



November 1, 2006

Quadrivalent Human Papillomavirus Recombinant Vaccine (Gardasil®)

DESCRIPTION

Gardasil® is a vaccine composed of virus-like particles containing the outer proteins found in strains of the human papillomavirus (HPV) that are commonly associated with cervical cancer and genital warts.

WHAT YOU SHOULD KNOW

Gardasil® is approved for the prevention of cervical cancer, genital warts and precancerous lesions of the cervix, vagina and vulva. The vaccine contains no viral DNA and therefore no infectious material; instead, the antibodies formed are directed at the external proteins found in the viral capsid. Patients who receive the vaccine should continue regular screening for cervical cancer.

WHAT YOU MAY NOT BE TOLD

While Gardasil® has been demonstrated to be highly effective in the prevention of persistent infection and disease attributable to the virus types included in the vaccine, approximately 30 percent of cases of cervical cancer are caused by virus types not included in the vaccine. In addition, cervical cancer represents only about two percent of new cancer cases and cancer deaths among women. The duration of antibody protection is as yet unknown; however, current studies indicate that high antibody levels persist for at least several years. Gardasil® is currently being studied in boys and young men for the prevention of genital warts.

TYPICAL PATIENT QUESTIONS

Who should get this vaccine? The target population for this vaccine is girls and women between the ages

of 10 and 26 years, the ages when HPV infection is most likely to occur. Women who are already infected with HPV can receive the vaccine to prevent infection with other types of the virus. **How effective is this vaccine?** The vaccine is at least 90 percent effective in preventing persistent infection and disease associated with the four types of HPV included; two of these types are responsible for 70 percent of all cases of cervical cancer. **How many doses will I receive?** The recommended dose of vaccine is one 0.5 mL injection initially, with subsequent 0.5 mL doses given two and six months later. No booster doses are recommended at this time. **What are the common side effects?** Gardasil® has been well tolerated, with pain, swelling, redness and itching at the injection site commonly reported. Patients may experience fever following vaccination. Autoimmune disorders, including juvenile, rheumatoid, reactive and nonspecified arthritis have occurred at a higher rate among vaccine recipients than among placebo recipients, but the clinical significance of this finding is unknown.

COST AND INSURANCE CONSIDERATIONS

The AWP for Gardasil® is \$150 per dose, or \$450 for a three-dose series. Many insurance companies may not yet have made a decision regarding coverage of this product. However, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) posted its provisional recommendations for Gardasil® on Aug. 18, 2006, in which the ACIP recommended the vaccine for girls ages 11 and 12 years and catch-up vaccination for girls and young women ages 13-26 years.

RESOURCES:

Gardasil Information: <http://www.gardasil.com/>

Patient Information: http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_ppi.pdf

Prescribing Information: http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf

DISCLAIMER

This publication is intended to provide key practical information regarding this drug product in a brief format. It does not contain sufficient information upon which to base formulary or other medication use policy decisions.

