Prescribing Information for Gardasil® 9 (Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)): United Kingdom
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Helping You Help Parents:

How to Respond to Frequently Asked Questions (FAQs) about HPV (Human Papillomavirus) with Confidence

MSD

Contents

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Understanding HPV

What is HPV?

HPV, or human papillomavirus, is the name for a common group of viruses. There are over 200 types of human papillomavirus. Around 40 types can affect the genital and anal area. Human papillomaviruses are grouped as either high-risk types or low-risk types depending on whether they are linked to cancer.

High-risk human papillomavirus types: infections caused by high-risk types may lead to certain HPV-related cancers and pre-cancerous cell changes in areas such as the cervix, vagina, vulva and anus in women, and the anus in men.

Low-risk human papillomavirus types: infections caused by low-risk types can lead to genital warts.

How do you get HPV?

The virus is transmitted through close skin-to-skin contact, often but not always during sexual contact with someone who has the virus. Most people who become infected with HPV do not know they have it as it doesn't cause any symptoms.

How would somebody know if they're infected with HPV?

Most HPV infections don't have any signs or symptoms. That means most people won't know they have a human papillomavirus unless it causes problems.

The NHS offer a cervical screening test that can help prevent cervical cancer. Women and people with a cervix between the ages of 25 and 64 are advised to go for regular screening.

During screening appointments, a small sample of cells are taken from the cervix. The sample will be checked for certain types of HPV, if high-risk types of HPV are found, the sample will also be checked for abnormal cell changes. Certain types of high-risk HPV can over time cause abnormal cell changes in the cervix. These changes may become cervical cancer if not monitored or treated.

After individuals have had their cervical screening, their GP or nurse will tell them when they can expect to receive their results which will explain if HPV was found in their sample.

What diseases can HPV cause?

Most HPV infections do not cause symptoms and most (9 out of 10) go away by themselves within 2 years. When the immune system does not clear the HPV, it can lead to health problems such as certain types of cancer.

An infection caused by a high-risk type of HPV can lay dormant for 20 years or more before causing damage to cells which can lead to certain HPV-related cancers and disease.

For example:

- HPV cancers of the anal and genital area (anus, vulva, vagina and cervix).
- Pre-cancerous lesions (areas of cells that are starting to show changes that could become cancer) of the anal and genital area (vulva, vagina, cervix and anus).

Are there other ways to help protect myself/my child against HPV?

Human papillomaviruses and other infections can be spread through close skin-to-skin contact, including during sex and sexual activities. HPV vaccination at the recommended age helps teach the immune system how to protect the body against types of human papillomavirus before it has been exposed to them. The immune system will then know how to fight off those viruses if it is exposed to them in the future.

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

There are other ways of helping stop the spread of certain human papillomaviruses and other diseases, including always wearing a condom during sex. Using a condom can help protect against lots of sexually transmitted diseases, but it won't stop all of them.

There is no treatment for HPV infections. Most HPV infections cause no symptoms and clear up on their own.

Women and individuals with a cervix aged 25 to 64 will be invited for cervical screening. Cervical screening tests for types of high-risk human papillomavirus and checks the health of the cervix.

You'll get an invitation through the NHS App, by text or by letter asking you to make an appointment and telling you how to book. You'll get your first invitation a few months before you turn 25 and will be invited for screening every 5 years from when you're 25 to 64 years old. This will help make sure that changes that may have been caused by HPV are picked up and dealt with before they have a chance to turn into cervical cancer.

Are "vaccination" and "immunisation" the same thing?

Immunisation is the action of making a person immune to infection. Vaccination is using a vaccination to produce immunity against a disease. For example, HPV vaccination helps to produce immunity against some types of HPV.

Purpose & Benefits of HPV Vaccination

Why vaccinate against HPV?

HPV infections are common. While most infections clear up on their own without causing symptoms, some infections caused by types of human papillomavirus may cause certain cancers, like anal or cervical cancer. HPV types that may cause cancer are called high-risk types. Some infections caused by low-risk types may also cause genital warts.

HPV vaccination helps protect people against certain types of human papillomaviruses. This helps prevent an infection caused by a high-risk human papillomavirus from happening before it can become more serious and increases the risk of certain HPV-related cancers in the future.

How do I make sure I am/my child is eligible for the HPV vaccination programme?

Boys and girls will be given the opportunity to be vaccinated against HPV as part of the NHS National Immunisation Programme at school in year 8/S1 when they're 12 to 13 years old (11 to 13 years old in Scotland).

If you have a child aged between 12-13, your child's school will contact you as soon as they become eligible. You will receive a consent letter, this may be a digital form, or a paper form depending on your school. If your child is home schooled, the school age immunisation service (SAIS) team will contact you directly to book an appointment at one of the community clinics.

If you/your child missed their vaccination when it was first offered at school, vaccination against HPV is still available on the NHS for all girls under the age of 25 and boys born after 1st September 2006.

Why are 12–13 year old children being vaccinated as part of the HPV vaccination programme?

HPV vaccination is most effective when given before any exposure to HPV viruses, so it's recommended for 12-13 year olds when they are at school, as well as other individuals that are considered at higher risk from HPV.

Why were boys added to the HPV vaccination programme in 2019?

Boys are at risk of HPV infections and certain HPV cancers when they grow up, just like girls. In adulthood, boys may be affected by human papillomavirus infections that can lead to genital warts or anal cancers.

Is the "cervical cancer vaccination" different to the HPV vaccination?

No, they are the same vaccination given on the NHS as part of the National Immunisation Programme. 99.8% of cervical cancer cases are caused by persistent infection with high-risk HPV types.

When the vaccination was offered only to girls, the programme was commonly referred to as the "cervical cancer programme". However, HPV vaccination has never been solely for preventing cervical cancer. HPV infection can also lead to certain HPV-related diseases and cancers in boys.

Boys are given the same HPV vaccination that have been given to millions of girls in the UK since 2008 as part of the NHS National Immunisation Programme. It works in the same way for boys as it does for girls, by teaching their body how to fight off certain types of human papillomavirus that can lead to certain cancers and disease.

Does the HPV vaccination program mean women no longer need to attend cervical screening?

HPV vaccination as part of the NHS National Immunisation Programme helps prevent cervical cancer caused by certain human papillomaviruses. HPV vaccinations may not protect everyone who receives them. That's why it's important that all people with a cervix go to all of their NHS cervical screening appointments when they're old enough.

Cervical screening (sometimes called a smear test) tests for certain high-risk types of HPV and checks the health of the cervix (the opening to the womb from the vagina). All women and people with a cervix aged 25 to 64 should be invited to cervical screening.

Eligibility for the NHS National Immunisation Programme (NIP)

I am/My child is older than 13 years. Can I/they still get vaccinated against HPV under the NHS National Immunisation programme?

Eligible for the NHS National Immunisation Programme (NIP):

Boys (born AFTER 1st September 2006):

You/my son was/were 12 to 13 years old when boys were added to the HPV vaccination programme (1st September 2019). You/they will be able to receive vaccination under the NHS National Immunisation Programme up until your/their 25th birthday.

Girls/women (born AFTER 1st September 1991):

You/your daughter was/were eligible for HPV vaccination when the HPV vaccination programme was introduced in 2008. You/they will be able to receive vaccination under the NHS National Immunisation Programme up until your/their 25th birthday.

Not eligible for the NHS NIP:

Boys (born BEFORE 1st September 2006):

You/your son turned 14 before HPV vaccination for boys was added to the HPV vaccination programme (1st September 2019) so they are not eligible to receive it on the NHS.

Girls/women (born BEFORE 1st September 1991):

You/your daughter is not eligible to receive HPV vaccination under the NHS National Immunisation Programme.

What are national Immunisation Programmes (NIPs)?

National Immunisation Programmes (NIPs) are services provided by the NHS to help stop the spread of infectious diseases, like HPV. For example, if your child was vaccinated as a baby, the vaccines they received would probably have been part of the NIP.

Missed Vaccinations & Programme Logistics

What happens if I/my child missed their vaccination?

If your child missed their vaccination when it was first offered at school, including due to school closures during the COVID-19 pandemic, vaccination against HPV is still available on the NHS for all girls under the age of 25 and boys born after 1st September 2006. Contact your school vaccination team or GP practice for more information.

Are HPV vaccination programmes just in the UK?

No, HPV vaccination happens around the world. More than 80 million people have been vaccinated against HPV worldwide since 2008.

Consent & Decision-Making

Who can give consent for the HPV vaccination programme?

Parents, carers or guardians would usually need to give consent for a child to receive the vaccination on the NHS National Immunisation Programme. School nurses, practice nurses and doctors will always aim to work with parents, carers or guardians where possible.

If a nurse or doctor is reassured that a child has the understanding to consent to the vaccination for themselves then this may be possible.

Are there any side effects?

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 vaccination.

The most common side effects are:

- redness, swelling or pain at the site of the injection
- headaches

Some people might get:

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

If you/your child experiences any side effects, please speak to their doctor, pharmacist or school or practice nurse. This includes any possible side effects not listed in the package leaflet.

You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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