# GARDASIL™

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

# ZERO BREAKTHROUGH

**High efficacy against HPV**
related cancers and genital warts.

**Long-lasting protection**
more than 10 years

# Favorable Safety Profile


**References:**

1. Ferris DG, et al. Pediatrics. 2017;140(6): e20163947.
2. Kjaer S, et al. Clinical Infectious Diseases. 66(3). 2018: 339–34.
3. Luna J, et al. PLoS ONE. 8(12): 2013: e83431.
4. Human papillomavirus vaccines: WHO position paper, May 2017.
5. Villa L, et al. The New England Journal of Medicine. 356(19); 2007: 1915-1927.
6. Gardasil package insert.
7. Markowitz L, et al. MMWR. 56(RR02);2007: 1-24.
8. CDC. https://www.cdc.gov/hpv/parents/vaccinesafety.html. Access October 1, 2019.


**Study Design:**

1. LTFU 1661 sexually inactive boys and girls received the 4vHPV vaccine (early vaccination group [EVG], managed for 9 9 years) or a placebo. Thereafter, at month 30, the placebo group (catch-up vaccination group [CVG]), received the 4vHPV vaccine. Long-term anti-HPV type 6, 11, 16, and 18 immune responses were assessed.
2. LTFU is an ongoing 10-year extension of the 4-year base study (FUTURE II) in the Nordic countries. Vaccine effectiveness against HPV16/18-related CIN2 or worse (CIN2+) was estimated by comparing the observed incidence with the expected incidence of CIN2+ in an unvaccinated cohort using historical registry data.
3. Follow-up data are from a study being conducted in 5 sites in Colombia designed to evaluate the long-term immunogenicity, effectiveness, and safety of the qHPV vaccine in women who were vaccinated at 24 to 45 years of age. This analysis summarizes data collected as of the year 6 post-vaccination visit relative to day 1 of the base study from both the original base study and the Colombian follow-up.
5. (The Future II) A randomized, double-blind trial, assigned 12,167 women between the ages of 15 and 26 years to receive three doses of either HPV-6/11/16/18 vaccine or placebo, administered at day 1, month 2, and month 6. The primary composite end point was cervical intraepithelial neoplasia grade 2 or 3,adenocarcinoma in situ, or cervical cancer related to HPV 16 or HPV-18.

**SUMMARY INFORMATION AND SAFETY PROFILE OF GARDASIL**

GARDASIL® is a vaccine indicated in girls and women 9 through 45 years for the prevention of cervical, vulvar, vaginal, and anal cancer; precancerous or dysplastic lesions; and genital warts caused by Human Papillomavirus (HPV) types.

**GARDASIL** is indicated to prevent the following diseases:

- Cervical, vulvar, vaginal, and anal cancer caused by HPV types 16 and 18
- Cervical, vulvar, and vaginal precancerous lesions grade 2/3 and cervical adenocarcinoma-in-situ (AIS)
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Anal precancerous lesions (AIN) grades 1, 2, and 3
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11
  And infections and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, and 18:
- Cervical intraepithelial neoplasia (CIN) grade 1
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Anal precancerous neoplasia (AIN) grades 1, 2, 3

The safety and efficacy of **GARDASIL** in female older than 26 years of age also have been evaluated.

**GARDASIL** is indicated in boys and men 9 through 26 years of age for the prevention of precancerous lesions and infection and the following diseases caused by HPV types included in the vaccine:

- Anal cancer caused by HPV types 16 and 18
- Anal precancerous neoplasia (AIN) grades 1, 2, and 3
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11
  And the precancerous or dysplastic lesions caused by HPV types 6, 11, 16, and 18.

**Limitation of GARDASIL** Use in Pregnancy

Women who receive **GARDASIL** should continue to undergo cervical cancer screening per standard of care.

**GARDASIL** has not been demonstrated to prevent disease from HPV types to which a person has previously been exposed through sexual activity.

**GARDASIL** is not intended to be used for treatment of active external genital lesions, cervical, vulvar, vaginal, or anal cancers, CIN, VIN, VaIN, or AIN.

**GARDASIL** has not been demonstrated to provide protection against disease due to HPV types not contained in the vaccine.

**GARDASIL** does not treat HPV infection or abnormal cervical, vulvar, vaginal, or anal cytology, including abnormal Pap tests and visual findings.

Abnormal vulvar and vaginal cancers are caused by HPV 16 and 18. **GARDASIL** protects only against those vulvar and vaginal cancers caused by HPV 16 and 18.

**GARDASIL** does not protect against genital diseases not caused by HPV.

Women who receive **GARDASIL** may not result in protection in all vaccinated subjects.

Women on with **GARDASIL** may not result in protection in all vaccinated subjects. The decision to vaccinate an individual woman should take into account

**DOSAGE AND ADMINISTRATION** **GARDASIL** 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 All three doses should be given within a 1-year period
Alternatively, in individuals 9 through 13 years of age, Gardasil can be administered according to a 2-dose (0, 6 months or 0, 12 months) schedule. Method of Administration
**GARDASIL** should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.
**GARDASIL** must not be injected intravascularly. Neither subcutaneous nor intradermal administration has been studied. These methods of administration are not recommended The prefilled syringe is for single use only and should not be used for more than one individual. For single-use vials a separate sterile syringe and needle must be used for each individual.

**Contraindication** **GARDASIL** contraindicated in individuals who are hypersensitive to the active substances or to any of the excipients of the vaccine.
Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of **GARDASIL** should not receive further doses of **GARDASIL**.

**Precaution** Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. Therefore, vaccinees should be carefully observed for approximately 15 minutes after administration of **GARDASIL**. 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.
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. This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals Pregnancy should be avoided during the vaccination regimen for **GARDASIL**.
**GARDASIL** may be administered to lactating women. The safety and efficacy of **GARDASIL** have not been evaluated in pediatric (younger than 9 years), elderly (adult above the age of 45 years) and HIV-infected individuals

**Side Effects** The vaccine-related adverse experiences that were observed among recipients of GARDASIL at a frequency of at least 1.0% and also at a greater frequency than that observed among placebo recipients are listed according to frequency and system organ class.

**Vaccine-Related Clinical Adverse Experiences in 9-Through 45-Year-Old Girls and Women**

| | | |
|---|---|---|
| Nervous system disorders | Gastrointestinal disorders | Musculoskeletal and connective tissue disorders |
| Very Common : headache | Common : nausea | Common : pain in extremity |
| Common : dizziness | | |

In addition, bronchospasm was reported very rarely as a serious adverse experience.

**Vaccine-Related Clinical Adverse Experiences in 9-Through 26-Year-Old Boys and Men**

| | |
|---|---|
| Nervous system disorders | General disorders and administration site conditions |
| Common : headache | Common : pyrexia |

Most injection-site reactions were mild to moderate;

**Post-Marketing reports**
The following adverse experiences have been spontaneously reported during post-approval use of **GARDASIL**: cellulitis, idiopathic thrombocytopenic purpura, lymphadenopathy, acute disseminated encephalomyelitis, dizziness, Guillain-Barr syndrome, headache, syncope sometimes accompanied by tonic-clonic movements, nausea, vomiting, arthralgia, myalgia, asthenia, chills, fatigue, malaise, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

**Storage** 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 totaltime of not more than 72 hours. Reference from PI THL-V501-102015 approved date 17 Sep 2018before Prescribing.
Please Read Full Product Information

Before prescribing, please review the full prescribing information. To report a product exposure, report adverse events, or report quality complaint, please contact MSD at the address below
MSD(Thailand) Ltd. The Offices at Central World 999/9, Unit 2801-2812, 28th Floor Rama 1 Road, Pathumwan, Bangkok, 10330 tel.02-262-1700 fax. 02-255-5096 or dpoc_thailand@merck.com

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