
Product Approval Information - Licensing Action

GARDASIL® Questions and Answers

1. What is FDA announcing?

FDA is announcing the licensure of Gardasil, the first vaccine for the prevention of cervical cancer, abnormal and precancerous cervical lesions, abnormal and precancerous vaginal and vulvar lesions and genital warts. Gardasil is a recombinant vaccine and is effective against HPV types 6, 11, 16 and 18, and is approved for use in females ages 9-26 years.

2. What is a recombinant vaccine?

Recombinant vaccines are made by genetic engineering, the process and method of manipulating the genetic material of an organism. In this case, the genes that code for a specific protein from each of the four virus types of HPV are expressed in yeast to create large quantities of the protein. The protein that is produced is purified and then used to make the vaccine. Because the vaccine only contains a protein, and not the entire virus, the vaccine cannot cause the HPV infection. It is the body's immune response to the recombinant protein(s) that then protects against infection by the naturally occurring virus.

3. What is Human Papillomavirus (HPV)?

HPV is the name of a group of viruses that includes more than 100 different types. More than 30 of these viruses can be passed from one person to another through sexual contact. For most women, the body's own defense system will clear the virus and they don't develop health problems. However, some types can cause cervical cancer or abnormal cells in the lining of the cervix that can sometimes progress to cancer. Other types are a major cause of genital warts.

For women who do develop cervical cancer, HPV is generally the root cause. In 2006, it is estimated that there will be 9,710 new cases of cervical cancer and 3,700 deaths attributed to it in the United States. Worldwide, cervical cancer is the second most common cancer in women; and it is estimated to cause over 470,000 new cases and 233,000 deaths per year.

4. How common is HPV infection?

HPV is the most common sexually transmitted infection in the United States. The Centers for Disease Control and Prevention (CDC) estimates that about 6.2 million Americans become infected with genital HPV each year and that over half of all sexually active men and women become infected at some time in their lives.

5. What does Gardasil protect against?

The vaccine is effective against HPV types 16 and 18 which cause approximately 70% of cervical cancers, and against HPV types 6 and 11 which cause approximately 90% of genital warts.

6. Does Gardasil protect against all HPVs?

Gardasil is expected to prevent up to 70% of cervical cancers, because they are due to HPV types against which the vaccine is directed. However, it does not protect against the types of HPV that are *not* included in the vaccine, which can also cause some cancers. Furthermore, women aren't protected if they have already been infected with the HPV types(s) that are covered by the vaccine prior to vaccination.

7. Are Pap tests still needed?

Yes. Since no vaccine is 100% effective and Gardasil won't provide protection against the HPV types *not* in the vaccine, or against existing HPV infections, routine Pap screening remains critically important to detect precancerous changes in the cervix to allow treatment before cervical cancer develops.

8. How well does Gardasil work?

Four multinational studies were conducted to show how well Gardasil worked in women between the ages of 16 and 26 by giving them either the vaccine or placebo. The results showed that in women who had not already been infected with the type of HPV contained in the vaccine, Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions and genital warts caused by infection with the HPV types against which the vaccine is directed. It is believed that prevention of cervical precancerous lesions is highly likely to result in the prevention of those cancers.

Two studies were also performed to measure the immune response to the vaccine among younger females aged 9-15 years. Their immune response was similar to that found in 16-26 year olds, indicating that the vaccine should have similar effectiveness when used in the 9-15 year age group.

It is important to note that Gardasil did *not* protect against HPV types that are not in the vaccine.

9. If a female already has a disease related to HPV types 6, 11, 16 or 18 will Gardasil help treat it?

No, Gardasil only works to *prevent* cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV); it won't work as treatment.

10. Will Gardasil help a female who already has a vaccine type HPV?

In the studies, females with current or past infection with one or more vaccine-related HPV types prior to vaccination were protected from the diseases caused by the other remaining HPV types contained in the vaccine.

11. Can males use Gardasil?

Gardasil is not approved for use in males, but the manufacturer currently has a study underway to see if it is safe and effective for them. Once the study is complete and submitted to FDA, the agency will review the data and decide whether to approve Gardasil for males.

12. How is Gardasil administered?

Gardasil is given as three injections over a six-month period; the first dose is given at an initial time selected by the vaccine recipient and her healthcare practitioner, followed by another dose 2 months later, and the third and last dose, six months after the first dose. The vaccine is administered intramuscularly in the upper arm or thigh.

13. When should Gardasil be given?

The results of the studies show that the vaccine only works when given prior to infection with HPV types 6, 11, 16 and 18.

14. At what age should Gardasil first be given?

FDA has approved Gardasil as safe and effective for use in females ages 9-26 years. Now that the vaccine has been licensed, CDC's Advisory Committee on Immunization Practices (ACIP) will discuss Gardasil at its June 29, 2006, meeting and make recommendations concerning its use.

15. Are there any possible adverse reactions associated with the use of Gardasil?

More than 10,500 females who received Gardasil were evaluated for adverse reactions. Most of the reactions experienced by the study participants were not serious and included mild or moderate local reactions, such as pain or tenderness at the site of the injection. It is always possible that unexpected and rare adverse events can occur when a vaccine is used more widely. The manufacturer has committed to FDA to performing additional studies of the safety of Gardasil. In addition, FDA and CDC carefully monitor the safety of approved vaccine through the Vaccine Adverse Event Reporting System (VAERS) in order to detect any problems.

16. Who should not be immunized with Gardasil?

Females who are allergic to yeast or to any component of the vaccine should not receive Gardasil. FDA has approved Gardasil as safe and effective for use in females ages 9-26 years.

17. Is it possible to become infected with HPV from Gardasil?

No, Gardasil is not a live virus vaccine; it does not contain the HPV virus and therefore, cannot cause the HPV infection.

18. Does Gardasil contain thimerosal?

No. Gardasil does not contain thimerosal or any other preservative.

19. How can I report a serious side effect with Gardasil, or other vaccines, to FDA?

Adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting System, which is maintained by FDA and CDC. For a copy of the vaccine reporting form, call 1-800-822-7697 or report on line to www.vaers.hhs.gov.

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