

What should I do if my child or I miss a dose?

Your doctor or health-care provider will decide when to give the missed dose.

It is important that you follow the instructions of your doctor or health-care provider regarding return visits for the follow-up doses.

What other important information about GARDASIL® 9 should I know?

GARDASIL® 9 will not protect against diseases that are not caused by HPV. HPV types, 6, 11, 16, 18, 31, 33, 45, 52, and 58 have been selected for GARDASIL® 9 because they cause 95% of cervical cancers and 90% of Genital warts worldwide.

As for any vaccine, GARDASIL® 9 may not fully protect everyone who gets the vaccination. Continue to follow your doctor or health-care provider's instructions on cervical cancer screening.

What are the possible side effects of GARDASIL® 9?

The vaccine-related adverse experiences that were observed among recipients aged between 9 to 45 years old of GARDASIL® 9 at a frequency of at least 1% include pain, swelling, erythema, pruritus, bruising, headache, pyrexia, nausea, dizziness and fatigue. The safety profile was similar between GARDASIL® 9 and GARDASIL® in women, men, girls and boys.

Use in children

The safety and efficacy of GARDASIL® 9 have not been evaluated in children younger than 9 years.

Use in pregnancy

Pregnancy should be avoided during the vaccination regimen for GARDASIL® 9. If you are pregnant, you should be vaccinated with GARDASIL® 9 only if your doctor or health-care provider decides it is clearly needed.

Women who become pregnant before completion of the 3-dose schedule should complete their vaccination schedule after childbirth.

Use in breast-feeding

It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. However, the World Health Organization (WHO) states "Breastfeeding is not a contraindication for HPV vaccination. Available evidence does not indicate an increased risk of adverse events linked to the vaccine in either the mothers or their babies after administration of HPV vaccine to lactating females."⁴

If you or your child has any unusual or severe symptoms after receiving GARDASIL® 9, contact your doctor or health-care provider right away.

Can other vaccines and medications be given at the same time as GARDASIL® 9?

Results from clinical studies indicate that GARDASIL® 9 may be administered concomitantly (at a separate injection site) with Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)], and Repevax [Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content)] (dTdap-IPV).

Please inform your doctor or health-care provider if you or your child are taking or have recently taken any other medicines, even those not prescribed.

This leaflet is a summary of information about GARDASIL® 9. If you would like more information, please talk to your doctor or health-care provider.

References : 1. Chesson HW et al. *Sex Transm Dis.* 2014;41 :660-664 2. Centers for Disease Control and Prevention (CDC). 2015 Sexually Transmitted Disease Guidelines - HPV (v1.0). <https://www.cdc.gov/std/tg2015/default.htm>. Last accessed on 3 February 2020. 3. American Cancer Society, Cervical Cancer Prevention and Early Detection, 2014. 4. World Health Organization (WHO). Human papillomavirus vaccines: WHO position paper, May 2017. <https://apps.who.int/iris/bitstream/handle/10665/255353/WER9219.pdf;jsessionid=87FB0448706BE0CFB717803A2B714172?sequence=1>. Accessed on 28 Sept 2020.

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GARDASIL™ 9 [Human Papillomavirus 9-valent Vaccine, Recombinant]

Information Strictly for Patients
who have been prescribed GARDASIL® 9
by their treating physician.



HPV = Human Papillomavirus

Your doctor has prescribed Gardasil® 9 for you or your child. This leaflet sets out important information about what Gardasil 9 is used for and how it will be given to you.

What is GARDASIL® 9 and what is it used for?

For Females

GARDASIL® 9 is a vaccine that helps protect against the following caused by Human Papillomavirus (HPV) in girls and women 9 through 45 years of age:

- Cervical, vulvar, vaginal, and anal cancer; premalignant genital lesions (cervical, vulvar and vaginal); premalignant anal lesions; HPV infections; cervical adenocarcinoma in situ (AIS); and external genital warts causally related to Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

For Males

GARDASIL® 9 helps protect against the following caused by HPV in boys and men 9 through 45 years of age:

- **Premalignant lesions and HPV infections caused** by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58;
- **Anal cancer** caused by HPV types 16, 18, 31, 33, 45, 52, and 58, and
- **Genital warts** caused by HPV types 6 and 11

Your child or yourself cannot get HPV or any of the above diseases from GARDASIL® 9.

GARDASIL® 9 helps prevent, but does not treat these diseases.

Why is vaccination with GARDASIL® 9 important?

Infection with HPV is common as 80% of sexually active individuals will get HPV infection at some point in their life.¹

HPV can affect everyone even those who are married or in a steady relationship.²

The recommended way to help protect yourself from HPV is to go for HPV vaccination or to perform safe sex in order to avoid skin to skin contact.³

Many people who have HPV may not show any signs or symptoms. This means that they can transmit (pass on) the virus to others without knowing it.³

Who should receive GARDASIL® 9?

Girls and women 9 through 45 years of age and boys and men 9 through 45 years of age can receive GARDASIL® 9. GARDASIL® 9 works best when given before a person has any contact with certain types of Human Papillomavirus.

Who should not receive GARDASIL® 9?

Anyone who:

- is allergic to any of the ingredients in the vaccine (including any of the ingredients listed under inactive ingredients)
- has an allergic reaction after receiving a dose of GARDASIL® or GARDASIL® 9.

What should I tell my doctor or health-care provider before I or my child is vaccinated with GARDASIL® 9?

Your doctor or health-care provider will decide if you or your child should receive the vaccine.

You should tell your doctor or health-care provider if you or your child:

- has had an allergic reaction to the vaccine
- has a bleeding disorder and cannot receive injections in the arm
- has any illness with a fever
- is pregnant or is planning to get pregnant
- has a weakened immune system, for example due to a genetic defect or Human Immunodeficiency Virus (HIV) infection, or if you take medicines that affect your immune system.

How is GARDASIL® 9 given?

GARDASIL® 9 is given as an injection usually in the arm muscle.

Individual who are 15 and above, should be administered as 3 separate doses according to the following schedule:

- **First dose:** at a date you and your doctor or health-care provider choose
- **Second dose:** 2 months after the first dose
- **Third dose:** 6 months after the first dose

All three doses are recommended to be given within a 1-year period.

If you or your child misses a dose, your doctor or healthcare provider will decide when to give the missed dose. Alternatively, in individuals 9 through 14 years of age, GARDASIL® 9 can be administered according to a 2-dose schedule; the second dose should be administered between 5 and 13 months after the first dose. If the second vaccine dose is administered earlier than 5 months after the first dose, a third dose should always be administered.