

Table 1. Use and overview of key features of IMVAMUNE[®] vaccine according to product monograph

Product brand name and formulation	IMVAMUNE [®] Smallpox and Monkeypox Vaccine
Type of vaccine	Modified Vaccinia Ankara-Bavarian Nordic [®] (live-attenuated, non-replicating)
Date of authorization in Canada	Date of Initial Approval: November 21, 2013 Date of authorization for Monkeypox as expanded indication: November 5, 2020 Date of latest Revision: November 26, 2021
Authorized ages for use	Adults 18 years of age and older
Authorized dose and schedule	Primary Series: Two doses of 0.5 mL (0.5 x 10 ⁸ Infectious Units), 28 days apart Booster dose (2 years after primary series): One dose of 0.5 mL (0.5 x 10 ⁸ Inf.U)

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Potential allergens	Traces of residual host (egg) cell DNA and protein ^a Tromethamine ^b (trometamol, Tris) Benzonase ^c Gentamicin and ciprofloxacin ^d
Adjuvant / Preservatives	The vaccine contains no adjuvant or preservatives
Contraindications	<ul style="list-style-type: none"> Patients who are hypersensitive to this vaccine or to any ingredient in the formulation or component of the container. 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.
Storage	<ul style="list-style-type: none"> Store frozen at -20°C ± 5°C or -50°C ± 10°C or -80°C ± 10°C. After thawing, the vaccine should be used immediately or can be stored at 2°C – 8°C for up to 2 weeks prior to use. Do not refreeze a vial once it has been thawed. Protect from light.
Handling	<ul style="list-style-type: none"> Thaw at room temperature. The drug product should appear as a pale milky colored homogeneous suspension. The single-dose vial should be swirled gently (not shaken) for at least 30 seconds to ensure homogeneity upon thawing, The vaccine must not be used if any foreign particulate matter are visible.
Reconstitution	No
Route of administration	0.5 mL subcutaneous injection, at any site
Syringe and needle selection	<ul style="list-style-type: none"> Withdraw with a syringe and needle long enough to reach the bottom of the vial. For injection, needle should be changed to a subcutaneous injection needle

^a In Canada, there are several vaccines manufactured by processes involving hens' eggs or their derivatives, such as chicken cell cultures

^b Tromethamine (trometamol, Tris) may very rarely cause allergic reactions and is found in some medications injected to do tests (contrast media) as well as other medications taken by mouth or injection, and some creams and lotions. Note that this is not a complete list.

^c Benzonase is used for purification of viral vaccines, viral vectors for vaccine, cell and gene therapy, and oncolytic viruses, removing DNA/RNA from proteins and other biologicals; reduction of viscosity caused by nucleic acids; sample preparation in electrophoresis and chromatography and prevention of cell clumping.

^d Gentamicin and ciprofloxacin are used as antibiotics in the treatment of some bacterial infections.