Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18)
Recombinant Vaccine (Preservative Free)

Manufacturer: Merck

Brand Name: Gardasil®

Formulation: Single dose vials and prefilled single dose syringes

Dosage: 0.5 ml

Storage: Store at 2° - 8° C (35° - 46° F). **Do Not Freeze**

Injection site: Deltoid or Anterolateral area of thigh

Route: Intramuscular (IM)

Needle Size: 20 to 25 gauge, 1 to 1½ inches

Indications: Gardasil® vaccine is indicated by FDA in females 9-26 years of age. ACIP recommends routine vaccination for all females 11-12 years of age.

VFC-eligible females 9 through 18 years of age are entitled to receive VFC vaccine. The advisory committee has noted that the vaccination series can be started as early as 9 years of age at the discretion of the physician or health care provider.

*HPV quadrivalent (Gardasil) vaccine may be administered to VFC-eligible males 9 through 18 years of age under ACIP "permissive use" language. HPV is not required for males to participate in the VFC program. The dosing and schedule are the same as for females. HPV vaccine "may not" be administered to "Underserved" males.

Schedule: Dosage Intervals

Dose 1	(Dose 1 to 2)	(Dose 2 to 3)
Elected date	2 months	4 months

There must be 6 months separating dose 1 and dose 3.

Contraindications:

Anaphylactic reaction following prior dose of Gardasil® vaccine.
Individuals with hypersensitivity, including severe allergic reactions to yeast

Note: Because vaccine recipients may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with Gardasil®. When syncope is associated with tonic-clonic movements, the activity is usually transient by maintaining a supine or Trendelenburg position.

Precautions:

Gardasil® should be used during pregnancy only if clearly needed.
The immunologic response to Gardasil® may be diminished in immunocompromised individuals
It is not known if Gardasil® is secreted through breast milk.

Reference: Gardasil vaccine package insert, Merck & Co., Inc, (Updated June 29, 2009)
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm165145.htm.

Additional information regarding syncope following vaccination may be found in the May 2, 2008, issue of the *Morbidity and Mortality Weekly Report* at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a2.htm.

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