Generic Name:
Human papillomavirus 9-valent vaccine, recombinant
Trade Name:
Gardasil 9
Company:
Merck, Sharp & Dohme
Notes:

FDA approved a supplemental application for human papillomavirus (HPV) 9-valent vaccine, recombinant (Gardasil 9), expanding the approved use to include women and men aged 27 through 45 years. Gardasil 9 prevents certain cancers and diseases caused by the nine HPV types covered by the vaccine.

Gardasil, a vaccine approved by FDA in 2006 to prevent certain cancers and diseases caused by four HPV types, is no longer distributed in the United States. In 2014, FDA approved Gardasil 9, which covers the same four HPV types as Gardasil, as well as an additional five HPV types. Gardasil 9 was approved for use in males and females aged 9 through 26 years.

Effectiveness of Gardasil is relevant to Gardasil 9 since the vaccines are manufactured similarly and cover four of the same HPV types. In a study in approximately 3,200 women aged 27 through 45 who were followed for an average of 3.5 years, Gardasil was 88% effective in preventing a combined endpoint of persistent infection, genital warts, vulvar and vaginal precancerous lesions, cervical precancerous lesions, and cervical cancer related to HPV types covered by the vaccine.

FDA?s approval of Gardasil 9 in women aged 27 through 45 is based on these results and new data on long-term follow-up from this study.

Effectiveness of Gardasil 9 in men aged 27 through 45 is inferred from the data described above in women aged 27 through 45, as well as efficacy data from Gardasil in younger men (aged 16?26 y) and immunogenicity data from a clinical trial in which 150 men, aged 27 through 45, received a three-dose regimen of Gardasil over 6 months.

Safety of Gardasil 9 was evaluated in approximately 13,000 males and females. The most commonly reported adverse reactions were injection-site pain, swelling, redness, and headaches.

FDA granted the Gardasil 9 application priority review status. This program facilitates and expedites the review of medical products that address a serious or life-threatening condition.

Medication Monitor Categories:
Supplemental Approvals