GARDASIL®9
Human Papillomavirus 9-valent Vaccine
(Recombinant, adsorbed)

MSD

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Full Prescribing Information and Adverse Events information available on page 4.


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Start an Impactful Conversation With Patients About HPV Vaccination

GARDASIL®9 Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)
GARDASIL®9 is indicated for active immunisation of individuals from the age of 9 years against the following HPV diseases: premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types and genital warts *(Condyloma acuminata)* caused by specific HPV types.[1]

WHY does prevention of HPV-related cancers and diseases matter?

Human papillomavirus (HPV) is a common sexually transmitted virus that may lead to infections associated with certain cancers and other diseases, including cervical, anal, vaginal, vulvar cancer, and genital warts.[2]

About 8 in 10 sexually active men and women will be infected with one or more sexually transmitted HPV types at some time in their lives.[3]

Most HPV infections are spontaneously cleared on their own.

However, persistent HPV infections with a high-risk HPV type can lead to HPV-related cancers and diseases.[4]

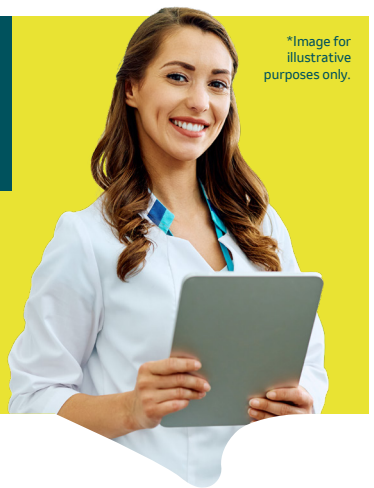
HPV-related cancers and diseases include **cervical, vulvar,** and **vaginal cancer** in women, and **anal cancer** and **genital warts** in both men and women.[1,a]

Who is the HPV vaccine for?

- **GARDASIL®9 may offer protection against HPV related cancers and diseases to unvaccinated adults.** There is no upper age limit for vaccination.[1]
- Many adult males and females continue to be at risk of acquiring new HPV infections throughout their lifetime.[5]

*GARDASIL®9 is the vaccine available to all children 12-13 years of age as part of the National HPV vaccination programme.

A recommendation from a healthcare provider may affirm patients' perceptions of the value of vaccination[6]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The decision to receive the HPV vaccine is strongly governed by the decisions of policy makers, healthcare professionals, and parents.[7]

Most HPV infections are spontaneously cleared on their own. However, persistent HPV infections with a high-risk HPV type can lead to HPV-related cancers and diseases.[4]

FREQUENTLY ASKED QUESTIONS

Have these answers ready for common queries from patients.

Why should I get the HPV vaccine?

HPV vaccination can help protect against certain HPV-related diseases. GARDASIL®9 is indicated for active immunisation against premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types, and genital warts *(Condyloma acuminata)* caused by specific HPV types.[1,3]

Can I get GARDASIL®9 if I've already had HPV?

Even if you've already had an HPV infection, you can still receive HPV vaccination. **If you're already infected with one type of HPV contained in the vaccine, GARDASIL®9 will help protect you against the other 8 types.** However, the vaccine cannot treat an existing HPV infection.[1,5,8]

Note: The vaccine is for prophylactic use only and has no effect on active HPV infections or established clinical disease. The vaccine has not been shown to have a therapeutic effect.

Can men benefit from HPV vaccination?

Yes, as **persistent HPV infection may lead to anal cancer and genital warts in men.**[7,5]

Is GARDASIL®9 covered by insurance or can I claim as a health expense in my tax return?

You may have private health insurance that partly covers vaccination with GARDASIL®9. Speak to your insurance company directly. **You can also claim tax back for the HPV vaccine by submitting your medical receipts through the Revenue's myAccount online service or by completing a paper Form 12.**

Source: www.revenue.ie

Is it too late to get vaccinated if I'm already sexually active?

It may not be too late to help protect yourself against HPV. **And if you're already infected with one type of the virus, it might not be too late to help protect yourself against other types of HPV you haven't been exposed to.**[8]

If I am a female and get vaccinated with GARDASIL®9, do I still need to get regular screenings?

Yes, even if you are vaccinated with GARDASIL®9, it is still important to continue with regular cervical screenings. The GARDASIL®9 vaccine may help protect against the most common types of HPV that cause cervical cancer, but it does not protect against all types of HPV or other factors that may lead to cervical cancer.[1]

Why should I get vaccinated if I only have one sexual partner?

You may be at risk of HPV infection regardless of sex, gender identity, sexual orientation or lifetime sexual partners.[5] HPV infections are common. Without vaccination, the majority of sexually active people will catch HPV during their lifetime.[5,9] Many people who have HPV may not show any signs or symptoms.[5] This means that they can transmit (pass on) the virus to others without knowing it.[5,9] Partner in a sexual relationship may carry the infection for many years without knowing it because there are often no visible symptoms.[5,9]

I've had a change in relationship status, how can GARDASIL®9 help me?

A change in sexual behaviour or sexual partners is a risk factor for HPV.[5]

Note: The vaccine is for prophylactic use only and has no effect on active HPV infections or established clinical disease. The vaccine has not been shown to have a therapeutic effect.

Most HPV infections are spontaneously cleared on their own. However, persistent HPV infections with a high-risk HPV type can lead to HPV-related cancers and diseases.[4]

RECOMMENDED SCHEDULE FOR GARDASIL®9[1]

Individuals 15 years of age and older at time of first injection:

15 & UP

3-dose schedule:***

1st dose	2nd dose	3rd dose
AT ELECTED DATE	THE SECOND DOSE SHOULD BE ADMINISTERED **AT LEAST ONE MONTH AFTER THE FIRST DOSE**	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 refer to the full Summary of Product Characteristics (SPC) for complete dosing information.[1]

GARDASIL®9 helps protect against 9 HPV types that may lead to approximately:

- **90%** of cervical cancers[1]
- **80-85%** of HPV-related vaginal cancers[1]
- **90-95%** of anal cancer[1]
- **85-90%** of HPV-related vulvar cancers[1]
- **90%** of genital warts[1]

Most HPV infections are spontaneously cleared on their own. However, persistent HPV infections with a high-risk HPV type can lead to HPV-related cancers and diseases.[4]

For Healthcare Professionals Only.

*Image for illustrative purposes only.

Scan here to learn more about HPV vaccination.

Scan here to access the Summary of Product Characteristics (SPC) for Ireland.

If you require MSD medical information, please contact: info@msd.ie or 01-299 8700

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-299 8700)

HPV = human papillomavirus
[a] Not all cervical, vulvar, vaginal, and anal cancers are caused by HPV.[11]

Prescribing Information

GARDASIL®9 (Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)).

ABRIDGED PRODUCT INFORMATION Refer to Summary of Product Characteristics before prescribing. **PRESENTATION** GARDASIL®9 is supplied as a single dose pre-filled syringe containing 0.5 millilitre of suspension. Each dose of vaccine contains highly purified virus-like particles (VLPs) of the major capsid L1 protein of Human Papillomavirus (HPV). These are type 6 (30 µg), type 11 (40 µg), type 16 (60 µg), type 18 (40 µg), type 31 (20 µg), type 33 (20 µg), type 45 (20 µg), type 52 (20 µg) and type 58 (20 µg). **INDICATIONS** GARDASIL®9 is a vaccine for use from the age of 9 years for the prevention of premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV-types and genital warts (condyloma acuminata) caused by specific HPV types. The use of GARDASIL®9 should be in accordance with official recommendations. **DOSAGE AND ADMINISTRATION** Individuals 9 to and including 14 years of age at time of first injection: GARDASIL®9 can be administered according to a 2-dose schedule. The second dose should be administered between 5 and 13 months after the first dose. 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 (0, 2, 6 months) schedule. 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. Individuals 15 years of age and older at time of first injection:GARDASIL®9 should be administered according to a 3-dose (0, 2, 6 months) schedule. 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. It is recommended that individuals who receive a first dose of GARDASIL®9 complete the vaccination course with GARDASIL®9. The need for a booster dose has not been established. Studies using a mixed regimen (interchangeability) of HPV vaccines were not performed forGARDASIL®9 . Subjects previously vaccinated with a 3 doses regimen of quadrivalent HPV types 6, 11, 16, and 18 vaccine (Gardasil or Silgard), hereafter referred to as qHPV vaccine, may receive 3 doses of GARDASIL®9 . The use of GARDASIL®9 should be in accordance with official recommendations. Paediatric population (children <9 years of age): The safety and efficacy ofGARDASIL®9 in children below 9 years of age have not been established. No data are available. The vaccine should be administered by intramuscular injection. The preferred site is the deltoid area of the upper arm or in the higher anterolateral area of the thigh. GARDASIL®9 must not be injected intravascularly, subcutaneously or intradermally. The vaccine should not be mixed in the same syringe with any other vaccines and solution. **CONTRAINDICATIONS** Hypersensitivity to any component of the vaccine including active substances and/or excipients. Individuals with hypersensitivity after previous administration of GARDASIL®9 or Gardasil /Silgard should not receive GARDASIL®9. **PRECAUTIONS AND WARNINGS** In order to improve traceability of biological medicinal products, the name and batch number of the administered product should be clearly recorded. The decision to vaccinate an individual should take into account the risk for previous HPV exposure and potential benefit from vaccination. As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. The vaccine should be given with caution to individuals with thrombocytopaenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. Syncope, sometimes associated with falling, can occur before or after vaccination with GARDASIL®9 as a psychogenic response to the needle injection. Vaccinees should be observed for approximately 15 minutes after vaccination; procedures should be in place to avoid injury from faints. Vaccination should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as a mild upper respiratory tract infection or low-grade fever, is not a contraindication for immunisation. As with any vaccine, vaccination with GARDASIL®9 may not result in protection in all vaccine recipients. GARDASIL®9 will only protect against diseases that are caused by HPV types targeted by the vaccine. The vaccine is for prophylactic use only and has no effect on active HPV infections or established clinical disease. The vaccine has not been shown to have a therapeutic effect and is not indicated for treatment of cervical, vulvar, vaginal and anal cancer, high-grade cervical, vulvar, vaginal and anal dysplastic lesions or genital warts. It is also not intended to prevent progression of other established HPV-related lesions. GARDASIL®9 does not prevent lesions due to a vaccine HPV type in individuals infected with that HPV type at the time of vaccination. Vaccination is not a substitute for routine cervical screening. There are no data on the use of GARDASIL®9 in individuals with impaired immune responsiveness. Safety and immunogenicity of a qHPV vaccine have been assessed in individuals aged from 7 to 12 years who are known to be infected with human immunodeficiency virus (HIV). Individuals with impaired immune responsiveness, due to either the use of potent immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may not respond to GARDASIL®9. Long-term follow-up studies are currently ongoing to determine the duration of protection. There are no safety, immunogenicity or efficacy data to support interchangeability of GARDASIL®9 with bivalent or quadrivalent HPV vaccines. **FERTILITY, PREGNANCY AND LACTATION** There are insufficient data to recommend use of GARDASIL®9 during pregnancy; therefore, vaccination should be postponed until after completion of pregnancy. The vaccine can be given to breastfeeding women. No human data on the effect of GARDASIL®9 on fertility are available. **SIDE EFFECTS** Very common side effects include: erythema, pain and swelling at the injection site and headache. Common side effects include: pruritus and bruising at the injection site, dizziness, nausea, pyrexia and fatigue. The post-marketing safety experience with qHPV vaccine is relevant to GARDASIL®9 since the vaccines contain L1 HPV proteins of 4 of the same HPV types. The following adverse experiences have been spontaneously reported during post-approval use of qHPV vaccine: urticaria, bronchospasm, idiopathic thrombocytopenic purpura, acute disseminated encephalomyelitis, Guillain-Barré Syndrome and hypersensitivity reactions, including anaphylactic/anaphylactoid reactions. For a complete list of undesirable effects please refer to the Summary of Product Characteristics. **PACKAGE QUANTITIES** Single pack containing one 0.5 millilitre dose pre-filled syringe with two separate needles. **Legal category:** POM **Marketing authorisation number:** EU/1/15/1007/002 (pre-filled syringe with two separate needles). **Marketing Authorisation holder:** Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands. Date of revision: March 2023. © 2023 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 D18 X5K7 or from www.medicines.ie. PSUR PSUSA/00010389/202206

Before prescribing, please read the Summary of Product Characteristics available on www.medicines.ie.

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