This is a photo of a fictional healthcare professional and is for illustrative purposes only.

Prescribing information and adverse event reporting can be found at the end of this document.

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

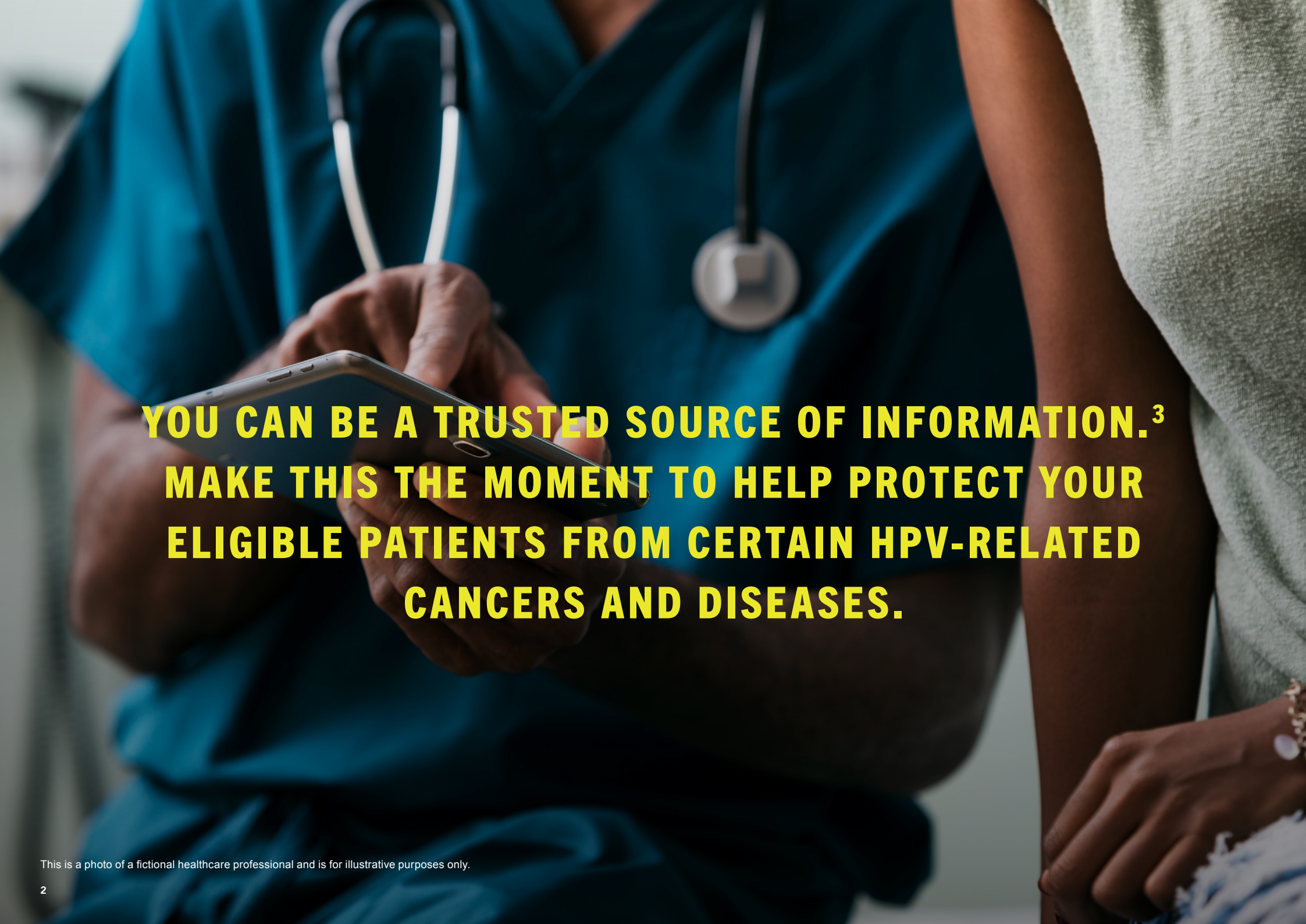
YOUR TRUSTED RECOMMENDATION IS KEY TO VACCINE CONFIDENCE.[2*]

*This information was derived from studies conducted in high-income countries.

MSD

IE-GSL-00205 I October 2025

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



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CONTENTS

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HPV VACCINATION FOR ADULTS

Recommending HPV vaccination today can help protect your eligible adult patients against certain HPV-related cancers and diseases, and **it can all start with your recommendation.**[4-6]

WHY

YOUR RECOMMENDATION MATTERS FOR ADULT PATIENTS

This is a photo of a fictional patient and healthcare professional and is for illustrative purposes only.

THE ROLE OF HEALTHCARE PROFESSIONALS IS CONSIDERED PARAMOUNT IN MAINTAINING AND IMPROVING HPV VACCINE UPTAKE.[7]

It has been estimated that UP TO 8 IN 10 sexually active people will get HPV at some point in their lives.[5] HPV is usually transmitted through sexual contact.

For most people, HPV clears on its own. But for those who don't clear the virus, it can cause certain cancers and diseases.[8]

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Human Papillomavirus 9-valent Vaccine
(Recombinant, adsorbed)

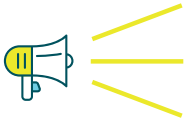
WHAT

A RECOMMENDATION PROCESS COULD **LOOK LIKE THIS**

1 IDENTIFY ELIGIBLE PATIENTS:

Talk to your adult patients who might be appropriate based on their immunisation history. Start the conversation during a visit.

I SEE THAT YOU HAVEN'T RECEIVED YOUR HPV VACCINATION.[1]



2 MAKE A CLEAR RECOMMENDATION:

I RECOMMEND HPV VACCINATION FOR YOU.[1]

3 IF THEY HAVE QUESTIONS, EDUCATE FURTHER:

HPV MAY BE MORE COMMON THAN YOU THINK.[5] HPV VACCINATION CAN HELP PROTECT YOU AGAINST CERTAIN HPV-RELATED CANCERS AND DISEASES.[1]

For most people, HPV clears on its own. But for those who don't clear the virus, it can cause certain cancers and diseases.[8]

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Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)

HOW TO ADDRESS POTENTIAL QUESTIONS

HOW IS THIS VACCINE STILL VALUABLE FOR ADULTS?

Men and women can be infected with HPV at any point in their lives while sexually active.[9]

40 – 60%

Models consistently estimate that 40 – 60% of HPV disease-causal infection occurred after the age of 25.[10-12]

- Based on three registry-informed models (US, Canada, England)
- Varies by screening practices and modelling assumptions

HPV vaccination can help protect you from certain HPV-related cancers and diseases caused by types to which you have not already been exposed.[1,5]

WHY DO WOMEN NEED HPV VACCINATION?

HPV can cause certain HPV-related cancers, including cervical, vaginal, vulvar, and anal cancers, as well as genital warts.[6]

WHY DO MEN NEED HPV VACCINATION?

There are no HPV-screening programs for men, and usually no symptoms of the virus, so HPV infection can remain undetected in men. **HPV can lead to certain HPV-related anal cancer and genital warts.[8]**

For most people, HPV clears on its own. But for those who don't clear the virus, it can cause certain cancers and diseases.[8]

GARDASIL®9
Human Papillomavirus 9-valent Vaccine
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HOW TO ADDRESS POTENTIAL QUESTIONS

WITH EFFECTIVE RESPONSES

CAN I GET GARDASIL®9 (HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE [RECOMBINANT, ADSORBED]) IF I'VE ALREADY HAD HPV?

Yes. Most people will contract at least one HPV type at some point in their lifetime through intimate skin-to-skin contact with someone who has HPV.[5] **GARDASIL®9 can still help protect men and women against certain HPV-related cancers and diseases caused by HPV** types to which they haven't been previously exposed.[5]

ISN'T THIS VACCINE ONLY FOR ADOLESCENTS?

GARDASIL®9 is indicated for adolescents and adults, male or female, from ages 9 and up.[1] **You can help prevent certain HPV-related cancers and diseases with HPV vaccination.[1]**

WHY SHOULD I GET HPV VACCINATION IF I'M IN A RELATIONSHIP?

HPV usually has no signs or symptoms, so you or your partner could have the virus and not know it, and pass it on through intimate skin-to-skin contact. GARDASIL®9 can help protect you from certain cancers and diseases caused by HPV.[1,5]

For most people, HPV clears on its own. But for those who don't clear the virus, it can cause certain cancers and diseases.[8]

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CONSIDER

RECOMMENDATION OF HPV VACCINATION TO YOUR ELIGIBLE ADULT PATIENTS[1]

This is a photo of a fictional patient and is for illustrative purposes only.

WHEN YOUR PATIENTS SAY YES TO VACCINATION:

Start the vaccination series, or provide a referral to a local pharmacy or clinic that carries the vaccine.[1]

Schedule a follow-up appointment for the next dose.[1]

IF YOUR PATIENTS SAY NO TO VACCINATION:

- Understand your patients' reasons for declining vaccination today.
- Make a note on your patients' chart so it's recorded for their next visit. If possible, **set a reminder to discuss HPV vaccination.**[1]
- Provide your patients with credible, **patient-friendly information they can take with them**, so they can **feel empowered** to make a decision on their own time.

GARDASIL®9
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SAFETY PROFILE OF GARDASIL®9

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Very common and common adverse reactions to GARDASIL®9 were:

- Very common (≥10%):
  Injection-site pain, swelling, erythema, and headache[1]
- Common (≥1% to <10%):
  Dizziness, nausea, pyrexia, fatigue, and injection-site pruritus and bruising[1]
- Disclaimer: Not all adverse reactions are listed here.

GARDASIL®9 is contraindicated in individuals with **hypersensitivity to the active substances or to any of the excipients.**[1]

Individuals with hypersensitivity after previous administration of GARDASIL®9 or GARDASIL/SILGARD® **should not receive GARDASIL®9.**[1]

For the full list of adverse reactions, please refer to the local prescribing information or full Summary of Product Characteristics (SmPC).

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

REFERENCES

1. GARDASIL®9 Ireland Summary of Product Characteristics (SmPC).
2. Ipsos. 2022. Nine in 10 people believe vaccines are effective, according to Ipsos survey for IPHA. Irish Pharmaceutical Healthcare Association (IPHA). Accessed July 2025. https://www.ipha.ie/nine-in-10-people-believe-vaccines-are-effective-according-to-ipsos-survey-for-ipha/
3. Ipsos Veracity Index 2024. Accessed July 2025. https://www.ipsos.com/sites/default/files/ct/news/documents/2024-09/Ipsos%20BandA%20%20Veracity%20Index%202024.pdf
4. Arevalo M, Brownstein NC, Whiting J, et al. Factors related to human papillomavirus vaccine uptake and intentions among adults aged 18–26 and 27–45 years in the United States: A cross-sectional study. *Cancer.* 2023;129(8):1237-1252. doi:https://doi.org/10.1002/cncr.34680
5. Questions and answers about human papillomavirus (HPV). World Health Organization. Published 2024. Accessed July 2025. https://iris.who.int/bitstream/handle/10665/376263/WHO-EURO-2024-5631-49185-73415-eng.pdf?sequence=1
6. World Health Organization (WHO). Human papillomavirus vaccines: WHO position paper (2022 update). *Wkly Epidemiol Rec.* 2022;97(50):645-672
7. Sackey ME, Markey K, Grealish A. Strategies used by healthcare professionals to increase the human papillomavirus vaccine uptake among adolescents in Ireland: A qualitative study. *Int J Nurs Stud.* 2025;167:105080. doi:10.1016/j.ijnurstu.2025.105080
8. HSE. About HPV. Accessed July 2025. https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/hpv/hpv-human-papillomavirus/
9. Human Papillomavirus (HPV) Vaccine - PAHO. WHO I Pan American Health Organization. Accessed March 13, 2024. https://www.paho.org/en/human-papillomavirus-hpv-vaccine
10. Cherif A, You X, Hillhouse E, et al. Estimating the Age of Disease-causal HPV Infection Based on the Natural History of CIN2+ Among Females in Canada. Open Forum Infect Dis. 2025;12(4):ofaf168. Published 2025 Mar 17. doi:10.1093/ofid/ofaf168
11. Kayla E, et al., Estimating the Age of Acquisition of Disease-causing HPV Infection for CIN2+ in England. IPVC 2024. Poster.
12. Prabhu VS, Roberts CS, Kothari S, Niccolai L. Median Age at HPV Infection Among Women in the United States: A Model-Based Analysis Informed by Real-world Data. Open Forum Infect Dis. 2021;8(7):ofab111. Published 2021 Mar 12. doi:10.1093/ofid/ofab111

Please consult the full prescribing information before prescribing or delivering the product.
HPV = human papillomavirus.

PRESCRIBING INFORMATION FOR GARDASIL®9

SELECT SAFETY 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 mg), type 11 (40 mg), type 16 (60 mg), type 18 (40 mg), type 31 (20 mg), type 33 (20 mg), type 45 (20 mg), type 52 (20 mg) and type 58 (20 mg). **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 indication is based on the demonstration of efficacy of Gardasil 9 in males and females 16 to 26 years of age and on the demonstration of immunogenicity of Gardasil 9 in children and adolescents aged 9 to 15 years. 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 for Gardasil 9. Subjects previously vaccinated with a 3dose 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 of Gardasil 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. 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

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: 01-2998700)

Registered Office: Red Oak North, South County Business Park, Leopardstown, Dublin D18 X5K7 Ireland. IE-GSL-00205 I October 2025
For Healthcare Professionals Only.

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