Approval Date: April 24, 2015

Product: Gardasil

Proper Name: Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant

Manufacturer: Merck & Co., Inc

Indication:

- Prevention of vulvar and vaginal cancer
- Vaccination in females 9 through 26 years of age for prevention of the following diseases caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18:
    - Cervical cancer
    - Genital warts (condyloma acuminata) and the following precancerous or dysplastic lesions:
        - Cervical adenocarcinoma in situ (AIS)
        - Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
        - Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
        - Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
        - Cervical intraepithelial neoplasia (CIN) grade 1
- Vaccination in boys and men 9 through 26 years of age for the prevention of genital warts caused by HPV types 6 and 11
- Vaccination in people ages 9 through 26 years for the prevention of anal cancer and associated precancerous lesions due to human papillomavirus (HPV) types 6, 11, 16, and 18

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. The L1 proteins are produced by separate fermentations in recombinant Saccharomyces cerevisiae and self-assembled into VLPs.

BLA: 125126

Regulatory Milestone:

Gardasil was first licensed for use in the U.S. on June 8, 2006 with subsequent approvals of supplements in 2008, 2009, and 2010.

PDUFA Goal Date: April 26, 2015

Package Insert: Package Insert - Gardasil

Summary Basis for Regulatory Approval: April 24, 2015 Summary Basis for Regulatory Action - Gardasil

European Public Assessment Report: Human medicine European public assessment report (EPAR): Gardasil

Advisory Committee:

This submission was not discussed at a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting because review of this submission did not identify concerns which would have benefitted from an advisory committee discussion.

Safety:

In the data presented in this submission, no signals of new medical conditions, new SAEs assessed as vaccine-related, or other new safety signals were identified. No new safety information was proposed to be included in the modified USPI.

NCT Numbers:

- NCT01741012
- NCT02567955
- NCT03431246
- NCT02993757
- NCT01456715
- NCT00786409
- NCT00157950
- NCT01304498
- NCT03083249
- NCT00727636
- NCT02114385
- NCT01062074
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- NCT03465280
- NCT02934724
- NCT01928225

EudraCT Numbers:

- 2019-003135-36
- 2006-000764-85
- 2020-002332-73
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- 2014-005717-23
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- 2015-004212-37
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- 2019-001153-10
- 2013-001314-15
- 2009-011617-25

Publications:

- FUTURE II Study Group (2007). Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions. *The New England journal of medicine*, *356*(19), 1915–1927. https://doi.org/10.1056/NEJMoa061741
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to Unilaterally Reduce Endo/Ectocervical Disease (FUTURE) I Investigators (2007). Quadrivalent vaccine against human papillomavirus to prevent anogenital diseases. *The New England journal of medicine*, *356*(19), 1928–1943. https://doi.org/10.1056/NEJMoa061760

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