GARDASIL®9
Human Papillomavirus
9-valent Vaccine, Recombinant

October 2018

Product Update:
GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Dear Customer:

Merck is pleased to announce that the US Food and Drug Administration (FDA) has approved an expanded age indication for GARDASIL 9, Merck's 9-valent human papillomavirus (HPV) vaccine. GARDASIL 9 is now approved for use in appropriate patients ages 9 through 45 years to help protect against certain HPV-related cancers and diseases. The previous indication for GARDASIL 9 was for appropriate 9- to 26-year-olds.

DOSING SCHEDULE	9 through 14 years	2-dose	0, 6 to 12 months*
		3-dose	0, 2, 6 months
	15 through 45 years	3-dose	0, 2, 6 months

*If the second dose is administered earlier than 5 months after the first dose, administer a third dose at least 4 months after the second dose.

GARDASIL 9 is supplied in 0.5-mL single-dose vials and prefilled syringes. For your convenience, the packaging, CPT® code, and NDC number are listed below. This information has not been changed.

HOW SUPPLIED	PACKAGING	CPT® CODE[1]	NDC NUMBER
GARDASIL 9 0.5-mL suspension	Carton of ten 0.5 mL single-dose vials	90651	00006-4119-03
GARDASIL 9 0.5-mL suspension	Carton of ten 0.5 mL single-dose prefilled Luer-Lock syringes with tip caps	90651	00006-4121-02

Please read the accompanying press release for GARDASIL 9 announcing the updated indication.

Indication
GARDASIL 9 is a vaccine indicated in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11. GARDASIL 9 is indicated in males 9 through 45 years of age for the prevention of anal cancer caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

IMPORTANT SAFETY INFORMATION ABOUT GARDASIL 9

Select Safety Information
GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL 9 or GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

IMPORTANT SAFETY INFORMATION ABOUT GARDASIL 9 CONTINUED ON NEXT PAGE

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IMPORTANT SAFETY INFORMATION ABOUT GARDASIL 9 (continued)

Limitations of Use

GARDASIL 9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening.

Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care professional.

GARDASIL 9 has not been demonstrated to provide protection against diseases from vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; or cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN).

Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

Select Safety Information (continued)

Because vaccinees 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 HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

Safety and effectiveness of GARDASIL 9 have not been established in pregnant women.

The most common (≥10%) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache. The most common (≥10%) local and systemic reactions in males were injection-site pain, swelling, and erythema.

Dosage and Administration

GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

For individuals 9 through 14 years of age, GARDASIL 9 can be administered using a 2-dose or 3-dose schedule. For the 2-dose schedule, the second dose should be administered 6–12 months after the first dose. If the second dose is administered less than 5 months after the first dose, a third dose should be given at least 4 months after the second dose. For the 3-dose schedule, GARDASIL 9 should be administered at 0, 2 months, and 6 months.

For individuals 15 through 45 years of age, GARDASIL 9 is administered using a 3-dose schedule at 0, 2 months, and 6 months.

Please see the Prescribing Information for GARDASIL 9 and the Patient Information for GARDASIL 9.

If you have any questions regarding GARDASIL 9, please feel free to contact me.

Sincerely,

Your Merck Account Executive

NDC=National Drug Code.

Reference

1. Centers for Disease Control and Prevention. CPT codes mapped to CVX codes. https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt. Updated September 12, 2018. Accessed September 21, 2018.

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