

Information Sheet

IMVAMUNE® (smallpox/monkeypox) 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 monkeypox?

- Monkeypox is a viral disease that can be transmitted from animals to humans, from person-to person or through direct contact with contaminated objects, 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 monkeypox) or during close contact during and after birth. Sexual transmission has not been previously identified as a mode of transmission, though sexual partners also have close direct contact. For more information on each mode of transmission, please consult this link: [Monkeypox: Risks - Canada.ca](http://Monkeypox:Risks-Canada.ca).
- Signs and symptoms of monkeypox can typically include 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 well-established treatments for monkeypox. However, antivirals developed for use against smallpox and post-exposure vaccination with the smallpox vaccine may help and prior vaccination against smallpox may provide cross-protection.

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.
- IMVAMUNE has been administered to 120 subjects 56 to 80 years of age with no difference in safety and immunogenicity compared to adults up to 55 years of age.

How is the vaccine administered?

- The vaccine is administered by subcutaneous injection in your arm.

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 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
 - 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/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