiting
- lump where you got the shot.

Additionally, the following side effects have been seen with the general use of GARDASIL.

GARDASIL

- skin infection
- bleeding or bruising more easily than normal
- swollen glands (neck, armpit or groin)
- Guillain-Barré syndrome (muscle weakness, abnormal sensations, tingling in the arms, legs and upper body)
- confusion
- joint pain
- aching muscles
- unusual tiredness, weakness
- chills
- generally feeling unwell.

Fainting can happen after getting a HPV vaccine. Sometimes people who faint can fall and hurt themselves. For this reason, your doctor or healthcare professional may ask the person getting GARDASIL 9 to sit or lie down for 15 minutes after getting the vaccine. Some people who faint might shake or become stiff. The doctor or healthcare professional may need to treat the person getting GARDASIL 9.

Other side effects may also occur rarely, and as with any vaccine, some side effects may be serious.

If you or your child has any unusual or severe symptoms after receiving GARDASIL 9, contact your doctor or healthcare provider right away.

Your doctor or healthcare provider has a more complete list of side effects for GARDASIL 9.

Not all side effects reported for GARDASIL 9 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using GARDASIL 9, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GARDASIL 9.

5. How to store GARDASIL 9

Store all medicines out of reach of children.

Store refrigerated at 2 to 8 °C. Protect from light. Do not remove from carton until required for use. GARDASIL 9 remains stable for up to 72 hours at 25 °C.

DO NOT FREEZE. DISCARD IF THE VACCINE HAS BEEN FROZEN.

Do not use GARDASIL 9 after the month and year following EXP.: on the container.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Discard the empty vial or syringe in approved biological waste containers according to local regulations.

6. Contents of the pack and other information

What GARDASIL 9 contains

30 µg of HPV Type 6 L1 protein, 40 µg of HPV Type 11 L1 protein, 60 µg of HPV Type 16 L1 protein, 40 µg of HPV Type 18 L1 protein, 20 µg of HPV Type 31 L1 protein, 20 µg of HPV Type 33 L1 protein, 20 µg of HPV Type 45 L1 protein, 20 µg of HPV Type 52 L1 protein and 20 µg of HPV Type 58 L1 protein as active ingredients.

In addition, GARDASIL 9 contains the following inactive ingredients: Each 0,5 mL dose of the vaccine contains approximately 500 µg of aluminium (provided as AAHS), 9,56 mg of sodium chloride, 0,78 mg of L-histidine, 50 µg of polysorbate 80, 35 µg of sodium borate and water for injection. The product does not contain a preservative or antibiotics.

What GARDASIL 9 looks like and contents of the pack

GARDASIL 9 is an aqueous suspension that appears as a white cloudy liquid.

Syringe

1,5 mL Type 1 glass syringe with a grey plunger stopper (rubber) and brown syringe plunger rod.

Vial

3 mL clear Type 1 borosilicate glass vial with a grey stopper (rubber) and a brown plastic flip-off cap.

Carton

1,5 mL syringe or 3 mL vial are packed together in a cardboard carton with the professional information and patient information leaflet.

Pack sizes of 1 or 10 syringes or vials.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in August 2025

Registration number

51/30.1/0264