

[Prescribing information for Gardasil-9® \(Human Papillomavirus 9-valent Vaccine \(Recombinant, adsorbed\)\)](#)

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HPV VACCINATION: WHAT DO I NEED TO KNOW?

A Nurse Immuniser's Guide



GARDASIL® 9
Human Papillomavirus
9-valent Vaccine, Recombinant



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:¹

- Premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types
- Genital warts (*Condyloma acuminata*) caused by specific HPV types

Please refer to the Summary of Product Characteristics for further information prior to making any prescribing decisions.¹

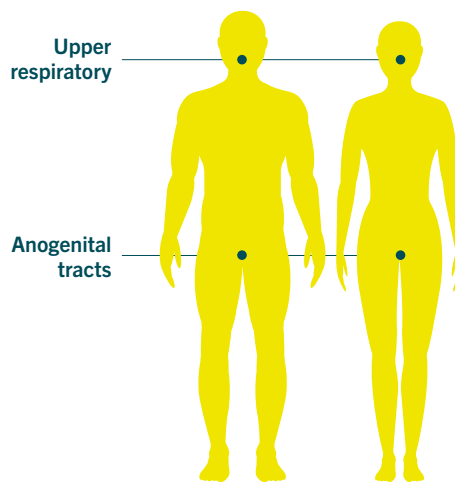
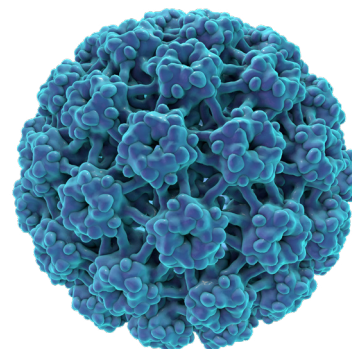
Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Merck Sharp & Dohme Limited (Tel: 0208 154 8000). By clicking the above link, you will leave the MSD website and be taken to the MHRA website.

WHAT IS HPV?

Human papillomavirus (HPV) is a double-stranded DNA virus that infects the skin and mucosae of the upper respiratory and anogenital tracts. Genital HPVs are transmitted by sexual contact with an infected individual and it affects both men and women.²

There are around 100 types of HPV, of which approximately 40 infect the genital tract. HPV viruses are classified as either 'high-risk' or 'low-risk' types, depending on their association with the development of HPV-related cancers. Infections can be composed of multiple different types of HPV simultaneously.²

For most people, HPV clears on its own, with 90% of HPV infections clearing within 2 years and 70% clearing within one year. But for those who don't clear the virus, it can cause certain HPV-related cancers and diseases.²



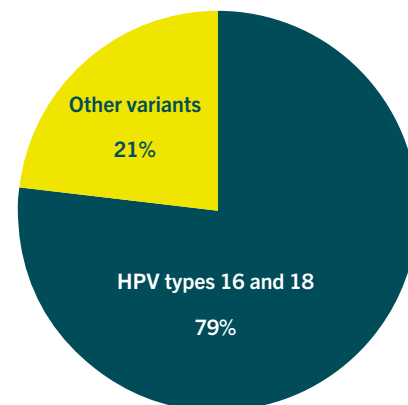
WHY TARGET HPV?

HPV is recognised as a cause of cervical cancer.

Persistent infection by high-risk HPV types is detectable in more than 99% of cervical cancers.²

Of these high-risk types, HPV16 is responsible for almost 60% and HPV18 for more than 15%, of all cervical cancers in Europe.³ Persistence and disease is more common for infections with HPV types 16 and 18 than other high-risk types.²

High-risk HPV types associated with invasive cervical cancer in the UK³



Persistent infection by a high-risk HPV type is an important causal factor for the development of cervical pre-cancerous and cancerous lesions²

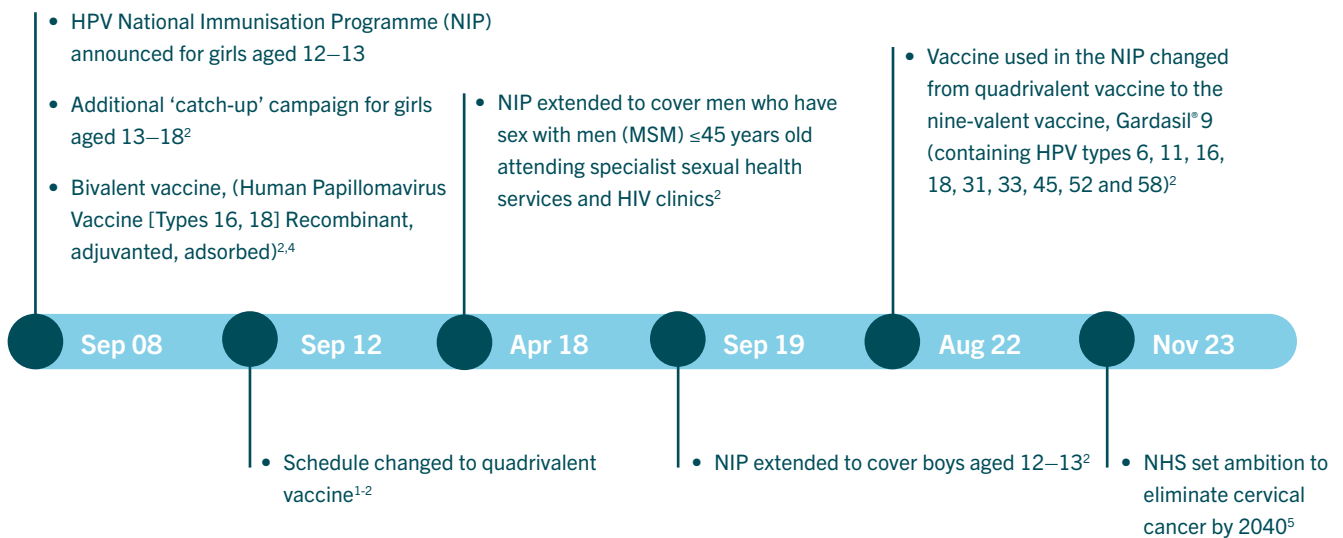
In addition to cervical cancer, HPV is causally associated with less common cancers at other sites, including cancer of the vulva, vagina, penis and anus, and some cancers of the head and neck. HPV poses risks to both men and women.²

Low-risk HPV types are responsible for genital warts, which is the most commonly diagnosed viral sexually transmitted infection in the UK.² In the absence of treatment, up to 30% of individuals clear the infection in the short term. Long-term rates of spontaneous regression are not known.²

~90%

HPV types 6 and 11 cause ~90% of all genital warts.²

THE HISTORY OF HPV VACCINATION²



The objective is to vaccinate boys and girls before they reach an age when the risk of HPV infection increases and puts them at subsequent risk of cervical and certain other HPV-related cancers.²

The long term ambition set by the NHS aims to eliminate cervical cancer by 2040. This could save thousands of lives in England.⁵

Make sure you know the arrangements for HPV vaccination in your local area.

IMPACT OF HPV VACCINATION IN THE UK

More than a decade after its introduction, there have been **reductions** in HPV type 16/18 infection, genital warts, pre-cancerous lesions and cervical cancer.²

In 2021, an observational study estimated that cervical cancer rates have been reduced by almost 90% in women in their 20s who were offered the vaccine at age 12 to 13 years in England, when compared to an unvaccinated population.⁶

This observational study used modelling data from a total of 13.7 million years of follow up of women aged 20 to younger than 30 years old, across three different cohorts.⁶

In 2023, the rate of first episode genital warts diagnoses among young women aged 15 to 17 years was 49.7% lower than the rate in this age group in 2019, (7.6 versus 15.1 per 100,000 population in 2023 versus 2019 respectively). A decline of 68.4% (2.9 versus 9.3 per 100,000 population) was seen in heterosexual young men of the same age over the same period. Declines were also seen in both men and women aged 18 to 20 years and 21 to 24 years.⁷

To strive for the future elimination of certain vaccine-preventable HPV-related cancers and diseases, starting with cervical cancer, there needs to be prioritisation of vaccination, screening and treatment⁸.

The decision to vaccinate an individual should take into account the risk for previous HPV exposure and potential benefit from vaccination. For more information on the safety profile and vaccine effectiveness of Gardasil® 9, please [click here](#) to be taken to the UK SmPC.

As with any vaccines and medicines, HPV vaccinations may cause side effects which affect people differently. Some people don't have any side effects after their HPV vaccine.⁹

Very common side effects include redness, swelling or pain at the site of injection and headaches.⁹

Common side effects include bruising or itching at the site of the injection, a high temperature or feeling hot and shivery, feeling sick (nausea) or pain in the arms, hands, fingers, legs, feet or toes.⁹

IMPROVING UPTAKE

In the early years of delivering HPV vaccination (2008–2013/14), national uptake in England for girls aged 12–13 was **consistently over 85%**, with over 40% of Primary Care Trusts in England achieving at least 90%.¹⁰

However, England has reported a drop in vaccine uptake since the start of the SARS-CoV-2 pandemic. The pandemic in early 2020 had a major impact on HPV vaccination rates:¹¹

HPV vaccination first dose uptake rates in Year 8 pupils aged 12-13 years:¹¹

2019-2020 ¹¹	2020-2021 ¹¹	2021-2022 ¹¹	2022-2023 ¹¹	2023-2024 ¹¹
59.2% of girls 54.4% of boys	76.6% of girls 71.0% of boys	69.6% of girls 62.4% of boys	71.3% of girls 65.2% of boys	72.9% of girls 67.7% of boys

Some young people were unable to receive their immunisation at school.

That's where primary care comes in.

When seeing patients over 14 and less than 25-years-old in general practice, ask them about their HPV vaccination status and whether they received this at school.¹² You can help those missed, but potentially eligible, patients by opportunistically offering vaccination against HPV.¹²

Find out more on [MSD Connect](#)

Clicking this link will take you to a promotional MSD webpage

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References:

1. Gardasil® 9 (Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed). Summary of Product Characteristics (SPC) for UK. Available at: <https://www.emcpi.com/pi/32240>.
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