# IMVAMUNE (smallpox and monkeypox) 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 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 identified previously.

| Last name | First name | Medicare number | D.O.B (YYYY/MM/DD) | Age |
|---|---|---|---|---|
| | | | | |

| Home phone | Email |
|---|---|
| | |

| Street address | City | Province | Postal code |
|---|---|---|---|
| | | | |

Gender ☐ Male ☐ Female ☐ Other

**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.

☐ No ☐ Yes If yes, please provide details

**Do you have or have you had a monkeypox infection?**

☐ No ☐ Yes If yes, please indicate when the symptoms started, if known.

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New Nouveau Brunswick

**If you have had one or more previous orthopoxvirus vaccine (Smallpox vaccine; live (freeze-dried), Smallpox vaccine; live (frozen-liquid) and/or IMVAMUNE), did you have any side effects after any previous dose(s) (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.

☐ No ☐ Yes If yes, please provide details

**Are you allergic or could you be allergic to eggs or egg products, tromethamine (trometamol, Tris), benzonase, gentamicin or ciprofloxacin which are contained in the vaccine?**

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.

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.

☐ No ☐ Yes If yes, please provide details

**Have you had an allergic reaction to another vaccine (another type of smallpox/monkeypox vaccine or a non-smallpox/monkeypox vaccine) 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.

☐ No ☐ Yes If yes, please provide details

**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.

☐ No ☐ Yes

**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)?**

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.

☐ No ☐ Yes ☐ Uncertain If yes, please provide details

**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

☐ No ☐ Yes ☐ Uncertain If yes, please provide details

**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.

☐ No ☐ Yes ☐ Uncertain If yes, please provide the date of the treatment

**Have you received another vaccine in the last four weeks, or do you anticipate receiving a vaccine in the next 4 weeks?**

To minimize the potential risk of interactions, it is recommended to administer certain types of vaccines 4 weeks before or after administration of IMVAMUNE. Consult your health care provider.

☐ No ☐ Yes ☐ Uncertain If yes, please provide details

**Have you ever felt faint or fainted after a past vaccination or medical procedure?**

☐ No ☐ Yes If yes, please provide details

For all doses of Imvamune your consent will confirm the following:

- I have read (or it has been read to me) and I understand the information I was given on the Imvamune (smallpox/ monkeypox) vaccine being offered to me today and consent to have administered the recommended dose based on Public Health recommendations.
- I understand the benefits and possible reaction(s) for the Imvamune vaccine and the risk of not being immunized.
- I have had an opportunity to discuss my questions and/or concerns as they relate to the Imvamune vaccine with the health care provider administering the Imvamune vaccine.
- I understand that I may withdraw this consent at any time by informing the health care provider giving the Imvamune vaccine.
- I confirm that I have the legal authority to consent to this immunization.

Signature: _____ Print name: _____

Date of signature: _____

If signing for someone other than yourself, indicate your relationship to that other person: _____

☐ I confirm that I am the parent / legal guardian or substitute decision maker.

**For Clinic Use Only**

| VACCINE | DOSE/ROUTE | LOT NUMBER | EXPIRY DATE | SITE and ROUTE | TIME GIVEN | DATE GIVEN Month/day/year | GIVEN BY Name and designation |
|---|---|---|---|---|---|---|---|
| IMVAMUNE smallpox / monkeypox vaccine | 0.5 ml/SC | | | | | | |

Should you decide to provide all of the information requested on the form, it is important to know that its submission constitutes consent to the collection, use and disclosure of your personal information.

The collection use and disclosure of personal information is protected by the *Right to Information and Protection of Privacy Act* (RTIPPA),

Personal Health Information Privacy and Access Act (PHIPAA) and all other applicable legislation, regulation, or policy.

If you wish to know more about your privacy rights, please consult:
gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/HealthActs/PrivacyNotice.pdf



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