Yukon Immunization Program Manual

Section 8 - Biological Products

Smallpox and Monkeypox Vaccines

SECTION 8 – BIOLOGICAL PRODUCTS

Contents

July 2022

Smallpox and Monkeypox Vaccine (Live, attenuated, non-replicating) (IMVAMUNE®)

Supplier: Bavarian Nordic A/S

INDICATIONS ❶❷	PRIMARY SERIES ❸❹❺❻
(1) Post-Exposure Prophylaxis (PEP) of medium-risk and high-risk close contacts to a probable or confirmed case of monkeypox, or within a setting where transmission is happening, as determined by Yukon Communicable Disease Control (YCDC).	1 dose given as 0.5 mL SC
(2) Pre-Exposure Prophylaxis (PrEP) of two-spirit, transgender, and cis-gender males who self-identify as belonging to the gay, bisexual, and other men who have sex with men (MSM) community with any one or more of the following risk factors: • Multiple sexual partners; • Self reported history of a STI within the last year; • Recent or planned attendance to locations for sexual contact, ex: sex clubs, park play; • Recent or anticipated participance in anonymous/casual sex **(3) Pre-Exposure Prophylaxis (PrEP)** of individuals who are engaged in sex work, either as a client or worker.	1 dose given as 0.5 mL SC
(4) Individuals who are moderately to severely immunocompromised should be offered 2 doses for either pre or post-exposure prophylaxis.	**2 doses:** 0.5 mL SC 0.5 mL SC at least 28 days later
(5) IMVAMUNE® is only indicated for clients 18 and older.	

REINFORCEMENTS

Booster doses: No booster doses of IMVAMUNE® are recommended at this time.

CONTRAINDICATIONS

History of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine.
The vaccine is not indicated for those with signs and symptoms of monkeypox.
Those who have recovered from laboratory confirmed monkeypox are assumed to have acquired immunity and vaccine is not indicated. The duration of protection following recovery from infection is unknown.
The vaccine is not approved for use in those less than 18 years of age.

PRODUCT COMPONENTS

Potential allergens: chicken protein, gentamicin, ciprofloxacin
Other components: trometamol, sodium chloride, benzonase

ADMINISTRATION

- No reconstitution is required.
- IMVAMUNE® is supplied in a single dose vial. Administer the entire volume of the vial for each dose.

- Withdraw the entire contents of the single dose vial (0.5 mL) using an injection needle long enough to reach the bottom of the vial. After withdrawal of the vaccine, change the injection needle to a subcutaneous injection needle and administer to the client immediately.

ADVERSE EVENTS ❼

Local: pain, redness, induration, swelling, pruritus.
Systemic: fatigue, headache, myalgia, arthralgia, fever, chills, nausea, loss of appetite.
Most of these reactions are mild to moderate in intensity and resolve within 7 days of vaccine receipt. Local and systemic reactions are more common in people with atopic dermatitis

STORAGE AND HANDLING

- IMVAMUNE® can be stored at -90°C to -70°C until the product expiry listed on the carton.
- IMVAMUNE® can be stored at -15°C to -25°C for up to 3 months (91 days).
- Once thawed, IMVAMUNE® can be stored in the refrigerator at +2°C to +8°C for up to two weeks (record the new expiry date on the vial prior to commencing refrigeration storage) and should be kept in the original packaging and protected from light.
- **Do not refreeze thawed vials**. If removing from freezer storage for use, thaw at refrigeration or room temperature. Gently swirl vaccine upon thawing for at least 30 seconds to ensure homogeneity; **do not shake**.
- A vial of vaccine will take approximately 5 minutes to thaw at room temperature.
- Once thawed, IMVAMUNE® will appear as a pale milky coloured homogeneous suspension. Inspect vial to confirm there is no foreign particulate matter. If any is observed, do not administer.

SPECIAL CONSIDERATIONS ❽

- IMVAMUNE® is a non-replicating live attenuated vaccine that contains genetically modified orthopoxvirus that has lost its ability to replicate in human cells.
- As IMVAMUNE® is a non-replicating live vaccine, a 4-week interval between administration of this vaccine and another live vaccine is not required. As data on co-administration of IMVAMUNE® and other vaccines is not available, it is recommended to not co-administer IMVAMUNE® with other vaccines and wait for a period of at least 14 days between administration of IMVAMUNE® and another live or inactivated vaccine when timing can be planned.
- This vaccine can be given any time before or after tuberculin skin testing.
- IMVAMUNE® may be offered to immunocompromised, pregnant, or lactating individuals, or individuals with atopic dermatitis after an informed discussion on potential risks and benefits.

PRECAUTIONS

IMVAMUNE® may be considered for those with immunosuppression due to disease or treatment, and pregnant or lactating people, if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the limited data available on the use of IMVAMUNE® in these populations

❶ IMVAMUNE® is only indicated for clients 18 and older. Contact the Yukon Immunization Program and Yukon Communicable Disease Control if there are clients younger than 18 years of age that are contacts of a positive or suspected case.
❷ **Moderately to severely immunosuppressed includes those who:**

- Have had a solid organ transplant and are taking immunosuppressive therapy (heart, lung, liver, kidney, pancreas or islet cells, bowel, or combination organ transplant).
- Will have, are having, or are on active treatment for solid tumour or haematologic malignancies (like myeloma or leukemia):
    - Will have, are having, or in the last 12 months have received systemic treatment for a haematological malignancy, or in the last 24 months have received anti-CD20 or other B-cell depleting therapies for a haematological malignancy.
    - Will have, are having, or in the last 24 months have had a bone marrow, stem cell transplant or CAR-T or who are still taking immunosuppressive drugs.
    - Will have, are having, or in the last 6 months have received anti-cancer systemic therapy for solid tumours (including but not limited to cytotoxic chemotherapy; molecular targeted therapy; immunotherapy; monoclonal antibodies; bone modifying agents used in the setting of metastatic disease; high dose steroids e.g., equivalent to > 20 mg/day for more than 1 month but excluding patients only receiving hormonal or bone modifying therapy in the adjuvant setting).
    - Are planned for radiation, are having or will have had radiation in the last 3 months.
    - Have a diagnosis of CLL/SLL, myeloma/plasmacytoma, or low grade lymphoma.
- Prior AIDS defining illness or prior CD4 count ≤ 200/mm3 or prior CD4 fraction ≤ 15% or any detectable plasma viral load since January 2021 or HIV infection and ≥ 65 years old or perinatally acquired HIV infection.
- Are on active treatment with the following categories of immunosuppressive therapies:
    - In the last 2 years, been treated with anti-CD20 agents, B-cell depleting agents or similar therapeutic agents.
    - In the last 3 months, been treated with biologic agents that are significantly immunosuppresive, oral immune-suppressing drugs, steroids (orally or by injection >14 days), immune-suppressing infusions/injections or intermittent high dose steroids administered as immune suppression prior to intravenous enzyme replacement treatment.
- Have combined immune deficiencies affecting T-cells, immune dysregulation (particularly familial hemophagocytic lymphohistiocytosis) or those with type 1 interferon defects (caused by a genetic primary immunodeficiency disorder or secondary to antiinterferon autoantibodies).
- Have a moderate to severe primary immunodeficiency which has been diagnosed by an adult or pediatric immunologist and requires ongoing immunoglobulin replacement therapy (IVIG or SCIG) or the primary immunodeficiency has a confirmed genetic cause (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
- On dialysis (hemodialysis or peritoneal dialysis) or have stage 5 chronic kidney disease (eGFR <15mL/min) or have glomerulonephritis and receiving steroid treatment.

❸ Those who have previously been vaccinated against smallpox should receive 1 dose for either pre or post-exposure prophylaxis.

❹ IMVAMUNE® can be given up to 14 days after exposure; immunization within 4 days of exposure is necessary to prevent infection. Immunization 4-14 days following exposure may reduce severity of clinical manifestations. The vaccine is **not** indicated for those with signs and symptoms of monkeypox.

❺ As data on co-administration of IMVAMUNE® and other vaccines are not available, it is recommended to not co-administer IMVAMUNE® with other vaccines and wait for a period of at least 14 days between administration of IMVAMUNE® and another live or inactivated vaccine. The administration of Imvamune® for post-exposure prophylaxis should not be delayed in an individual who has recently received another vaccine

❻ Eligibility for a second dose of Imvamune® for both pre and post exposure prophylaxis will be determined by the Yukon MOH based on ongoing risk of exposure and evidence of transmission.

❼ The benefit of protection against infection should be discussed with a healthcare provider and weighed against the potential risk of recurrent myocarditis. Cardiac adverse events such as myocarditis, pericarditis or any other type of cardiac inflammatory disease have not been clearly shown to be associated with use of IMVAMUNE®. However, cardiac adverse events are of interest given recognized association with smallpox vaccine. Recipients of IMVAMUNE® experiencing chest pain, shortness of breath or palpitations should be assessed by a physician as soon as possible.

❽ Data on the use of Imvamune® in immunocompromised, pregnant, or lactating individuals, or individuals with atopic dermatitis is limited.

- Imvamune® has never been tested in persons who are pregnant or lactating. Though limited, safety and toxicity studies have identified no concerning safety signals.
- People with atopic dermatitis were a risk group with severe adverse outcomes for earlier generations of smallpox vaccines. The Imvamune® vaccine was developed to overcome those adverse effects using a non-replicating virus.