Yukon Immunization Program Manual

Section 8 — Biological Products

Smallpox and Mpox Vaccines

June 2026

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<table>
<tr><th colspan="4">Smallpox and Mpox Virus Vaccine — IMVAMUNE®</th></tr>
<tr><td>Manufacturer</td><td>Bavarian Nordic A/S</td><td>Biological Classification</td><td>Live, attenuated, non-replicating</td></tr>
<tr><td rowspan="8">INDICATIONS</td><td colspan="3">SCHEDULE</td></tr>
<tr><td colspan="3">PRE-EXPOSURE PROPHYLAXIS (PrEP)</td></tr>
<tr><td colspan="2">MSM (man or Two-Spirit identifying individual who has sex with another person who identifies as a man), including but not limited to transgender, cisgender, Two-Spirit, gender-queer, intersex, and non-binary individuals who meet one or more of the following:
More than one sexual partner
In a relationship where at least one partner has other sexual partners
History of a confirmed sexually transmitted infection in the past year
Sexual contact in sex-on-premises venues</td><td rowspan="6">1st Dose: 0.5 mL SC
2nd Dose: 0.5 mL SC, 28 days after Dose 1</td></tr>
<tr><td colspan="2">Sexual partners of individuals meeting the above criteria</td></tr>
<tr><td colspan="2">Sex workers (all genders, sexes assigned at birth, sexual orientations)</td></tr>
<tr><td colspan="2">Staff or volunteers in sex-on-premises venues where exposure to contaminated fomites may occur</td></tr>
<tr><td colspan="2">Individuals engaged in sex tourism (all genders)</td></tr>
<tr><td colspan="2">Individuals anticipating any of the above scenarios</td></tr>
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	POST-EXPOSURE PROPHYLAXIS (PEP)	
	For individuals with high-risk exposure to a probable or confirmed mpox case, or within a setting where transmission is occurring, who have not received both doses of PrEP.	• **1st Dose:** 0.5 mL SC as soon as possible, ideally within 4 days of last exposure (may be given up to 14 days post-exposure) • **2nd Dose:** 0.5 mL SC, 28 days after Dose 1
CONTRAINDICATIONS	• **History of hypersensitivity** to IMVAMUNE® or any component of the vaccine or container. • **History of myocarditis or pericarditis** linked to a previous 1st- or 2nd-generation smallpox vaccine (consult provider). • **For non-emergency prophylaxis, defer vaccination** if the client has an acute febrile illness.	
PRECAUTIONS & SPECIAL CONSIDERATIONS	• Minor illnesses (e.g., colds) are **not** a reason to defer vaccination. • May be considered for **immunosuppressed individuals, and pregnant or lactating people**, if risk-benefit assessment supports use and informed consent includes discussion of limited safety data. • **Contact YIP and YCDC for clients <18 years** who are contacts of a positive or suspected case. • **Do NOT vaccinate** individuals with current or past Mpox infection. • Egg allergy is not a contraindication. • **Diffuse vaccinia infection** may occur with acute atopic dermatitis or other widespread exfoliative skin disorders.	
PREGNANCY AND LACTATION	Safety not established in pregnancy or lactation.	
INTERCHANGEABILITY	No interchangeability data available.	
RECONSTITUTION AND DILUTION	Not required.	

ADMINISTRATION	1. Thaw vial (5–10 minutes at fridge or room temperature). 2. Once thawed, gently swirl for ≥30 seconds to ensure homogeneity; do NOT shake 3. Single-dose vial: withdraw 0.5 mL, change to SC needle, and administer immediately

CONCURRENT ADMINISTRATION WITH OTHER VACCINES AND TST	• May be given concurrently or at any interval before/after other live or non-live vaccines.
	• Tuberculin Skin Test (TST):
	  ○ May be performed on the same day as IMVAMUNE®
	  ○ If not done the same day, delay TST for 4 weeks after administering a first- or second-generation smallpox vaccine

SEROLOGICAL TESTING	Not recommended before or after vaccination.
VACCINE COMPONENTS	• Tris-hydroxymethyl-aminomethane (trometamol), sodium chloride, water for injection, hydrochloric acid • Trace amounts: chicken egg DNA/protein, benzonase, gentamicin, ciprofloxacin • No adjuvants or preservatives.
APPEARANCE	• Pale, milky, homogeneous suspension once thawed. • Do NOT use if particulate matter is present.
BLOOD/ BLOOD PRODUCTS	Does not contain blood or blood products.
BOVINE/ PORCINE PRODUCTS	Does not contain bovine or porcine products.
LATEX	Latex-free vial stopper, tip cap, and plunger.
EXPECTED REACTIONS	• **Local:** pain, erythema, induration and swelling at the site of injection • **Systemic:** fatigue, headache, myalgia, and nausea

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<tr><td rowspan="8">STORAGE AND HANDLING</td><td>Storage:</td></tr>
<tr><td>–80 °C long term storage</td></tr>
<tr><td>• Imvamune is stored at –80 °C at the WGH depot whenever possible.
• Shelf life at –80 °C is up to 9 years from the date of manufacture, as per label on the box.
• –25 °C to –15 °C (–20 °C) interim storage:
○ Includes time in transit and storage after removal from –80 °C.
○ Total cumulative time at –20 °C interim storage must not exceed 90 days after removal from –80 °C.
○ Remaining allowable time should be provided with shipments.
○ Product may be returned to –80 °C within the 90-day window.
○ If remaining allowable interim storage time at –20 °C is not known, do not administer and contact the Yukon Immunization Program.</td></tr>
<tr><td>–25 °C to –15 °C (–20 °C) long term storage</td></tr>
<tr><td>• If stored long-term at –20 °C, the total shelf life is up to 3 years from the date of manufacture.
• If the product is outside allowable storage timelines, do not use and contact YIP.</td></tr>
<tr><td>+2 °C to +8 °C storage</td></tr>
<tr><td>• After removal from frozen long-term storage (–80 °C or –20 °C), unopened vials may be stored at +2 °C to +8 °C for up to 8 weeks (56 days) provided the vaccine remains within its approved frozen storage shelf life.
• The vaccine must not be used beyond the original carton expiry date or allowable frozen-storage stability window, whichever comes first.
• Do not refreeze after thawing.</td></tr>
<tr><td>Handling:</td></tr>
<tr><td>• Store in original packaging and protect from light.
• Thaw in refrigerator (+2 °C to +8 °C) or at room temperature (~10 minutes).
• Do not pre-draw vaccine into syringes.
• Do not use past the original carton expiry date or updated recorded discard date.
• If storage timelines are unclear at any stage, contact YIP before administration.</td></tr>
<tr><td colspan="2">REFERENCES AND RESOURCES</td></tr>
<tr><td colspan="2">National Advisory Committee on Immunization Statements
Canadian Immunization Guide
IMVAMUNE® Product Monograph</td></tr>
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