

Human Papillomavirus Vaccine [Nonavalent (types 6, 11, 16, 18, 31, 33, 45, 52, and 58)] GARDASIL®9

Supplier: Merck Canada Inc.

INDICATIONS: ^A

- All students in grade 6 to 12. Routine program in Grade 6, with catch-up in other grades and a variety of community based settings.^{B, C, D}
- HIV positive individuals 9-26 years of age (inclusive) who have not received a complete series of HPV vaccine ^E
- Cisgender males 19-26 years of age (inclusive) at the time of series commencement who are:^D
 - men who have sex with men (including those who are not yet sexually active and are questioning their sexual orientation)
 - street involved
- Two-Spirit, transgender, and non-binary individuals 19-26 years of age (inclusive) at the time of series commencement ^D

RECOMMENDED BY THE NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION BUT NOT PROVIDED FREE IN BC:

- Women 19-45 years of age
- Males 19-26 years of age (who are not indicated above) ^F
- Males 27 years of age and older who are men who have sex with men

DOSES AND SCHEDULE: ^G

Immunocompetent individuals 9-14 years of age (inclusive): 2 doses given as 0.5 mL **IM**, separated by at least 6 months.^H

Immunocompromised individuals 9-14 years of age (inclusive): 3 doses given as 0.5 mL **IM** at 0, 2, and 6 months.

Individuals 15 years of age and older: 3 doses given as 0.5 mL **IM** at 0, 2, and 6 months.

ADMINISTRATION:

No additional requirements.

^A Information regarding gender terminology can be found in the PHSA [glossary of terms](#) related to trans health and services.

^B These individuals are eligible to initiate a series prior to age 19, but not thereafter. The exception to this is for the cohort of cisgender males born in the first half of 2005 (i.e., January to June), who can initiate their series until June 30, 2024. A series commenced prior to age 19 may be completed with publicly funded HPV vaccine prior to the 26th birthday.

^C Can be given as early as 9 years of age in exceptional circumstances (e.g., at high risk of HPV exposure).

^D GARDASIL®9 should be used to complete an HPV series that was initiated with GARDASIL®. Clients should be informed that a complete series of GARDASIL®9 is recommended to ensure protection against the five additional HPV types in the vaccine; however, additional doses of GARDASIL®9 beyond a complete HPV series are not part of the publicly-funded program.

^E Those HIV positive individuals who are incompletely immunized and have started an HPV series with either CERVARIX® or GARDASIL® should receive a complete series of GARDASIL®9.

^F The vaccine is approved for use in males up to 45 years of age, although not yet addressed by NACI.

^G Immunocompetent individuals initiating immunization prior to their 15th birthday should be immunized using a 2-dose series. Immunocompromised individuals (including those with HIV infection) and those initiating immunization at 15 years of age and older should be immunized using a 3-dose series.

^H If the interval between doses in a 2-dose HPV schedule is shorter than 5 months (150 days), a 3rd dose should be given at least 24 weeks after the 1st dose and 12 weeks after the 2nd dose.

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BOOSTER DOSES:

No booster doses are recommended at this time.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of any HPV vaccine or to any component of GARDASIL®9.

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80, yeast protein.

Other components: amorphous aluminum hydroxyphosphate sulfate, L-histidine, sodium borate.

PRECAUTIONS:

- HPV vaccine is not recommended during pregnancy. Individuals who become pregnant before series completion should defer immunization until no longer pregnant. In pregnant individuals who are inadvertently vaccinated, there is no need to consider any intervention except reassurance, as the vaccine has not been associated with teratogenicity. Data from post-licensure surveillance indicate no greater rates of adverse outcomes of pregnancy or adverse events in the developing fetus in individuals who received the HPV vaccine during pregnancy compared to the general population. ^{A, B, C} Given these data and low rates of live births within the under 15 year age group, screening for pregnancy is not required prior to offering HPV vaccine within routine school-based programs (i.e., grade 6 and 9). The HPV vaccine may be administered to individuals who are breast/chest feeding.

SPECIAL CONSIDERATIONS:

- Individuals may be immunized even if they are already sexually active or have had a known HPV infection. The likelihood they have been exposed to all types of HPV contained in the vaccine is low and they stand to benefit from immunization.
- Those with previous Pap abnormalities (including cervical cancer) may be immunized. Sexually active vaccine recipients should continue to be routinely screened for cervical cancer based on BC Cancer Cervix Screening Program recommendations.
- If applicable, advise vaccine recipients that the HPV vaccine is a preventive vaccine, and does not have any therapeutic effect on existing cervical lesions (i.e., vaccine does not prevent the consequences of current HPV infection). Although there is some emerging evidence that there is some reduction in recurrence of anal and cervical intraepithelial neoplasia when the HPV vaccine is used for clients in the anoscopy and colposcopy setting, these benefits are still to be confirmed, and there are no therapeutic indications for the use of the vaccine.

^A Goss MA, Lievano F, Buchanan KM, et al. Final report on exposure during pregnancy from a pregnancy registry for quadrivalent human papillomavirus vaccine. *Vaccine* 2015;33:3422-8.

^B Phillips A, Hickie M, Totterdell J, et al. Adverse events following HPV vaccination: 11 years of surveillance in Australia. *Vaccine* 2020;38:6038-46.

^C Sy LS, Meyer KI, Klein NP, et al. Postlicensure safety surveillance of congenital anomaly and miscarriage among pregnancies exposed to quadrivalent human papillomavirus vaccine. *Hum Vaccine Immunother* 2018;14(2):412-19.

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SPECIAL CONSIDERATIONS (continued):

- Those who are immunocompromised, either from disease or medication, can be immunized; however, the immune response to vaccination and vaccine efficacy may be less than in immunocompetent individuals.
- Individuals who started an HPV series with GARDASIL® and wish to complete the series with GARDASIL®9 should be informed that a complete series of GARDASIL®9 is recommended to ensure protection against the 5 additional HPV types in the vaccine.
- While there are no supporting data at this time, a minimum interval of 6 months is recommended between completion of a GARDASIL® series and initiation of a GARDASIL®9 series.

ADVERSE EVENTS:

Local: pain, redness, swelling.

Systemic: headache, fever.