SUMMARY PRODUCT CHARECTERISTICS

[Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]

DESCRIPTION	GARDASIL, Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant, is a non-infectious recombinant quadrivalent vaccine prepared from the purified virus-like particles (VLPs) of the major capsid (L1) protein of HPV Types 6, 11, 16, and 18. After thorough agitation, GARDASIL is a white, cloudy liquid.
POTENCY	Each 0.5-mL dose contains approximately 20 mcg of HPV 6 L1 protein, 40 mcg of HPV 11 L1 protein, 40 mcg of HPV 16 L1 protein, and 20 mcg of HPV 18 L1 protein.
THERAPEUTIC INDICATIONS	GARDASIL is a vaccine indicated in girls and women 9 through 26 years of age for the prevention of the following diseases caused by Human Papillomavirus (HPV) types included in the vaccine: 1. Cervical, vulvar, vaginal, and anal cancer caused by HPV types 16 and 18. 2. Genital warts (condyloma acuminata) caused by HPV types 6 and 11. And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, and 18: 3. Cervical intraepithelial neoplasia (CIN) grade 2/3 and Cervical adenocarcinoma in situ (AIS). 4. Cervical intraepithelial neoplasia (CIN) grade 1. 5. Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3. 6. Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3. 7. Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3. GARDASIL is indicated in boys and men 9 through 26 years of age for the prevention of the following diseases caused by HPV types included in the vaccine: 1. Anal cancer caused by HPV types 16 and 18. 2. Genital warts (condyloma acuminata) caused by HPV types 6 and 11. And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, and 18: 1. Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.
DOSAGE & METHOD OF ADMINISTRATION	0.5-mL suspension for intramuscular injection at the following schedule: 0, 2 months, 6 months.
CONTRAINDICATONS	Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of GARDASIL.
SPECIAL WARNINGS & PRECAUTION FOR USE	Because vaccines 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 and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER FORM OF INTERACTION	Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune responses to vaccines.
PREGNANCY & LACTATION	GARDASIL should be used during pregnancy only if clearly needed. It is not known whether GARDASIL is excreted in human milk. Because many drugs

	are excreted in human milk, caution should be exercised when GARDASIL is administered to a nursing woman.
UNDESIRABLE EFFECTS	The most common adverse reaction was headache. Common adverse reactions (frequency of at least 1.0% and greater than AAHS control or saline placebo) are fever, nausea, dizziness; and injection-site pain, swelling, erythema, pruritus, and bruising.
OVERDOSE	There have been reports of administration of higher than recommended doses of GARDASIL. In general, the adverse event profile reported with overdose was comparable to recommended single doses of GARDASIL.
STORAGE OF VACCINES	Store refrigerated at 2 to 8°C (36 to 46°F). Do not freeze. Protect from light. GARDASIL should be administered as soon as possible after being removed from refrigeration. GARDASIL can be out of refrigeration (at temperatures at or below 25°C/77°F), for a total time of not more than 72 hours.
PRESENTATION	1 dose vial plus diluent (0.5ml).
MARKETING AUTHORIZATON HOLDER	Merck Sharp & Dohme Westpoint
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02827