



# **Yukon Immunization Program Manual**

## **Section 8 - Biological Products**

### **Human Papilloma Virus (HPV) Vaccine**





SECTION 8 – BIOLOGICAL PRODUCTS

Community Health Programs  
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**GARDASIL®9 Human Papilloma Virus Vaccine**

<b>Manufacturer</b>	Merk Canada Inc.	<b>Biological Classification</b>	Recombinant Vaccine
<b>INDICATIONS</b>	<b>Publicly funded Indication</b>		<b>Standard Schedule</b>
	1. Individuals aged 9 years – 20 years (currently offered in routine grade 6 program)		0.5 mL IM
	2. Individuals aged 21 years - 26 years		<b>2 Dose Series:</b> Dose 1: 0.5 mL IM Dose 2: 0.5 mL IM at 24 weeks
	3. Immunocompromised individuals (Table 1) aged 9 years - 26 years		<b>3 Dose Series</b> Dose 1: 0.5 ml IM Dose 2: 0.5 ml IM at 8 weeks Dose 3: 0.5 ml IM at 24 weeks
	4. Individuals HIV+ aged 9-45 years		<b>3 Dose Series</b> Dose 1: 0.5 ml IM Dose 2: 0.5 ml IM at 8 weeks Dose 3: 0.5 ml IM at 24 weeks
	<b>Recommended but NOT provided free</b>		<b>Standard Schedule</b>
	5. Females aged 27 years – 45 years		<b>2 Dose Series:</b> Dose 1: 0.5 mL IM Dose 2: 0.5 mL IM at 24 weeks

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**TABLE 1: IMMUNOCOMPROMISED INDIVIDUALS INCLUDE:**

- Immunocompromised due to solid tumour or hematologic malignancies or treatments for these conditions
- Solid-organ transplant and taking immunosuppressive therapy
- Hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Immunocompromise due to chimeric antigen receptor (CAR) T cell therapy targeting lymphocytes
- Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation
- HIV with AIDS-defining illness or TB diagnosis in last 12 months before starting vaccine series, or severe immune compromise with CD4<200 cells/μL or CD4%<15%, or without HIV viral suppression
- Recent treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive
- Chronic kidney disease on dialysis

**CONTRAINDICATIONS**

- GARDASIL®9 is contraindicated in individuals less than 9 years of age.
- GARDASIL®9 should not be given to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any of its components.
- Vaccination with GARDASIL®9 should be postponed in individuals suffering from an acute febrile illness.

**PRECAUTIONS & SPECIAL CONSIDERATIONS**

- The presence of a minor infection, such as a cold, should not result in the deferral of vaccination
- Individuals for whom HPV vaccine is recommended may be immunized even if already sexually active or have had a known HPV infection. The likelihood that they have been infected with all types of HPV contained in the vaccine is low and they stand to benefit from immunization
- Provision of HPV9 vaccine for individuals at no charge, referred to YCDC or rural health centers by Yukon OB/GYN specialists, for individuals with CIN2+ with a demonstrated financial need, as determined by specialist. All other indications for immunization apply (age, dosing and spacing). Document high risk in Panorama under the Reason for Immunization Tab.

**PREGNANCY AND LACTATION**

- HPV vaccines can be offered in pregnancy. Evidence to date demonstrates no increased risk of adverse pregnancy or fetal outcomes associated with HPV vaccination during pregnancy
- Routine questioning about last menstrual period or pregnancy is not required or recommended before offering HPV vaccine.

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<p><b>INTERCHANGEABILITY</b></p>	<ul style="list-style-type: none"> <li>• The dose administered should be that recommended by the manufacturer for the specific product being used.</li> <li>• Individuals who started an HPV series with Gardasil® and complete the series with Gardasil®9 are considered up to date for program purposes. Clients can be reassured that although a complete series of Gardasil®9 is currently recommended to ensure protection against the five additional HPV types in the vaccine, there is already substantial cross-protection against other strains not included in the Gardasil® vaccine, and even one dose of Gardasil®9 is likely to offer significant additional protection against these strains.</li> </ul>
<p><b>RECONSTITUTION AND DILUTION</b></p>	<ul style="list-style-type: none"> <li>• None</li> </ul>
<p><b>ADMINISTRATION</b></p>	<ul style="list-style-type: none"> <li>• Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine.</li> <li>• Do not use the product if particulates are present or if it appears discolored.</li> <li>• Each 0.5 mL dose is to be injected intramuscularly, into the deltoid muscle, with care to avoid injection into or near nerves and blood vessels.</li> <li>• GARDASIL®9 should be administered as soon as possible after being removed from refrigeration.</li> </ul>
<p><b>CONCURRENT ADMINISTRATION WITH OTHER VACCINES</b></p>	<ul style="list-style-type: none"> <li>• May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine.</li> <li>• The same limb may be used if necessary, but different sites on the limb must be chosen</li> </ul>
<p><b>SEROLOGICAL TESTING</b></p>	<ul style="list-style-type: none"> <li>• Serologic testing is not recommended before or after receiving GARDASIL®9</li> </ul>
<p><b>VACCINE COMPONENTS</b></p>	<ul style="list-style-type: none"> <li>• Each 0.5-mL sterile dose of the vaccine contains approximately 500 mcg of aluminum (as Amorphous Aluminum Hydroxyphosphate Sulfate adjuvant), 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, 9.56 mg of sodium chloride, and water for injection. The product does not contain preservatives or antibiotics</li> </ul>
<p><b>APPEARANCE</b></p>	<ul style="list-style-type: none"> <li>• GARDASIL®9 is a white, cloudy liquid after thorough agitation</li> </ul>
<p><b>BLOOD/ BLOOD PRODUCTS</b></p>	<ul style="list-style-type: none"> <li>• Does not contain blood or blood products.</li> </ul>
<p><b>BOVINE/ PORCINE PRODUCTS</b></p>	<ul style="list-style-type: none"> <li>• Does not contain bovine or porcine products.</li> </ul>
<p><b>LATEX</b></p>	<ul style="list-style-type: none"> <li>• The vial stopper, the tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.</li> </ul>

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**EXPECTED REACTIONS**

- **Local:** pain, swelling, erythema at the injection site
- **Systemic:** Headache, fever, nausea, dizziness, fatigue

**STORAGE AND HANDLING**

- Store in a refrigerator between 2°C and 8°C
- Store in original package to protect from light

**RELATED RESOURCES & REFERENCES**

- [National Advisory Committee on Immunization Statements](#)
- [Canadian Immunization Guide](#)
- [GARDASIL®9 Product Monograph](#)