

GARDASIL®9
HELPS PREVENT INFECTION
CAUSED BY 9 HPV TYPES
(6, 11, 16, 18, 31, 33, 45, 52 AND 58)

GARDASIL™9
[Human Papillomavirus
9-valent Vaccine, Recombinant]

NEW!



Worldwide estimated type contribution for certain HPV-related cancer and disease cases³

	4 HPV types (6, 11, 16 and 18) cause:	9 HPV types (6, 11, 16, 18, 31, 33, 45, 52 and 58) cause a total of:
Cervical cancer	70%	90%
High-grade cervical lesions (CIN 2/3)*	50%	80%
Low-grade cervical lesions (CIN 1)*	25%	50%
Vulvar cancer*²	80%	90%
Vaginal cancer*	65%	85%
Anal cancer cases*	85%	90-95%
Genital warts	90%	90%

*Not all cervical precancers, and vulvar, vaginal and anal cancer cases are caused by HPV.

EFFICACY AGAINST CANCERS AND DISEASES CAUSED BY 9 HPV TYPES



**PLUS EFFICACY
AGAINST 5
ADDITIONAL
HPV TYPES**

**CERVICAL CANCER,
VULVAR CANCER,
VAGINAL CANCER,
CIN 2/3, AIS,
VIN 2/3, VaIN 2/3**

HPV 31-, 33-, 45-, 52-,
and 58-related

97%
efficacy

³Study Design: Efficacy of GARDASIL 9 in 16- to 26-year-old women was assessed in an active comparator-controlled, double-blind, randomized clinical study that included a total of 14,204 women (GARDASIL 9=7,099; GARDASIL=7,105). Subjects were followed up to Month 54, with a median duration of follow-up of 40 months, and efficacy was measured starting after the Month 7 visit. Efficacy was evaluated in subjects who received all 3 vaccinations within 1 year of enrollment, had no major deviations from the study protocol, and were naive to the relevant HPV type(s) prior to dose 1 and through 1 month postdose 3 (Month 7).

AiN=anal intraepithelial neoplasia; AIS=adenocarcinoma in situ; CI=confidence interval; CIN=cervical intraepithelial neoplasia; VaIN=vaginal intraepithelial neoplasia; VIN=vulvar intraepithelial neoplasia.

RECOMMENDED DOSING OF GARDASIL®9¹

DOSING REGIMEN

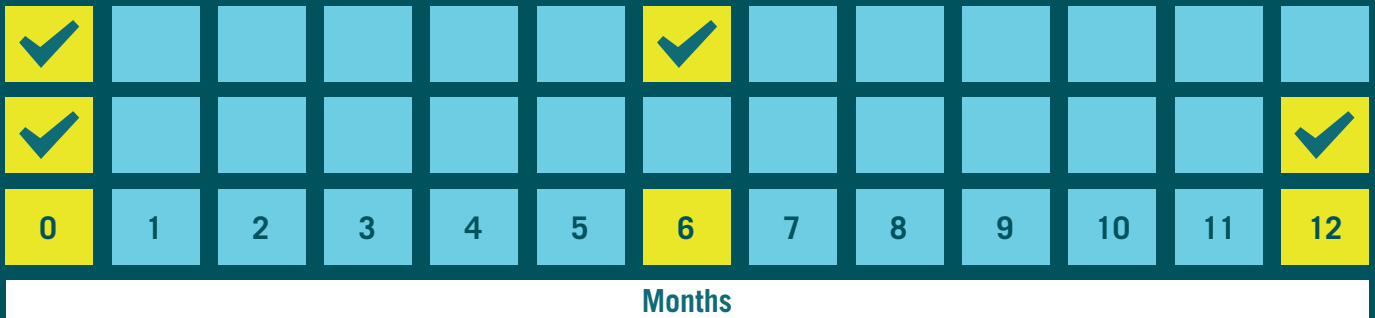


✓ Dosing schedule

Individuals are encouraged to adhere to the 0-, 2- and 6-month vaccination schedule.

If an alternate vaccination schedule is necessary, the second dose should be administered at least 1 month after the first dose, and the third dose should be administered at least 3 months after the second dose.

ALTERNATIVE 2 DOSE REGIMEN IN 9-14 YEARS (0,6 or 0,12 months)



✓ Dosing schedule

Alternatively, in individuals 9 through 14 years of age, GARDASIL 9 can be administered according to a 2-dose schedule; the second dose should be administered between 5 and 13 months after the first dose. If the second vaccine dose is administered earlier than 5 months after the first dose, a third dose should always be administered.

Reference:

- GARDASIL[®]9 package insert
- Z. Zhang et al. *HUMAN VACCINES & IMMUNOTHERAPEUTICS*. 2017; 13(10): 2280-2291
- de Sanjose S, Alemany L, Ordi J, et al. *Eur J Cancer*. 2013;49(16):3450-3461.

GARDASIL 9 is a recombinant vaccine that protects against 9 genotypes of Human Papillomavirus (HPV). **INDICATIONS** GARDASIL 9 is a vaccine indicated in girls and women from 9 years of age on ward for the prevention of cervical, vulvar, vaginal, and anal cancer; precancerous or dysplastic lesions; genital warts; and persistent infections caused by Human Papillomavirus (HPV). GARDASIL 9 is indicated to prevent the following diseases: • Cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 • Genital warts (condyloma acuminata) caused by HPV types 6 and 11 And persistent infections and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 • Cervical intraepithelial neoplasia (CIN) grade 2/3 and Cervical adenocarcinoma in situ (AIS) • Cervical intraepithelial neoplasia (CIN) grade 1 • Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3 • Vaginal intraepithelial neoplasia (VaIN) grade 1 and VaIN grade 1 • Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3. GARDASIL 9 is indicated in boys and men from 9 years of age on ward for the of anal cancer, anal precancerous or dysplastic lesions; external genital lesions (including genital warts); and persistent infections caused by HPV. GARDASIL 9 is indicated to prevent the following diseases: • Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 • Genital warts (condyloma acuminata) caused by HPV types 6 and 11. And persistent infections and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58: • Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3. **DOSAGE AND ADMINISTRATION** GARDASIL 9 should be administered intramuscularly as 3 separate 0.5-mL doses according to the following schedule: First dose: at elected date Second dose: 2 months after the first dose Third dose: 6 months after the first dose Alternatively, in individuals 9 through 14 years of age, GARDASIL 9 can be administered according to a 2-dose schedule; the second dose should be administered between 5 and 13 months after the first dose. If the second vaccine dose is administered earlier than 5 months after the first dose, a third dose should always be administered. **CONTRAINDICATIONS** GARDASIL 9 is contraindicated in patients with hypersensitivity to either GARDASIL 9 or GARDASIL9 or any of the inactive ingredients in either vaccine. Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL 9 or GARDASIL should not receive further doses of GARDASIL 9. **PRECAUTIONS** As for any vaccine, vaccination with GARDASIL 9 may not result in protection in all vaccine recipients. This vaccine is not intended to be used for treatment of active external genital lesions; cervical, vulvar, vaginal, or anal cancers; CIN, VIN, VaIN, or AIN. This vaccine will not protect against diseases that are not caused by HPV. As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. Syncope, sometimes associated with falling, has occurred after HPV vaccination. Therefore, vaccines should be carefully observed for approximately 15 minutes after administration of GARDASIL 9. The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination. Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization. Thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. **DRUG INTERACTIONS** Use with other Vaccines Results from clinical studies indicate that GARDASIL 9 may be administered concomitantly (at a separate injection site) with Menactra (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine), Adacel (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)), and Repevac (Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content) (dTap-IPV). Use of hormonal contraceptives did not appear to affect the type specific immune responses to GARDASIL 9. Use with Steroids 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** There are no adequate and well-controlled studies in pregnant women. **NURSING MOTHERS** GARDASIL 9 may be administered to lactating women. It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. **PEDIATRIC USE** The safety and efficacy of GARDASIL 9 have not been evaluated in children younger than 9 years. **GERIATRIC USE** The safety and efficacy of GARDASIL 9 have not been evaluated in individuals aged 65 years and over. **IMMUNOCOMPROMISED INDIVIDUALS** The immunologic response to GARDASIL 9 may be diminished in immunocompromised individuals. **SIDE EFFECTS** The safety of GARDASIL 9 was evaluated in 7 clinical studies (Protocols 001, 002, 003, 005, 006, 007, 009) Systemic and Injection-Site Adverse Reactions in Clinical Trials of GARDASIL 9 The vaccine-related adverse experiences that were observed among recipients of either GARDASIL 9 or GARDASIL at a frequency of at least 1%. Few individuals (GARDASIL 9 = 0.1% vs. GARDASIL <0.1%) discontinued due to adverse experiences after receiving either vaccine. The safety profile was similar between GARDASIL 9 and GARDASIL in women, men, girls and boys ≥1% Injection-Site Adverse Reactions (1 to 5 Days Postvaccination): Pain, Swelling, Erythema, Pruritus, Bruising. ≥1% Systemic Adverse Reactions (1 to 15 Days Postvaccination): Headache, Pyrexia, Nausea, Dizziness, Fatigue. Post-marketing Experience: syncope sometimes accompanied by tonic-clonic movements, vomiting, cellulitis, idiopathic thrombocytopenic purpura, lymphadenopathy, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, urticaria, acute disseminated encephalomyelitis, Guillain-Barré syndrome, arthralgia, myalgia, asthenia, chills and malaise. **STORAGE** Store refrigerated at 2 to 8°C (36 to 46°F). Do not freeze. Protect from light. Discard the product if it is frozen, particulates are present, or if it appears discolored.

Reference from PI S-LPV903-14032020 approved date 16 Mar 2021

เลขทะเบียนตำรับยา: 1C 50/60 (NCC)

Before Prescribing, Please Read Full Product Information

To request product information, report adverse events, or report product defect, please contact MSD at the address below or dpoc_Thailand@merck.com

ข้อมูลยาใช้เฉพาะแพทย์ รหัส: 915/2564

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารอ้างอิงฉบับสมบูรณ์และเอกสารกำกับยา

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