

Human Papillomavirus 9-Valent Vaccine

BIOLOGICAL PAGE

Section 7	Biological Product Information	Standard # 07.241
Created and approved by	Provincial Immunization Program	
Approval date	September 1, 2016	Published March 2, 2026
	Gardasil 9	
Manufacturer	Merck Canada Inc.	
Classification	Inactivated: Recombinant	
Indications for Provincially Funded Vaccine	Grade 6 students – routine immunization program - For students in ungraded classes, vaccine can be provided on a case-by-case basis, generally at 11 to 12 years up to and including 26 years of age. - The guiding principle is to offer protection to students prior to them leaving the school system. Note: - Public health will assess all students in grades 6 through 9 to ensure they are up to date for HPV-9. Individuals who did not receive HPV in grade 6 remain eligible to receive the vaccine up to and including 26 years of age. - Individuals initiating the HPV vaccine series at 26 years of age who will be 27 years of age when they complete the series are eligible for provincially funded vaccine. Individuals who do not complete the series before their 28th birthday will no longer be eligible for provincially funded vaccine. Hematopoietic Stem Cell Transplantation (HSCT) Recipients: - All HSCT recipients 9 years up to and including 45 years of age. See Standard for Immunization of Transplant Candidates and Recipients. Solid Organ Transplant (SOT) Candidates and Recipients: - SOT candidates 7 and 8 years of age at the request of their specialist - All SOT candidates and recipients 9 years up to and including 45 years of age. See Standard for Immunization of Transplant Candidates and Recipients.	
Schedule	Immunocompetent and non-HIV infected individuals (2-dose series): - Dose 1: day 0 - Dose 2: 6 months after dose 1 Immunocompromised and/or HIV infected individuals (3-dose series): - Dose 1: day 0 - Dose 2 –: 2 months after dose 1 - Dose 3 –: 6 months after dose 1 Note: - In a 2-dose schedule the minimum interval is 24 weeks between the first and second doses. - 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. The minimum interval between the first and last dose is 24 weeks. - When reviewing immunization records, for HPV4 vaccine, if the third dose was administered at less than the interval outlined above, the dose can be considered valid.	

	Gardasil 9
	Vaccine would not need to be repeated if there is a minimum interval of at least 4 months (16 weeks) between the first and third dose. This spacing must not be used to schedule immunization rounds/appointments. This direction does not apply to HPV9. • Individuals who have received the first 2 doses of a 3-dose schedule, with less than a 24-week interval between doses 1 and 2, need to complete the 3-dose series. • Do not restart an interrupted schedule. • Individuals who are immunocompetent and started an HPV series between 9 to 14 years of age prior to September 1, 2018, can be considered complete if they received 2 doses of vaccine a minimum of 24 weeks apart. • Individuals with immunization started in another province or territory as part of a funded program can be completed as they present to public health. Use the current Alberta schedule and dose. • There is insufficient evidence to recommend the re-immunization with HPV-9 of individuals who have completed an immunization series with another HPV vaccine.
Preferred Use	N/A
Dose	0.5 mL
Route	IM
Contraindications/ Precautions	Contraindications: • Known severe hypersensitivity to any component of the vaccine. • Anaphylactic or other allergic reaction to previous dose of vaccine containing similar components. Precautions: • None identified.
Possible Reactions	Common: • Pain, swelling, redness, itching, bruising, mass, hemorrhage, hematoma and redness at injection site • Headache, fever, nausea, dizziness, fatigue, diarrhea, myalgia, oropharyngeal pain, abdominal pain. Rare: • Anaphylaxis, allergic reactions • Asthmatic crisis • Serious adverse events are rare, and, in most cases, data are insufficient to determine a causal association. Clinical trials have found no increase in the number or type of serious adverse events in recipients of HPV vaccine compared with those who received placebo. • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	May be used during pregnancy. • Pregnant individuals who are unimmunized remain at risk of HPV infection and HPV related morbidity during their pregnancy. • Current evidence suggests there is no increased risk of adverse pregnancy or fetal outcomes linked to HPV immunization during pregnancy. • Routine questioning about last menstrual period or pregnancy is not required or recommended before offering HPV vaccine.
Lactation	May use for individuals who are lactating/feeding their milk to infants or children.
Composition	Each 0.5 mL dose contains:

	Gardasil 9
	• 30 mcg of HPV 6 L1 protein • 40 mcg of HPV 11 L1 protein • 60 mcg of HPV 16 L1 protein • 40 mcg of HPV 18 L1 protein • 20 mcg of HPV 31 L1 protein • 20 mcg of HPV 33 L1 protein • 20 mcg of HPV 45 L1 protein • 20 mcg of HPV 52 L1 protein • 20 mcg of HPV 58 L1 protein • 500 mcg aluminum (amorphous aluminum hydroxyphosphate sulphate adjuvant) • 9.56 mg sodium chloride • 0.78 mg L-histidine • 50 mcg polysorbate 80 • 35 mcg sodium borate • water for injection
Blood/Blood Products	Does not contain human blood/blood products.
Bovine/Porcine Products	Does not contain bovine or porcine products.
Latex	Does not contain latex.
Interchangeability	HPV vaccines can be used interchangeably. • Individuals who began their immunization series with CERVARIX or Gardasil can complete the series using GARDASIL9. • All 3 vaccines provide protection against HPV types 16 and 18. • If less than the recommended number of doses of Gardasil9 vaccine are provided, protection against the additional HPV types cannot be ensured. ◦ Provide client counseling at the time of immunization. • Use the manufacturer recommended dose and schedule.
Administration with Other Products	May be given at the same time as other inactivated and live vaccines. • Use a separate needle and syringe for each vaccine. • The same limb may be used if necessary but use different sites on the limb.
Additional Preparation Instructions	Shake well before use.
Appearance	Vaccine appears as a white, cloudy liquid after agitation.
Storage	• Store at +2°C to +8°C • Do not freeze • Do not use beyond the labeled expiry date • Store in original package to protect from light
Vaccine Code	HPV-9
Antigen Code	HPV
Licensed for	• Individuals 9 years of age up to and including 45 years of age.
Notes	• 2008/2009 School Year: HPV vaccine became part of the routine Alberta Immunization Program for grade 5 girls. • 2009/2010 School Year: HPV vaccine was made available to grade 9 girls for a 3 year catch up program. • November 2012: HPV vaccine eligibility expanded to include: ◦ Females who were eligible in grade 5 would remain eligible to the end of grade 12 ◦ Male and female recipients of HSCT 9 years up to and including 17 years of age.

	Gardasil 9
	- July 2014: HPV vaccine eligibility expanded to include male recipients of HSCT 9 years up to the end of grade 12. - September 2014: HPV vaccine was included in the routine school immunization program for boys in grade 5. In addition, a catch-up program was offered to grade 9 boys for a 4-year time period, ending in June 2018. - September 1, 2016: Gardasil® 9 vaccine replaced Gardasil® vaccine for all eligible individuals. - October 2017: HPV eligibility was expanded to include MSM age 17 up to and including 26 years. - September 2018: HPV schedule was changed to a 2-dose series for immunocompetent and non-HIV infected individuals ages 9 to 14 years of age inclusive. In addition, the routine school immunization program for HPV vaccine changed from being offered in grade 5 to grade 6. - May 2020: Expanded eligibility to include males and females 17 years up to and including 26 years of age starting July 1, 2020. Students remain eligible up to and including 26 years of age. - January 29, 2024: Expanded indications for provincially funded vaccine to include SOT and HSCT recipients up to and including 45 years of age - August 1, 2025: Updated to include that pregnant individuals and SOT candidates who are 7 up to including 8 years of age can receive HPV vaccine, and to incorporate 2-dose scheduling for all individuals who are immunocompetent and non-HIV infected.
Related Resources	Human Papillomavirus Vaccine Information Sheet
References Chin-Hong, P. V. et al. (2019 May). <i>Human papillomavirus infection in solid organ transplant recipients: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice</i>. (2019;33:e13590. Doi.org/10.1111/ctr.13590). <i>Clinical Transplantation</i>. Expert opinion of Alberta HSCT, SOT and infectious disease physicians. (November 2023). Hilgendorf, I. et al. (2010, October 14). Vaccination of allogeneic hematopoietic stem cell transplant recipients. Report from the International Consensus Conference on Clinical Practice in chronic GVHD. (29 (2011) 2825-2833). <i>Vaccine</i>. Imburgia, T. I. et al. (2021 April). Considerations for Child Cancer Survivors and Immunocompromised Children to Prevent Secondary HPV-associated Cancers. (2021; 105: 736-742). <i>Transplantation</i> Madeleine, M. et al. (2013, August 12) HPV-Related Cancers After Solid Organ Transplantation in the United States. (2013: 13: 3202-3209). <i>American Journal of Transplantation</i>. Merck Canada Inc. (2024, May 17). GARDASIL9: Human Papillomavirus 9-valent Vaccine, Recombinant. Health Canada drug product database. 00075639.PDF (hres.ca) Miller, P.D. et al. (2022, November 10) Joint consensus statement on the vaccination of adult and pediatric hematopoietic stem cell transplant recipients: Prepared on behalf of the British society of blood and marrow transplantation and cellular therapy (BSBMTCT), the Children's cancer and Leukemia Group (CCLG), and British Infection Association (BIA). In <i>Journal of Infections</i> 86 (2023) 1-8. National Advisory Committee on Immunization. (2016, July 7). <i>Updated Recommendations on Human Papillomavirus (HPV) Vaccines: 9-valent HPV vaccine and clarification of minimum intervals between doses in the HPV immunization schedule</i>. Public Health Agency of Canada. Papastamelis, C. & Linder, M. (2022 April) Human papillomavirus anogenital screening in solid organ transplant recipients: a narrative review. In <i>Archives of Gynecology and Obstetrics</i> 307:1277-1283. Primary and Preventative Health Services. (2025, August 1) Human Papillomavirus 9-valent Vaccine. In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta. Primary and Preventative Health Services. (2024, April 2) Adverse Events Following immunization (AEFI) Policy for Alberta Immunization Providers. In <i>Alberta Immunization Policy: Adverse events – immunization</i>. Government of Alberta. Shanis, D. et al. (2012 January). Female long-term survivors after allo-HSCT: evaluation and management. <i>NIH Public Access</i>. (nihms330040.pdf doi:10).	