RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant) Injection Clinical Update

Clinical update: FDA Approves Merck's Gardasil 9 for the Prevention of Certain HPV-Related Head and Neck Cancers.
FDA approval date: June 12, 2020

Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant) is a 9-valent HPV vaccine indicated for use in:

- Girls and women 9 through 45 years of age for the prevention of:
  - cervical, vulvar, vaginal, oropharyngeal and other head and neck cancers caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58.
  - genital warts (condyloma acuminata) caused by HPV types 6 and 11.
  - precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.
- Boys and men 9 through 45 years for the prevention of:
  - anal, oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58.
  - genital warts (condyloma acuminata) caused by HPV types 6 and 11.
  - precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

Gardasil 9 does not eliminate the necessity for vaccine recipients to undergo screening for cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers as recommended by a healthcare provider.
Gardasil 9 is ineffective against diseases caused by HPV types not covered by the vaccine and HPV types to which a person has previously been exposed through sexual activity.
Vaccination with Gardasil 9 may not result in protection in all vaccine recipients.

The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The trial is currently underway.
Gardasil 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast.
The most common (≥10%) local and systemic adverse reactions in both males and females were injection-site pain, swelling, erythema, and headache.