Prescribing Information: Great Britain | Northern Ireland

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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, adsorbed) is indicated for active immunisation of individuals from the age of 9 years against the following HPV diseases:^{1,2}

- 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.^{1,2}

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.³

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.³

Most HPV infections are transient and cause no clinical problems, with 90% of HPV infections clearing within 2 years and 70% clearing within one year.³

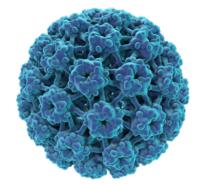
WHY TARGET HPV?

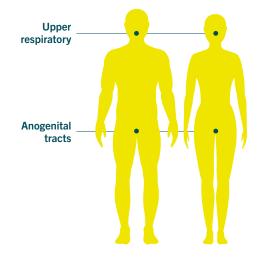
HPV is recognised as a cause of cervical cancer.

Approximately 99.7% of cervical cancer cases are caused by persistent infection with genital high-risk HPV infection.⁴

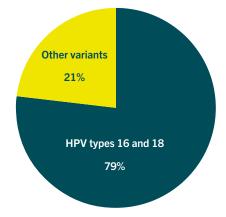
Together, HPV types 16 and 18 account for almost 80% of all invasive cervical cancers in the UK.⁵ Persistence and disease is more common for infections with HPV types 16 and 18 than other high-risk types.³

Persistent infection by a high-risk HPV type is an important causal factor for the development of cervical pre-cancerous and cancerous lesions³





High-risk HPV types associated with invasive cervical cancer in the UK⁵





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HPV is also associated with certain cancers, including of the cervix, vulva, vagina, and anus. HPV poses risks to both men and women.³

Low-risk HPV types are responsible for genital warts, which is the most commonly diagnosed viral sexually transmitted infection in the UK.³ 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.³

~90%

HPV types 6 and 11 cause ~90% of all genital warts.³

THE HISTORY OF HPV VACCINATION³

- HPV National Immunisation Programme (NIP) announced for girls aged 12–13
- Additional 'catch-up' campaign for girls aged 13–18³
- Bivalent vaccine, (Human Papillomavirus Vaccine [Types 16, 18] Recombinant, adjuvanted, adsorbed)^{3,6}
- NIP extended to cover men who have sex with men (MSM) ≤45 years old attending specialist sexual health services and HIV clinics³
- Vaccine used in the NIP changed from quadrivalent vaccine to the nine-valent vaccine, Gardasil[®]9 (containing HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58)³

Sep 08	Sep 12	Apr 18	Sep 19	Aug 22	Nov 23
	Schedule changed to quadrivalent		NIP extended to c	• NHS set ambition	
	vaccine ¹⁻³				eliminate cervical cancer by 2040 ⁷



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.³

The long term ambition set by the NHS aims to eliminate cervical cancer by 2040. This could save thousands of lives in England.⁷

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.³

Additionally, evidence of herd protection among unvaccinated groups is emerging in the UK and globally.³

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.⁸

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.⁸ In 2022, the rate of first episode genital warts diagnoses among 15–17-year-old girls attending sexual health services in England, was almost 68% lower compared to 2018 (7.0 vs. 21.8 *per* 100,000 population) and a decline of almost 71.5% (3.1 vs. 10.9 *per* 100,000 population) was seen in the same aged heterosexual boys over the same period, suggesting substantial herd protection.⁹

Reflecting the high uptake rates and efficacy of vaccines in preventing infection with cancer-inducing HPV types, the World Health Organisation is aiming for the ambitious target of **eliminating cervical cancer within the century**.¹⁰

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 <u>click here</u> to be taken to the SmPC for Great Britain and <u>click here</u> to be taken to the SmPC for Northern Ireland.

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.¹¹

Very common side effects include redness, swelling or pain at the site of injection and headaches.¹¹

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.¹¹

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%.¹²

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:¹³

HPV vaccination first dose uptake rates in Year 8 pupils aged 12-13 years:¹³⁻¹⁵



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.¹⁶ You can help those missed, but potentially eligible, patients by opportunistically offering vaccination against HPV.¹⁶

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