queerdoc.com
queerdoc@queerdoc.com
(541) 604-8276 (office)
(352) 553-4934 (fax)

Patient Information about GARDASIL®9 (pronounced "gard-Ah-sill nīn") (Human Papillomavirus 9-valent Vaccine, Recombinant)

Read this information with care before getting GARDASIL®9. You or your child (the person getting GARDASIL 9) will need 2 or 3 doses of the vaccine, depending on how old you are. It is important to read this information before getting each dose. This information does not take the place of talking with your health care professional about GARDASIL 9.

What is GARDASIL 9? GARDASIL 9 is a vaccine (injection/shot) given to individuals 9 through 45 years of age to help protect against diseases caused by some types of Human Papillomavirus (HPV).

What diseases can GARDASIL 9 help protect against? In people with cervixes through 45 years of age, GARDASIL 9 helps protect against:

- Cervical cancer
- Vulvar and vaginal cancers
- Anal cancer
- Precancerous cervical, vulvar, vaginal and anal lesions
- Genital warts

In people without cervixes 9 through 45 years of age, GARDASIL 9 helps protect against:

- Anal cancer
- Precancerous anal lesions
- Genital warts

These diseases have many causes. Most of the time, these diseases are caused by nine types of HPV: HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL 9 only protects against diseases caused by these nine types of HPV.

People cannot get HPV or any of these diseases from GARDASIL 9.

What important information about GARDASIL 9 should I know? GARDASIL 9:

- Does not remove the need for cervical cancer screening; people with cervixes should still get routine cervical cancer screening.
- Does not protect the person getting GARDASIL 9 from a disease that is caused by other types of HPV, other viruses or bacteria.
- Does not treat HPV infection.
- Does not protect the person getting GARDASIL 9 from HPV types that they may already have.

GARDASIL 9 may not fully protect each person who gets it.

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Who should not get GARDASIL 9? Anyone with an allergic reaction to:

- A previous dose of GARDASIL 9
- A previous dose of GARDASIL®
- Yeast (severe allergic reaction)
- Amorphous aluminum hydroxyphosphate sulfate
- Polysorbate 80

What should I tell the health care professional before getting GARDASIL 9? Tell the health care professional if you or your child (the person getting GARDASIL 9):

- Are pregnant or planning to get pregnant.
- Have immune problems, like HIV or cancer.
- Take medicines that affect the immune system.
- Have a fever over 100°F (37.8°C).
- Might have had an allergic reaction to a previous dose of GARDASIL 9 or GARDASIL.
- Take any medicines, even those you can buy over the counter.

The health care professional will help decide if you or your child should get the vaccine.

How is GARDASIL 9 given? GARDASIL 9 is a shot that is usually given in the arm muscle. GARDASIL 9 may be given as 2 or 3 shots.

For persons who are 9 through 14 years old
You will need 2-shots
Given as

Dose 1: first shot
Dose 2: second shot given between 6 and 12 months after the first shot
*If the second shot is given earlier than 5 months after the first shot, you will need to get a third shot at least 4 months after the second shot was given.

For persons who are 15 through 45 years old
You will need 3-shots
Given as

Dose 1: first shot
Dose 2: second shot given 2 months after the first shot
Dose 3: third shot given 6 months after the first shot 15 through 45 years old 3-shots

Make sure that you or your child gets all doses recommended by your health care professional so that you or your child gets the best protection. If the person getting GARDASIL 9 misses a dose, tell the health care professional and they will decide when to give the missed dose. It is important that you follow the instructions of your health care professional regarding return visits for the follow-up doses.

Fainting can happen after getting an HPV vaccine. Sometimes people who faint can fall and hurt themselves. For this reason, the health care professional may ask the person getting GARDASIL 9 to sit or lie down for 15 minutes after getting the vaccine. Some people who faint

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might shake or become stiff. The health care professional may need to treat the person getting GARDASIL 9.

Can I get GARDASIL 9 if I have already gotten GARDASIL? If you have already gotten GARDASIL, talk to your health care professional to see if GARDASIL 9 is right for you.

Can I get GARDASIL 9 with other vaccines? GARDASIL 9 can be given at the same time as:

- 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)]

What are the possible side effects of GARDASIL 9? The most common side effects seen with GARDASIL 9 are:

- pain, swelling, redness, itching, bruising, bleeding, and a lump where you got the shot
- headache
- fever
- nausea
- dizziness
- tiredness
- diarrhea
- abdominal pain
- sore throat

Studies show that there was more swelling where the shot was given when GARDASIL 9 was given at the same time as Menactra and Adacel.

Tell the health care professional if you have any of these problems because these may be signs of an allergic reaction:

- difficulty breathing
- wheezing (bronchospasm)
- hives
- rash

These side effects have been seen with GARDASIL. Because GARDASIL 9 is related to GARDASIL, they may also be seen after getting GARDASIL 9:

- swollen glands (neck, armpit, or groin)
- joint pain
- unusual tiredness, weakness, or

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confusion
- chills
- generally feeling unwell
- leg pain
- shortness of breath
- chest pain
- aching muscles
- muscle weakness
- seizure
- bad stomach ache
- bleeding or bruising more easily than normal
- skin infection
- fainting

You should contact your health care professional right away if you get any symptoms that bother you.

For a more complete list of side effects, ask the health care professional.

Call your health care professional for medical advice about side effects. You may also report any side effects to your doctor or directly to Vaccine Adverse Event Reporting System (VAERS). The VAERS toll- free number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

GARDASIL 9 was not studied in people who knew they were pregnant. A pregnancy registry is available. You are encouraged to contact the registry as soon as you become aware of your pregnancy by calling 1- 800-986-8999, or ask your health care professional to contact the registry for you.

What is in GARDASIL 9? GARDASIL 9 contains:
- Proteins of HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Amorphous aluminum hydroxyphosphate sulfate
- Yeast protein
- Sodium chloride
- L-histidine
- Polysorbate 80
- Sodium borate
- Water

This document is a summary of information about GARDASIL 9.

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To learn more about GARDASIL 9, please talk to the health care professional or visit www.GARDASIL9.com.

For patent information: www.merck.com/product/patent/home.html

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