COVID 19 Vaccine Implementation Task Force **Clinic Reference**	
Title:	**Imvamune® Smallpox and Monkeypox Vaccine Quick Reference for Immunizers**
Area:	**Reference for Immunizers**
Effective Date:	August 4, 2022
Revised Date:	October 3, 2022
Approver:	FINAL

IMVAMUNE® vaccine is indicated for active immunization against smallpox, monkeypox and related *orthopoxvirus* infection

Disclaimer: this Quick Reference is not intended to replace other product specific vaccine references but simply lists some frequently referred to information. Please refer to the product monograph for all current and complete information.

Product Monograph: https://pdf.hres.ca/dpd_pm/00063755.PDF

NACI Statement: guidance-imvamune-monkeypox-en.pdf (canada.ca)

Imvamune®			
Indication (age group)	**Composition/Packaging**	**Supplied/Storage**	**Preparation/Administration**
Approved for **adults 18 years of age and older and determined to be high risk.** **Refer to Government of Manitoba website for current eligibility criteria:**	Each vial of liquid-frozen Imvamune®is formulated to have a titer of at least 0.5 x 10^8 infectious units (Inf.U) per 0.5 mL (1 dose) of the Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN) orthopoxvirus strain.	**Single dose vial supplied as:** **2.0 mL glass vial containing a single 0.5mL dose** Store frozen at -20°C ± 5°C or -50°C ± 10°C or -80°C ± 10°C. **Expiry date depends on storage temperature**. • No change in shelf life if kept at -80°C ± 10°C.	**Inspect vials:** The product should appear as a pale milky colored homogeneous suspension after thawing. The liquid vaccine should be visually inspected for any foreign particulate matter prior to administration. **In case of foreign particulate matter being visible, the vaccine must not be used**. The injection volume of 0.5 mL per dose should be withdrawn with a syringe using an injection needle long enough to reach the bottom of the vial. After withdrawal of the vaccine, the injection needle should be changed to a subcutaneous injection needle and the vaccine administered to the subject immediately.

Monkeypox | Health | Province of Manitoba (gov.mb.ca)	Each dose contains 0.61 mg trometamol and 4.1 mg sodium chloride. The product contains no preservatives and no adjuvants. Imvamune® is supplied as a single dose in a 2 mL type I borosilicate glass vial closed with a sterile bromobutyl rubber stopper (latex free), crimped with an aluminum cap and covered with a polypropylene closure.	IMVAMUNE® Vaccine: Updated Storage Conditions and Shelf Life - Canada.ca • Available stability data suggests that up to 5 cycles of shipment at -20°C ± 5°C and storage at -80°C should not impact the product quality. • Cumulative time of shipment or storage at -20°C ± 5°C must be less than 3 months (91 days). **Must be thawed before use**: • Thaw at room temperature. • To ensure homogeneity upon thawing, the vial should be swirled gently (not shaken) for at least 30 seconds. **Does not require reconstitution.** **After thawing, the vaccine, preference is that it should be used immediately or can be stored at 2°C – 8°C for up to 2 weeks prior to use.** • **Store in the original package in order to protect from light** • **-Do not refreeze once thawed.**	However, it is acceptable to use the same needle to draw up and inject as long as it is a subcut (5/8) needle, and the vial can be inverted in order to draw up the contents of the vial. **Recommended subcutaneous needle:** 25g 5/8" is the recommended needle for subcutaneous injection. (Vaccine administration practices: Canadian Immunization Guide - Canada.ca) **Each vial is for single use only and should not be used for more than one individual. The entire contents of the vial should be injected.** **The primary vaccination schedule:** 2 doses regimen of 0.5 mL (0.5×10^8 Infectious units). **Recommended interval:** 4 weeks apart. **Administered:** Subcutaneous route; preferably in the non-dominant upper arm**.** **The vaccine must not be administered intravascularly.**

Key Point Summary

Health Canada has authorized the sale of Imvamune® based on limited clinical testing in humans under the provision of the Extraordinary Use New Drug regulations. The authorization is based on the Health Canada review of the available quality, non-clinical and clinical data. Health Canada considers that the benefit/risk profile of Imvamune® is favourable for

- Active immunization against smallpox, monkeypox and related orthopoxvirus infection and disease in adults 18 years of age and older determined to be at high risk for exposure

NACI Recommendation

NACI recommendation for the use of Imvamune® as Post-Exposure Prophylaxis (PEP) in adults:

- NACI recommends that PEP using a single dose of the Imvamune® vaccine may be offered to individuals with high risk exposures to a probable or confirmed case of monkeypox, or within a setting where transmission is happening.
- PEP should be offered as soon as possible and within 4 days of last exposure and can be considered up to 14 days since last exposure.
- PEP should not be offered to individuals who are symptomatic and who meet the definition of suspect, probable or confirmed case.

NACI recommends that Imvamune® vaccine may be offered to the following populations, **if recommended to receive vaccine based on exposure risk.**

- Individuals who are immunocompromised due to disease or treatment
- Individuals who are pregnant
- Individuals who are lactating
- Children and youth

Guidance for those who have already received a smallpox/monkeypox vaccine

Since we do not know the effectiveness of a previous smallpox vaccination against current monkeypox infection, individuals should receive one dose of Imvamune® as pre-exposure prophylaxis (PrEP) provided they meet the eligibility criteria or PEP if they have been exposed to a probable or confirmed case of monkeypox. Note: if someone with a previous history of smallpox vaccine receives a dose of Imvamune® as pre-exposure prophylaxis, that person does not need a dose of vaccine for post-exposure prophylaxis if the exposure occurs within two years of the pre-exposure vaccination.

If an individual without a prior history of smallpox vaccination receives one dose as PrEP, they may receive one dose of Imvamune® as PEP depending on their exposure risk and whether it has been at least 28 days since their first dose. This would complete their primary series.

Contraindications

- Patients who are hypersensitive to this vaccine or to any ingredient in the formulation or component of the container. For a complete listing, see Dosage Forms, Strengths, Composition and Packaging.
- Individuals who show hypersensitivity reactions after receiving the first dose of the vaccine should not be given the second dose.
- As with other vaccines, vaccination with Imvamune® must be postponed in persons with acute febrile conditions if used for non-emergency (pre-event) prophylaxis**.**

Allergies

***Medical and non-medical vaccine ingredients**

Ask specifically about allergies to: ciprofloxacin, gentamicin

Medicinal ingredient:
Imvamune® is a live viral vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated non-replicating orthopoxvirus. Imvamune® contains trace amounts of host cell (egg) DNA and protein, benzonase, ciprofloxacin and gentamicin. No preservative or adjuvant is added to the formulation.

Non-medicinal ingredients:
- Tris buffer (10 mM Tris containing 140 mM NaCl, pH 7.7):
- Tris-hydroxymethyl-amino methane
- Sodium chloride
- Water for injection
- Hydrochloric acid

For a complete listing see Dosage Forms, Composition and Packaging section.

Warnings and Precautions:

General

- As with any other vaccine, vaccination with Imvamune® may not result in protection in all cases.
- As with all injectable vaccines, appropriate medical treatment and supervision should always be available to treat rare cases of anaphylactic reactions following the administration of the vaccine.

- Imvamune® should not be administered intravascularly.
- Syncope (fainting) can occur with any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.
- Interactions with other vaccines have not been established. Therefore, concomitant administration of other vaccines should be avoided. If co-administration with another vaccine is indicated, immunization should be carried out on separate limbs.
- Imvamune® given as PEP or PrEP should not be delayed due to recent receipt of an mRNA COVID-19 vaccine. If vaccine timing can be planned (i.e., prior to employment within a research laboratory), NACI recommends that Imvamune® be given at least 4 weeks after or before an mRNA vaccine for COVID-19.

Monitoring and Laboratory Tests

Replicating smallpox vaccines have been associated with myopericarditis. If a vaccinated subject exhibits signs and symptoms potentially associated with a cardiac disorder (e.g. chest pain or discomfort, dyspnea, or palpitations), ECG and troponin I tests should be performed. In case of ECG changes or troponin I elevations, further cardiologic examination should be performed.

Special Populations

Pregnant Women

Available human data on Imvamune® administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Animal reproductive studies did not reveal any evidence of impaired fertility or harm to the fetus.
Imvamune® should be administered to pregnant women only if they are at risk of infection and if the benefit of immunization outweighs the potential risks to the mother and fetus.

Breast-feeding

Safety during lactation has not been established. It is unknown if vaccine antigens or antibodies are excreted in human milk.
Imvamune® should be administered to women who are breastfeeding only if they are at risk of infection and if the benefit of immunization outweighs the potential risks.

Immunosuppressed Individuals

The use of Imvamune® in immunosuppressed patients is supported by clinical trials which include individuals who are human immunodeficiency virus (HIV) infected (CD4 ≥ 100 cells/μL), and individuals with atopic dermatitis (AD). (Refer to section 9.1 in the product monograph for more details). An adequate immune response may be diminished in HIV positive individuals as well as in other patients with immunodeficiency or patients receiving immunosuppressive therapy. Imvamune® should be administered to immunosuppressed individuals only if they are at risk of infection and if the benefit of immunization outweighs the potential risks.

Pediatrics
Pediatrics (< 18 years of age): Imvamune® has not been studied in subjects below 18 years of age. Before the eradication of smallpox disease, smallpox vaccination was administered routinely during childhood since the benefits were considered to outweigh the risks. Imvamune® should be administered to children only if they are at risk of infection and if the benefit of immunization outweighs the potential risks to the child.

Geriatrics
Geriatrics (≥ 56 years of age): Imvamune® has been administered to 120 subjects 56 to 80 years of age. No overall differences in safety and immunogenicity were observed between these subjects and those < 56 years of age.

Shelf Life:

Imvamune®: Storage temperatures, shelf life, shipment and supportive temperature excursion information
Imvamune® Vaccine: Updated Storage Conditions and Shelf Life - Canada.ca
Expiry date depends on storage temperature.
No change in shelf life if kept at -80°C.
Can be stored at -20°C for 3 months.
Can be stored at 2°C – 8°C for up to 2 weeks (preference being that it is administered immediately after thawing)
Do not refreeze a vial once it has been thawed.
Store in the original package in order to protect from light
Do not use after the expiry date shown on the label