

Human Papillomavirus 9-valent Vaccine (HPV 9)

Date: January 4, 2018

Rationale for update: Two-dose schedule for immunocompetent individuals ages 9-14 years of age inclusive.

Implementation date: September 1, 2018	
Please consult the Product Monograph ¹ for further information about the vaccine.	
	GARDASIL[®] 9
Manufacturer	Merck Canada Inc.
Licensed for	<ul style="list-style-type: none"> Females 9 years of age up to and including 45 years of age. Males 9 years up to and including 26 years of age.
Off-license use	None
Indications for use of provincially funded vaccine	<ul style="list-style-type: none"> Grade 6 students – routine immunization program. Students eligible to receive vaccine in Grade 6 continue to be eligible to receive the vaccine until the end of Grade 12 if they present to public health. Individuals 17 to 26 years of age biologically male at birth who have sex with individuals biologically male at birth.² Hematopoietic Stem Cell Transplantation (HSCT) recipients: See Immunization for Child Hematopoietic Stem Cell Transplant Recipients. Solid organ transplant (SOT) candidates and recipients: See Immunization for children Expecting Solid Organ Transplant after 18 Months of Age (Catch-up Schedule) and Immunization for Adult Solid Organ Transplant Candidates and Recipients.
Dose	0.5 mL
Route	Intramuscular injection
Schedule	<p>Immunocompetent and non HIV infected individuals ages 9-14 years of age inclusive (2-dose series):²</p> <p style="padding-left: 40px;">Dose 1: day 0</p> <p style="padding-left: 40px;">Dose 2: six months after dose 1</p> <p>Immunocompromised and/or HIV infected individuals ages 9-14 years of age inclusive (3-dose series):²</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: two months after dose 1 ❖ Dose 3: six months after dose 1 <p>Individuals 15 years of age and older (3 dose series):²</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: two months after dose 1 ❖ Dose 3: six months after dose 1 <p>Notes:</p> <ul style="list-style-type: none"> The number of recommended doses in a series is based on the age at administration of the first dose. In immunocompetent individuals 15 years of age and older who received the first dose between 9 to less than 15 years of age a two-dose schedule can be used, with the second dose administered at least 6 months after the first dose.^{2,3}

	<ul style="list-style-type: none"> • In a two-dose schedule the minimum interval is 24 weeks between the first and second dose.^{2,3} • In a three-dose schedule the minimum interval between the first and second doses of vaccine is 4 weeks, the minimum interval between the second and third doses of vaccine is 12 weeks, and the minimum interval between first and last doses is 24 weeks.⁴ • Eligible individuals, who began their series with GARDASIL[®] (HPV4) can complete the series using GARDASIL[®]9.³ However, they should be advised that protection against HPV types 31, 33, 45, 52, and 58 cannot be ensured.² • There is insufficient evidence at this time to recommend, at a population level, the re-immunization with HPV9 of individuals who have completed an immunization series with another HPV vaccine.²
Contraindications	<ul style="list-style-type: none"> • Known severe hypersensitivity to any component of GARDASIL[®]9. • Anaphylactic reactions to a previous dose of vaccine.
Precautions	<ul style="list-style-type: none"> • None identified
Possible reactions	<p>Local reactions:</p> <ul style="list-style-type: none"> • Pain, swelling, erythema, and pruritus at the injection site.¹ <p>Systemic reactions:</p> <ul style="list-style-type: none"> • Fever, nausea, dizziness, headache, fatigue, myalgia, diarrhea and upper abdominal pain.¹ • The following events have been reported from post-marketing surveillance of GARDASIL[®] and may also be seen in post-marketing with GARDASIL[®]9: anaphylaxis, bronchospasm, autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy, acute disseminated encephalomyelitis, Guillain-Barré syndrome, motor neuron disease, paralysis, syncope, transverse myelitis, pancreatitis, pulmonary embolus, asthenia, chills, fatigue, malaise, cellulitis, urticaria, vomiting, diarrhea, myalgia, arthralgia and death.¹ <p>Refer to: <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.</i>⁵</p>
Pregnancy	<p>HPV vaccine is not recommended for use in pregnancy or women who become pregnant before the completion of the three-dose schedule. If pregnant, immunization with the remaining doses of vaccine should be delayed until after delivery.^{1,2} If a vaccine dose has been administered during pregnancy, Merck Canada should be contacted to report incident.¹ The effect of GARDASIL[®]9 upon embryonic and fetal development has not been assessed in humans.¹</p>
Lactation	<p>GARDASIL[®]9 may be administered to breastfeeding women. It is not known if GARDASIL[®]9 vaccine antigens or antibodies induced by vaccine are excreted in human milk.²</p>

References

- ¹ Merck Canada Inc. (2016, December 15). GARDASIL®9: Human Papillomavirus 9-valent Vaccine, Recombinant. *Product Monograph*.
- ² National Advisory Committee on Immunization. (2017). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html
- ³ Immunization Action Coalition. (2017, July 26). Ask the Experts. Retrieved December 21, 2017 from http://www.immunize.org/askexperts/experts_hpv.asp
- ⁴ National Advisory Committee on Immunization. (2016 July 7). Updated Recommendations on Human Papillomavirus (HPV) Vaccines: 9-valent HPV vaccine and clarification of minimum intervals between doses in the HPV immunization schedule.
- ⁵ Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*. <https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/7598f59a-3dfc-4c70-9065-c3bf5b4ee363/download/AIP-AEFI-Policy.pdf>