PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

IMVAMUNE®
Smallpox and mpox Vaccine
Modified Vaccinia Ankara-Bavarian Nordic® (live-attenuated, non-replicating)

Health Canada has authorized the sale of IMVAMUNE based on limited clinical testing in humans under the provision of the Extraordinary Use New Drug regulations. The authorization is based on the Health Canada review of the available quality, non-clinical and clinical data. Health Canada considers that the benefit/risk profile of IMVAMUNE is favourable for:

- active immunization against smallpox, mpox and related *orthopoxvirus* infection and disease in adults 18 years of age and older determined to be at high risk for exposure.

As part of the authorization for sale for IMVAMUNE Health Canada has requested the sponsor agree to post-market commitments. Adherence to these commitments, as well as updates to information on quality, non-clinical, and clinical data will be continuously monitored by Health Canada.
This vaccine is for exclusive use by the Canadian Government.

Read this carefully before you receive **IMVAMUNE**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **IMVAMUNE**.

What is IMVAMUNE used for?

- IMVAMUNE is a vaccine that helps protect against smallpox, mpox and related *orthopoxvirus* infection and disease
- IMVAMUNE is indicated for individuals 18 years of age and older. This could include individuals:
  - Who are human immunodeficiency virus infected (CD4 ≥ 100 cells/µL)
  - Who have atopic dermatitis

How does IMVAMUNE work?

IMVAMUNE is used for vaccination (active immunization) against smallpox, mpox, and other orthopoxviruses. IMVAMUNE activates your immune system to help protect you from smallpox, mpox and *orthopoxvirus* infection and disease.
IMVAMUNE does not contain replicating viruses and cannot spread or cause orthopoxvirus disease (including smallpox and mpox).

What are the ingredients in IMVAMUNE?

Medicinal ingredients: Smallpox and mpox Vaccine
Modified Vaccinia Ankara-BN (live-attenuated, non-replicating)

Non-medicinal ingredients: sodium chloride
Trometamol
Water for injection
Traces of residual host cell DNA and protein, benzonase, gentamicin and ciprofloxacin

IMVAMUNE comes in the following dosage forms:

Suspension for injection, at least 0.5 x 10^8 Inf.U MVA-BN / dose

Do not use IMVAMUNE if:

- **You are below 18 years of age**

Individuals with the following conditions should discuss vaccination with their physician, who will be able to advise on safe vaccination or on alternative preventative measures to avoid infection with smallpox, mpox or other *orthopoxviruses*:

- Pregnant or breast feeding woman
- Persons with fever (temperature above 38.5°C)
- Persons with allergies to the active substance or any of the excipients (see ingredients)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive IMVAMUNE. Talk about any health conditions or problems you may have, including if you:

- are or think you are pregnant or if you are breast feeding
- have any known allergies
- have a fever or you think you may be getting a fever

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines or vaccines.

How to receive IMVAMUNE:
The vaccine is to be given as a single dose by injection under the skin.

DO NOT INJECT INTRAVASCULARLY

Usual dose:
The primary vaccination series consists of two doses of 0.5 mL each according to the following schedule:
First dose: Day 0
Second dose: 28 days after first dose
Your doctor will advise on the need for a booster dose.

Overdose:
No case of overdose has been reported.

If you think you have received too much IMVAMUNE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
Make sure you finish the complete vaccination course of two injections. If not, you may not be fully protected against the disease. If you miss a scheduled injection, talk to your doctor and arrange another visit.

What are possible side effects from using IMVAMUNE?

These are not all the possible side effects you may feel when receiving IMVAMUNE. If you experience any side effects not listed here, contact your healthcare professional.
Like all vaccines, IMVAMUNE can cause side effects, although not everybody gets them.

Anaphylactic shock is a rare but very serious event. Although no cases have been observed during clinical development of IMVAMUNE, these events may occur with any injectable vaccine. An allergic reaction causes symptoms in many parts of the body, often starting with tingling or swelling around the mouth and lips. The face and neck may swell and breathing may become difficult. Heartbeat is fast and may be irregular. A rash, hives or redness of the skin may occur and there may be diarrhea. If these symptoms occur, contact your physician or call your emergency services immediately.

The adverse reactions listed below have been observed during clinical studies. The most common side effects reported were at the injection site. Most of the reported adverse reactions are mild to moderate in intensity and resolving without intervention within seven days following vaccination.

Very common side effects reported in at least 1 in 10 persons were:
Pain, redness, swelling, hardness, or itching at the injection site.
Tiredness, headache, aching muscles, nausea.

Common side effects reported in at least 1 in 100 but less than 1 in 10 persons were:
Nodule, discolouration, bruising, warmth at the injection site, chills, fever, pain in extremity, joint pain, or loss of appetite.

Uncommon side effects reported in at least 1 in 1000 but less than 1 in 100 persons were:
Irritation, bleeding, scaling, inflammation, sensibility disorder, or reaction at the injection site. Underarm swelling, malaise, flushing, axillary pain, chest pain, dizziness, sensibility disorder, musculoskeletal stiffness, back pain, neck pain, rash, pruritus, dermatitis, skin discolouration, diarrhea, vomiting, dry mouth, throat pain, flu-like symptoms, cough, sleep disorder, clinically not relevant increase of cardiac enzymes, hepatic enzyme increased, white blood cell count decreased, mean platelet volume decreased, contusion, nose and throat infection, upper respiratory tract infection or temporarily enlarged lymph nodes.

Rare side effects reported in less than 1 in 1000 persons were:
Rash, anesthesia, dryness, movement impairment or vesicles at the injection site.
Weakness, influenza like illness, oedema peripheral, migraine, peripheral nerve sensations, muscle spasms, musculoskeletal pain, muscular weakness, urticarial, ecchymosis, increased sweating, night sweats, subcutaneous nodule, angioedema, abdominal pain, increased heartbeat, sinusitis, pink eye, mouth and throat pain, influenza, white blood cell count increased, vertigo.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Angioedema (swelling of the face, mouth and throat)		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough

to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Vaccine Side Effects

For the general public: Should you experience a side effect following immunization, please report it to your doctor, nurse, pharmacist, or immunization provider.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and Bavarian Nordic cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit, or according to specified public health guidance.

STORAGE:
Your doctor or pharmacist is responsible for storing this vaccine and disposing of any unused product correctly. Do not use after the expiry date stated on the label.
Keep out of reach and sight of children.

If you want more information about IMVAMUNE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website http://www.bavarian-nordic.com, or by calling +45-3326-8383.

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