Imvamune Vaccine Information Sheet for Healthcare Providers

How does the IMVAMUNE vaccine protect against monkeypox?

- IMVAMUNE is a Modified Vaccinia Ankara (MVA) vaccine, manufactured by Bavarian Nordic. It was initially developed to be used for the prevention of smallpox. When a person is given the vaccine, the immune system (the body's natural defense system) will produce its own protection in the form of antibodies against the smallpox virus. IMVAMUNE does not contain smallpox virus and cannot spread or cause smallpox.
- Vaccination against smallpox was demonstrated through several observational studies to be about 85% effective in preventing monkeypox. Prior smallpox vaccination may result in milder illness.

Who can and cannot receive the smallpox/monkeypox vaccine at this time?

- The IMVAMUNE vaccine may be offered to adults 18 years of age and older who do not have contraindications.
- Although IMVAMUNE is not authorized for children and has not been studied in this population, they may be at higher risk of severe outcomes from monkeypox infection and may benefit from vaccination. There is a lack of evidence of safety and efficacy of IMVAMUNE pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) in this group, though indirect evidence of clinical testing of other vaccine types indicates that IMVAMUNE components are well tolerated in recipients under 18 years of age.
- **Table 1** indicates who should and should not receive the IMVAMUNE vaccine and provides some questions before being vaccinated and possible recommendations based on your response. These recommendations are based on the advice of the National Advisory Committee on Immunization (NACI).

Table 1: Questions and possible recommendations with regards to receiving the IMVAMUNE vaccine

Questions	Possible recommendations
Are you feeling ill today?	Vaccination with IMVAMUNE must be postponed in persons with fever or general malaise. Talk with your health care provider about your symptoms. Your health care provider will advise you when you are able to receive the vaccine.
If you received a previous dose of an orthopoxvirus vaccine (Smallpox vaccine; live (freeze-dried), Smallpox vaccine; live (frozen-liquid) and/or IMVAMUNE), did you have any side effects after vaccination (including allergic reactions, hypersensitivity reactions or heart inflammation [myocarditis/pericarditis]**)?**	Individuals who show hypersensitivity reactions after receiving the first dose of the vaccine should not be given the second dose. IMVAMUNE is not recommended for individuals with a history of myocarditis/pericarditis linked to a previous dose of an orthopoxvirus vaccine as a precautionary approach at this time, until more information is available. Consult with your health care provider.
Are you allergic to eggs or egg products?	Allergic reactions are not a contraindication to immunization with egg protein-containing vaccines. Consult with your health care provider who may advise on extra precautions.

Are you allergic or do you have a confirmed allergy to tromethamine[2] (trometamol, Tris), benzonase[3], gentamicin[4] or ciprofloxacin[4] which are contained in the IMVAMUNE vaccine?	If you are allergic to tromethamine (trometamol, Tris), benzonase, gentamicin or ciprofloxacin, consult with your health care provider about whether to receive the IMVAMUNE vaccine.
Do you have a suspected but unproven allergy to a vaccine component e.g., tromethamine[2] (trometamol, Tris), benzonase[3], gentamicin[4] or ciprofloxacin[4]?	If “yes”, you may receive the IMVAMUNE vaccine. You will be asked to wait in the clinic for 30 minutes after receiving the vaccine to make sure you are feeling well.
Have you had an allergic reaction to another vaccine type or other medication given by injection or intravenously in the past?	If "yes", you may receive the IMVAMUNE vaccine. You will be asked to wait in the clinic for 30 minutes after receiving the vaccine to make sure you are feeling well.
Are you or could you be pregnant or breastfeeding?	Pregnant populations may particularly benefit from vaccination as these populations may be at risk for severe outcomes from disease. There is a lack of evidence of safety and efficacy of IMVAMUNE PrEP or PEP in this group, though at this time there is no reason to believe that vaccination would have any adverse impact on parent or fetus. Breastfeeding populations are not at higher risk for negative outcomes due to monkeypox infection. There are no IMVAMUNE studies in this population. There is a lack of evidence of safety and efficacy of IMVAMUNE PrEP or PEP in this group, though at this time there is no reason to believe that vaccination would have any adverse impact on parent or child in relation to breastfeeding.
Do you have any problems with your immune system or are you taking any medications that can affect your immune system (e.g., high dose steroids, chemotherapy, some arthritis medications)? Ask the health care provider if you are not sure about your medical conditions	The use of IMVAMUNE in immunosuppressed patients is supported by clinical trials which include individuals who are human immunodeficiency virus (HIV) infected. Immune response may be diminished in HIV positive individuals as well as in other patients with immunodeficiency or patients receiving immunosuppressive therapy. Immunosuppressed populations (including those infected with HIV) may benefit from vaccination as these populations may be at risk for more severe outcomes depending on the nature of the immunosuppression. Live vaccines are usually contraindicated for immunocompromised populations; however, IMVAMUNE may be recommended in this group as it is considered a non-replicating vaccine.
Do you have skin conditions such as atopic dermatitis?	The use of IMVAMUNE in immunosuppressed patients is supported by clinical trials which include individuals with atopic dermatitis (AD). Evidence is available which has not indicated any safety concerns for individuals with atopic dermatitis. It is anticipated that some local and systemic reactions may come at higher frequency. Some may also experience a flare up or a worsening of their condition.
Have you recently received specific medications for monkeypox treatment (e.g., immunoglobulins)?	Interaction with concomitant administration of immunoglobulins has not been established. If "yes", consult your health care provider.
Have you received another vaccine in the last four weeks or do you anticipate receiving another vaccine in the next 4 weeks?	It is recommended that IMVAMUNE not be given within 4 weeks of an mRNA vaccine for COVID-19. However, in a high-risk exposure scenario, IMVAMUNE PrEP or PEP should not be delayed due to the receipt of an mRNA COVID-19 vaccine. Consult your health care provider.
Have you ever felt faint or fainted after a past vaccination or medical procedure?	If “yes”, the health care provider may vaccinate you lying down to prevent you from fainting.

Footnote:

1. In Canada, there are several vaccines manufactured by processes involving hens' eggs or their derivatives, such as chick cell cultures

2. 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.
3. 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
4. Gentamicin and ciprofloxacin are used as antibiotics in the treatment of some bacterial infections.

How is the vaccine administered?

The vaccine is administered by subcutaneous injection, preferably in over the area of the deltoid muscle. The vaccine dose is 0.5mL.

What are the risks of the vaccine?

- IMVAMUNE vaccine has been authorized by Health Canada for active immunization against smallpox, monkeypox and related orthopoxvirus infection and disease under the provision of the Extraordinary Use New Drug (EUND) regulations in adults 18 years of age and older determined to be at high risk for exposure. EUND vaccines are part of emergency preparedness in Canada where manufacturers may not be required to provide substantial evidence demonstrating the safety and efficacy of the product before being authorized. Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect exactly what will be experienced in practice, including side effects that may not have been previously identified.
- Side effects can develop within a few days after receiving the vaccine and their frequency may depend whether the individual previously received an orthopoxvirus vaccine (Smallpox vaccine; live (freeze-dried), Smallpox vaccine; live (frozen-liquid) and/or IMVAMUNE). Although most side effects are not serious to an individual's health, they may make the person feel unwell for a few days; they will go away on their own. **Some common and expected side effects** include one or more of the following:
    - injection site reactions (e.g. pain, redness, swelling, induration, itching)
    - fatigue
    - headache
    - muscle aches/pain
    - chills
    - nausea
- **Rarely allergic reactions** can occur after receiving a vaccine. Symptoms of an allergic reaction include:
    - hives (bumps on the skin that are often very itchy)
    - swelling of your face, tongue or throat
    - difficulty breathing
- IMVAMUNE is a smallpox/monkeypox vaccine that has been associated with **myocarditis/pericarditis**. Signs and symptoms associated with cardiac disorder may include:
    - Chest pain or discomfort
    - Shortness of breath
    - Fast or irregular heart beat
- If possible, **wait at least two weeks after vaccination or completing your IMVAMUNE vaccination series before starting drugs that suppress the immune system.**