MPOX

Information Sheet

IMVAMUNE (smallpox/mpox) vaccine.

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 disease caused by the mpox virus, which enters the body through broken skin, the respiratory tract, or the mucous membranes (e.g., eyes, nose, or mouth). It is spread through close contact with an infected individual, such as coming into contact with their body fluids - for example, mucus, saliva –or sores.
- Mpox can also be spread by sharing clothing, bedding or other items that have been contaminated with the infected person's fluids or sores, as well as by respiratory droplets from coughs or sneezes during prolonged intimate contact.
- Signs and symptoms of mpox typically occur in two stages and last from two to four weeks.
    - In stage 1, symptoms may include fever, chills, swollen lymph nodes, headache, muscle pain, joint pain, back pain, and/or exhaustion.
    - In stage 2, a rash typically develops on your skin, often starting on your face, arms, and/or legs. It can also appear on your hands, feet, mouth, or genitals.
- During the current outbreak, many people are reporting a different pattern of symptoms, such as experiencing a rash before a fever or having only one sore, often in the genital or anal area, rather than multiple scattered lesions.
- You can be contagious from start of first symptoms until scabs have fallen off on their own and the skin is healed.
- Mpox is usually mild, and most people recover on their own after a few weeks. However, in rare situations, people may become very sick, resulting in hospitalization and/or death.
- There are no treatments specific to mpox. However, antivirals developed for use against smallpox, and vaccination after an exposure with the smallpox vaccine, may help prevent serious illness, while prior vaccination against smallpox may provide cross-protection.

HOW DOES THE IMVAMUNE VACCINE PROTECT AGAINST MPOX?

- IMVAMUNE is a Modified Vaccinia Ankara (MVA) vaccine, manufactured by Bavarian Nordic. It was initially developed to prevent smallpox.
- When a person is given the vaccine, the immune system produces its own protection – in the form of antibodies – against the smallpox virus. IMVAMUNE does not contain smallpox virus and cannot spread or cause smallpox.

WHO CAN AND CANNOT RECEIVE THE SMALLPOX/MPOX VACCINE 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 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 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).

QUESTIONS	POSSIBLE RECOMMENDATIONS
Are you feeling ill today?	Vaccination with IMVAMUNE must be postponed in persons with fever or generally feeling unwell. Talk with your health-care provider about your symptoms, so they can advise you when you are able to receive the vaccine.
If you received a previous dose of a smallpox or mpox (ie IMVAMUNE) vaccine, did you have any side effects after vaccination (including allergic reactions, hypersensitivity reactions or heart inflammation [myocarditis/pericarditis])?	Individuals who experienced allergic reactions after receiving the first dose of the vaccine should be assessed to see if a second dose would be safe. IMVAMUNE is not recommended for individuals with a history of myocarditis/pericarditis linked to a previous dose of a smallpox vaccine or imvamune vaccine as a precautionary approach at this time, until more information is available. Consult with your health care provider if you have concerns.

Are you allergic or do you have a confirmed allergy to tromethamine (trometamol, Tris), benzonase, gentamicin or ciprofloxacin 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 (trometamol, Tris), benzonase, gentamicin or ciprofloxacin?	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 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 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.
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 occur more often in those with AD. Some may also experience a flare up or a worsening of their condition.
Have you recently received specific medications for mpox treatment?	Interaction 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 four weeks?	It is recommended that IMVAMUNE not be given within four 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.

HOW IS THE VACCINE ADMINISTERED?

The vaccine is administered by injection in your arm.

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 who are 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 a smallpox vaccine or IMVAMUNE vaccine. Although most side effects are not serious to your health, they may make you feel unwell for a few days, but 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 in clinical trials with cardiac adverse events that were not considered serious in nature. Signs and symptoms associated with cardiac disorder may include:
  - Chest pain or discomfort
  - Shortness of breath
  - Fast or irregular heartbeat

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.
- Bring your Medicare card.
- If you are suspected of having or are confirmed to have mpox, follow any isolation instructions provided by Public Health, avoid close contact with or directly touching other people, wear a well-fitting medical mask if you must be close to others, and cover all sores as best as possible with bandages or clothing.

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, wait 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.
- Keep your immunization record with information about the IMVAMUNE vaccine in a safe place.

WHEN SHOULD I RETURN FOR MY NEXT DOSE (IF INDICATED)?

- Depending on if IMVAMUNE is used as a pre-exposure prophylaxis (PrEP) or post-exposure (PEP), and/or if you have received an anti-orthopoxvirus vaccine in the past, and 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 four 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 receipt of an mRNA COVID-19 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. Your local Public Health office or 811 can be reached if you have any further questions once you return home.