Mpox(Monkeypox)/Smallpox Vaccine Information Sheet

IMVAMUNE vaccine for adults 18 years of age and older

Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine.

What is mpox?

- Mpox is a viral disease that can be transmitted from animals to humans or humans to humans through direct contact, contaminated objects, or respiratory secretions, though the exact way the virus spreads is not completely known at this time. Transmission can also occur from mother to fetus (which can lead to congenital mpox) or during close contact during and after birth. Although the role of sexual transmission in the current outbreak is not fully understood, close direct contact and multiple different sexual partners are known risk factors.
- For more information on each mode of transmission, please visit canada.ca/mpox.
- You can be contagious from the first signs or symptoms of mpox. These typically include a few days of flu-like symptoms followed by lesions or sores on your skin, including in your mouth, genitals, or peri-anal area, fever, and swollen lymph nodes.
- The number of lesions varies, and you can be contagious from onset of first symptoms until scabs have fallen off on their own and the skin is healed.
- There are no specific treatments for mpox, but antivirals developed for use against smallpox, and prior or post-exposure vaccination with the smallpox vaccine, may provide protection.

How does the IMVAMUNE vaccine protect against mpox?

IMVAMUNE is a Modified Vaccinia Ankara (MVA) vaccine, manufactured by Bavarian Nordic. The vaccine contains a modified virus that is not able to cause infection. 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 mpox. Prior smallpox vaccination may result in milder illness.

About the IMVAMUNE vaccine

Imvamune as a preventive vaccine will be offered to individuals that are at greater risk of a mpox infection. Only individuals who meet the eligibility criteria will be offered Imvamune due to limited vaccine supply.

Following guidance from the National Advisory Committee on Immunization (NACI), Imvamune as a preventive vaccine against a mpox infection is a two-dose series, with doses separated by at least 28 days.

Given that eligibility criteria has varied across Canada since the beginning of preventive vaccination campaigns against mpox, anyone who has already received one dose of Imvamune as part of a vaccination campaign is eligible for a second dose to complete their series.

Due to limited supply, the two-dose series for pre-exposure prophylaxis will only be started for residents of Nova Scotia or those visiting Nova Scotia for prolonged periods of time. Imvamune pre-exposure prophylaxis vaccination cannot be provided to those visiting the province for the purpose of being vaccinated.

Individuals concerned about a potential exposure to mpox and are seeking post-exposure prophylaxis (PEP) are asked to contact a healthcare provider for clinical assessment and management.

Imvamune is not indicated for individuals currently experiencing any signs or symptoms of mpox.

Who can receive the mpox/smallpox vaccine as PrEP at this time?

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 mpox infection and may benefit from vaccination. There is a lack of evidence of safety and efficacy of IMVAMUNE pre-exposure prophylaxis (PrEP) 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.

The IMVAMUNE vaccine is offered to anyone who identifies as a cisgender or transgender queer man, a two-spirit person, or a non-binary person, who has sexual contact with a cisgender or transgender queer man, a two-spirit person, or a non-binary person AND has at least one of the following:

- 2+ sexual partners as defined above since May 2022, or are planning to
- A diagnosis of bacterial STI since May 2022
- Attended, worked at, or volunteered at an event/social venue for sexual contact since May 2022, or are planning to
- Had anonymous sex since May 2022, or are planning to
- Engaged as a worker or a client in sex work, or are planning to

OR

- A sexual contact of someone who meets the above criteria

Table 1 *indicates who should and should not receive the IMVAMUNE vaccine and provides some questions you may be asked 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

Question	Possible recommandations
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? [1]	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 post-exposure 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 post-exposure (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 mpox infection. There are no IMVAMUNE studies in this population. There is a lack of evidence of safety and efficacy of IMVAMUNE 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 mpox 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 including the recent mpox outbreaks in Canada, IMVAMUNE should not be delayed due to 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.

What are the risks of the vaccine?

IMVAMUNE vaccine has been authorized by Health Canada for active immunization against smallpox, mpox 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 on whether you 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 your health, they may make you 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

The clinic staff are prepared to manage an allergic reaction should it occur. Seek immediate medical care if you develop any of these symptoms.

IMVAMUNE is a smallpox/mpox 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 heartbeat

Seek immediate medical care if you develop any of these symptoms.

How is the vaccine administered?

The vaccine is administered by subcutaneous injection in your arm.

What should you do before coming to the clinic?

- Wear a short-sleeve shirt or top with sleeves that are easy to roll up.
- To prevent feeling faint while being vaccinated, have something to eat before coming to the clinic.
- Be sure to adhere to public health measures as advised.
- Bring any identification required by the clinic, such as your health card and your immunization record.
- If you are suspected of having or are confirmed to have mpox, contact your local Public Health office before arriving for a vaccination appointment.

What should you do after receiving the vaccine?

- You will be asked to **wait at least 15 minutes after receiving the vaccine** to be sure you are feeling well. Longer waiting times of 30 minutes may be recommended if there is concern about a possible vaccine allergy. Inform a health care provider right away if you feel unwell while waiting. You should not leave the clinic for at least 15 to 30 minutes after receiving your vaccine, based on the recommendation of the health care provider, and should not leave if you are feeling unwell.
- **Once you leave the clinic, call 9-1-1 right away if you develop any serious symptoms or symptoms of an allergic reaction** such as hives (bumps on the skin that are often very itchy), swelling of your face, tongue or throat, or difficulty breathing. Inform your health care provider of any concerning side effects after receiving the vaccine.
- If possible, w**ait at least two weeks after vaccination or completing your IMVAMUNE vaccination series before starting drugs that suppress your immune system**, as recommended by your health care provider or local public health office in your community.
- **Keep your immunization record** with information about the IMVAMUNE vaccine in a safe place.

When should I return for my next dose (if indicated)?

• If you received Imvamune for pre-exposure prophylaxis (PrEP), you should receive a second dose a minimum of 28 days later.

• If you received IMVAMUNE as post-exposure (PEP), depending on predictable ongoing high risk of exposure, a second dose may be recommended 28 days after the first dose.

• NACI recommends that IMVAMUNE not be given within 4 weeks of an mRNA vaccine for COVID-19. However, in a high-risk exposure scenario including the recent mpox outbreaks in Canada, IMVAMUNE should not be delayed due to receipt of an mRNA COVID-19 vaccine.

• NACI recommends individuals who have documented evidence of receiving a live replicating first- or second- generation smallpox vaccine in the past should receive only a single dose of Imvamune PrEP or PEP. However, individuals considered moderately to severely immunocompromised should receive two doses regardless of previous smallpox vaccine.

Bring your immunization record with you when you come for your next dose.

If you have any questions, please speak with the person providing the vaccine or contact your local Public Health office.