

Gardasil 9 vaccine

This leaflet explains what the Gardasil 9 vaccine is, why it has been prescribed for you, how it is given, and any side effects it may cause. Please read carefully as it provides information regarding potential side effects and further scheduled appointments. If you have any concerns or would like further information, please do not hesitate to contact one of the Uro-Oncology Nursing Team on the number at the end of the leaflet.

What is Gardasil 9 vaccine?

Gardasil 9 is a vaccine that is given to protect against diseases caused by human papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58. These diseases include pre-cancerous lesions and cancers of the female genitals (cervix, vulva and vagina), pre-cancerous lesions and cancers of the anus and genital warts in males and females.

How does the vaccine work?

When an individual is vaccinated with Gardasil 9, the immune system (the body's natural defence system) stimulates production of antibodies against the nine vaccine HPV types, to help protect against the diseases caused by the virus. **Gardasil 9 cannot cause HPV-related diseases.**

Why have I been prescribed Gardasil 9?

You have had a diagnosis of undifferentiated intraepithelial neoplasia (PeIN). Penile intraepithelial neoplasia (PeIN) – a pre-cancerous condition – is commonly associated with HPV infection.

The Gardasil 9 vaccine is being offered to you as a protective treatment against HPV infection. It aims to reduce the risk of disease reoccurrence, although currently there is not a lot of evidence about how effective it is. As with any vaccine, Gardasil 9 may not fully protect all of those who receive the vaccine, and how long the protection lasts is not yet known. Longer-term follow-up studies are ongoing to determine whether a booster may be needed.

Who is not suitable for Gardasil 9?

- You should not receive the vaccine if you know you are allergic to any of the active substances or any of the other ingredients of this vaccine (see the following paragraph for ingredients). Also, you should not receive it if:
- You have developed an allergic reaction after receiving a dose of Gardasil 9 previously.
- You have a bleeding disorder.
- You have a weakened immune system.
- You suffer from an illness with a high fever.

Ingredients of each vaccine

Gardasil 9 contains:

- Human Papillomavirus Type 6 L1 protein – 30 Micrograms
- Human Papillomavirus1 Type 11 L1 protein^{2,3} – 40 Micrograms
- Human Papillomavirus1 Type 16 L1 protein^{2,3} – 60 Micrograms
- Human Papillomavirus1 Type 18 L1 protein^{2,3} – 40 Micrograms
- Human Papillomavirus1 Type 31 L1 protein^{2,3} – 20 Micrograms
- Human Papillomavirus1 Type 33 L1 protein^{2,3} – 20 Micrograms
- Human Papillomavirus1 Type 45 L1 protein^{2,3} – 20 Micrograms
- Human Papillomavirus1 Type 52 L1 protein^{2,3} – 20 Micrograms
- Human Papillomavirus1 Type 58 L1 protein^{2,3} – 20 Micrograms

L1 protein in the form of virus-like particles is produced in the laboratory from yeast cells using DNA technology. Amorphous aluminium hydroxyphosphate sulfate is included in the vaccine as an adjuvant (enhancer). Adjuvants are included to improve the immune response of vaccines. The other ingredients in the vaccine are: sodium chloride, histidine, polysorbate 80, borax and water.

How is Gardasil 9 given?

- Gardasil 9 is given as an injection into the muscle of the upper arm or thigh.
- Gardasil 9 is a course of three injections. The second is given one month after the first and the third, three months after the second.
- All three doses should be received within a one-year period.
- You will receive letters in the post confirming all three appointments.
- If you forget, or are not able to attend your booked appointments, **please contact one of the Uro-Oncology Nursing Team** on the number provided at the end of the leaflet.

COVID-19 vaccine

There needs to be a two-week gap between receiving your COVID-19 vaccine (first or second dose) and having your Gardasil 9 vaccine. Your COVID-19 vaccine takes priority over the Gardasil 9 vaccine and it is important you do not defer or delay your COVID-19 vaccine course.

Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

Gardasil 9 injections may cause:

- **Very common (may affect more than 1 in 10 people):** side effects found at the injection site (pain, swelling and redness) and headache.
- **Common (may affect up to 1 in 10 people):** side effects found at the injection site (bruising, and itching), fever, tiredness, dizziness, and nausea.

- Although fainting episodes are uncommon, it is a requirement that you are observed for 15 minutes after you have received the HPV vaccine.
- Allergic reactions have been reported. Some of these reactions have been severe. Symptoms may include **difficulty in breathing, wheezing, hives and/or rash**.
- Gardasil 9 may slightly and temporarily **affect your ability to drive or use machines**.

Reporting side effects

If you get any side effects, inform your Uro-Oncology Clinical Nurse Specialist.

You can also report side effects directly via the Yellow Card Scheme

www.mhra.gov.uk/yellowcard

By reporting side effects, you can help provide more information on the safety of this vaccine.

Who can I contact if I have any questions?

If you have any questions about this treatment, please feel free to phone the Uro-Oncology Clinical Nursing Team.

Tel: **0118 322 7905** or email **urology.nurses@royalberkshire.nhs.uk**

We work Monday-Friday 8.00am-4.00pm. There is an answer machine, and we will return your call if we are not in the office, so please leave a message and we will get back to you.

Out of hours, contact NHS 111 for further advice.

To find out more about our Trust visit www.royalberkshire.nhs.uk

Please ask if you need this information in another language or format.

Uro-Oncology Clinical Nursing Team, May 2023.

Next review due: May 2025