

Prescribing Information for Gardasil® 9 (Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)): United Kingdom
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Guiding conversations around HPV vaccination

GARDASIL® 9
Human Papillomavirus
9-valent Vaccine, Recombinant

A guide for healthcare professionals to support discussions with members of the public around HPV vaccination.

This resource has been fully funded and developed by MSD for UK healthcare professionals only.

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.
- Genital warts (Condyloma acuminata) caused by specific HPV types

MSD does not recommend the use of any of its products outside any of the terms of its marketing authorisation indications. Always refer to the Summary of Product Characteristics before prescribing to help minimise the risks associated with the use of Gardasil® 9.

*HPV = Human Papillomavirus

This guide provides examples of what hesitation may sound like along with information to address the needs of the individual. The discussion points included are a guide only to aid conversations with members of the public and **must not be given to members of the public**. Please use the information provided at your clinical discretion.

Your opinion is valued when it comes to HPV vaccination.

Recommending HPV vaccination to parents - especially those who are hesitant - can help them consider protecting their children against certain HPV-related cancers and diseases in later life¹.



For parents wanting to learn more, **help ensure they have the right information when making the decision to vaccinate their child².**

Share why you support and recommend HPV vaccination, use personal experience, and assess what additional questions remain from parents³.

Understanding why a parent did not provide consent for their child to be vaccinated against HPV

Some parents may end the call when they hear you are phoning on behalf of the local School Age Immunisation Service, so to build trust, consider leading the conversation with the child's name and their school.

It is important to listen with empathy and acknowledge how they are feeling, so perhaps say to the parent "I understand that decisions about vaccinations can be overwhelming. If you have any questions or concerns about HPV vaccination, I am happy to provide information and support".

How to effectively address potential questions from parents

Parent says:

"I want to **re-gain control** over what **vaccines** my child receives".

Response:

Ask for permission to discuss HPV vaccination and reassure the parent that it is their decision whether to consent to vaccination or not. **Offer them the chance to discuss any questions** or concerns they may have, before making their decision.

Parent says:

"Why is HPV vaccination **relevant** to my child at this age when they are **not sexually active**?"

Response:

HPV is a common virus that can be passed via skin-to-skin contact, not just through sex³.

Vaccination against HPV is most effective when given before exposure to HPV⁴, so it is first offered to 12- and 13-year-olds as part of the NHS National Immunisation Programme⁵.

They may be young now, but later in life, **your child could be at risk of developing certain cancers caused by HPV**. For most people, HPV clears on its own. But for those who don't clear the virus, it can lead to certain HPV-related cancers and diseases over time⁵.

Parent says:

"**How common is HPV-related cancer**, and is it really a cause for concern?"

Response:

Each year in the UK, there are **3,256 new cases of cervical cancer⁶ and 1,557 new cases of anal cancer⁷**. Vaccination can help protect your **son or daughter** against certain HPV-related cancers and diseases in later life such as:

- **Cervical cancer³**
- **Genital warts³**
- **Anal cancer⁸**

Parent says:

"**Why do boys** need to be vaccinated against HPV?"

Response:

Boys can also be affected by certain HPV-related cancers and diseases like **anal cancer** and **genital warts** in later life³.

In 2019 the HPV National Immunisation Programme was extended to include boys born **AFTER 1st September 2006** up until their 25th birthday⁹.

Also, **there are no HPV screening programs for men**, and usually no symptoms of the virus, so HPV infection can remain undetected in men⁴.

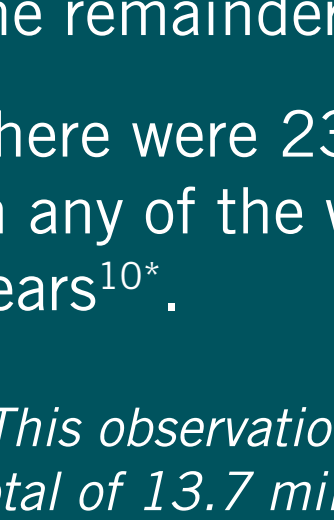
Parent says:

"**How effective** is HPV vaccination?"

Response:

In the UK, HPV vaccination has significantly reduced the incidence of cervical cancer in young women⁹. For example, a study in Scotland detected **no cases of cervical cancer in women who were vaccinated before the age of 14¹⁰**. HPV vaccination has also resulted in a **large decline in the rate of genital warts seen in young men and women¹¹**.

A note for HCPs:



A study estimated that **cervical cancer rates have been reduced by almost 90%** in women in their 20s who were offered HPV vaccination between 12 and 13 years of age in England compared with an unvaccinated population⁹.

A population-based, retrospective study using routinely collected data on all women in Scotland eligible for cervical cancer screening who were born on or after 1st January 1988 up to 6th June 2016. 447,845 individual records were included in the study.

Approximately 40,000 of the women included in the study were vaccinated against HPV with the bivalent vaccine at 12 or 13 years, approximately 114,000 were vaccinated with the same vaccine at 14 years or older, and the remainder were not vaccinated.

There were 239 cases of invasive cervical cancer, none of which occurred in any of the women who were vaccinated with 2 doses before the age of 14 years¹⁰.

**This observational study used the bi-valent vaccine, and includes 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.*



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, **a decline of 68.4%** was seen in heterosexual young men of the same age over the same period¹¹.

Parent says:

"I am worried about the **potential side effects** of vaccination"

Response:

Over 10 million doses of HPV vaccines have been given in the UK in over 10 years¹². The side effects commonly seen with HPV vaccination are mild such as redness, swelling or pain at the site of injection and headaches¹³.

Parent says:

"Does HPV vaccination contain any **animal products**?"

Response:

HPV vaccination in the UK **does not contain** pork or gelatine¹⁴.

Parent says:

"**What are your thoughts** on HPV vaccination for my child?"

Response:

You could share why you support and recommend HPV vaccination by using personal experience. For example, if your child or relative has been vaccinated against HPV, be open about your own reasons for wanting them to be vaccinated.



WHAT TO DO IF A PARENT STILL DOES NOT WANT TO PROVIDE CONSENT...

If the parent is still unsure about their decision to get their child vaccinated against HPV, consider asking an open-ended question such as '**Could you tell me more about why you feel that way?**'. These questions may elicit a deeper response and can help you better understand their concerns.

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.

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