

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

Supplier: Merck Canada Inc.

INDICATIONS:

- Grade 6 students – routine immunization program ^{A, B}
- HIV positive individuals 9-26 years of age (inclusive) who have not received a complete series of HPV vaccine ^C
- Males 9-26 years of age (inclusive) at the time of series commencement who are: ^B
 - men who have sex with men (including those who are not yet sexually active and are questioning their sexual orientation)
 - street involved
- Males 9-18 years of age (inclusive) in the care of the Ministry of Children and Family Development (MCFD) ^B
- Males in youth custody services centres ^B
- Transgender individuals 9-26 years of age (inclusive) ^B

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

- Women 19-45 years of age
- Males 9-26 years of age (who are not indicated above)
- Males 27 years of age and older who are men who have sex with men

DOSES AND SCHEDULE: ^D

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

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 Those who do not commence a series in grade 6 are eligible to initiate a series prior to age 19 (for males, born in 2006 or later), but not thereafter. A series commenced prior to age 19 may be completed with publicly funded HPV vaccine prior to the 26th birthday.

^B 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.

^C 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.

^D 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.

^E 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.
2. Pregnancy. The vaccine should not be given during pregnancy because safety of receipt of HPV vaccine during pregnancy has not been adequately studied. Women who become pregnant before series completion should defer immunization until no longer pregnant. In pregnant women who are inadvertently vaccinated, there is no need to consider any intervention except reassurance, as the vaccine has not been associated with teratogenicity.

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80, yeast protein.

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

PRECAUTIONS:

Not applicable.

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.
- Women who have had previous Pap abnormalities (including cervical cancer) may be immunized. Sexually active female vaccine recipients should continue to be routinely screened for cervical cancer.
- 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.
- 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.

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ADVERSE EVENTS:

Local: pain, redness, swelling.

Systemic: headache, fever.