IMVAMUNE® Vaccine FAQ for Immunizers

VCH IMVAMUNE® Campaign 2022-2023

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1. **Who is eligible for Mpox vaccination?**

   Close contacts of a confirmed positive case of Mpox are eligible for post-exposure prophylaxis if they are:

   - Asymptomatic AND
   - Within 14 days of last close exposure to a confirmed case

   Immunization within 4 days of exposure is necessary to prevent infection. Immunization 5-14 days following exposure may reduce severity of clinical manifestations.

   Also eligible, asymptomatic individuals who identify as:
   Two-Spirit and transgender people and cisgender males who self-identify as belonging to the gay, bisexual and other men who have sex with men community.

   With at least one of the following:

   - Has sex with more than one partner,
   - Has sex with a partner who has more than one partner,
   - Has casual sex (e.g. cruising),
   - Engages in sex work as a worker or client.

2. **How was the vaccine eligibility group decided?**

   The vaccine is provided to population subgroups based on federal and provincial guidance on the use of vaccine to protect those at highest risk of contracting Mpox.

3. **Is IMVAMUNE® vaccine safe?**

   As with all vaccines, safety of IMVAMUNE® was assessed in pre-licensure trials. While limited, there were no concerning safety signals identified in safety and toxicity studies on IMVAMUNE®. Vaccine safety continues to be monitored now that vaccines are available for use.

4. **Who should <u>not</u> receive the IMVAMUNE® vaccine?**

   Individuals with a history of anaphylactic reaction to a previous dose of the vaccine or any component of the vaccine should not receive IMVAMUNE®.

5. **Can the IMVAMUNE® vaccine be given to those under 18?**

   IMMVAMUNE® vaccine should be offered to individuals less than 18 years who present for immunization. Informed consent should include a discussion about the absence of trial data on the use of this vaccine in this age group, but vaccination is still highly recommended by public health to ensure personal protection.

6. **What is in the IMVAMUNE® vaccine?**

   - Active ingredient: MVA-BN
   - **Potential allergens: chicken protein, gentamicin, ciprofloxacin**

- Other components: trometamol, sodium chloride, benzonase

The product contains no preservatives or adjuvants. The stopper is sterile bromobutyl rubber which is latex-free.

7. **Can pregnant individuals receive the vaccine?**

   Yes, pregnant individuals can be offered IMVAMUNE® if they are considered to be at risk of Mpox exposure. While available human data on IMVAMUNE® administration to pregnant individuals are insufficient to inform vaccine-associated risk, animal reproductive studies did not reveal any evidence of impaired fertility or harm to the fetus.

   Immunization with IMVAMUNE® may be considered in pregnant individuals if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent includes discussion about the limited data available on the use of IMVAMUNE® in this population.

8. **Can chest-feeding individuals receive the vaccine?**

   Safety during lactation has not been established and it is unknown if the vaccine antigens or antibodies are excreted in human milk.

   Immunization with IMVAMUNE® may be considered in chest-feeding individuals if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent includes discussion about the limited data available on the use of IMVAMUNE® in this population

9. **Are there any precautions for immunocompromised individuals?**

   Use of IMVAMUNE® in immunosuppressed individuals is supported by trial data. Provide counsel that an adequate immune response may be diminished in individuals with immunodeficiency or receiving immunosuppressive therapy.

10. **Can IMVAMUNE® vaccine be given at the same time as other vaccines?**

    IMVAMUNE® is a non-replicating live attenuated vaccine that contains genetically modified orthopoxvirus that has lost its ability to replicate in human cells. As it is a non-replicating live vaccine, a 4-week interval between administration of this vaccine and another live vaccine is not required. IMVAMUNE® can be co-administered or given any time before or after other live or inactivated vaccines including COVID-19 vaccines.

11. **How long do vaccine recipients need to wait to receive other vaccines?**

    Individuals do not need to wait to receive other vaccines. IMVAMUNE® can be co-administered or given any time before or after other live or inactivated vaccines.

12. **What if an individual received a tuberculin skin test in the past 14 days or is scheduled to receive one in the next 14 days?**

    IMVAMUNE® can be given any time before or after tuberculin skin testing.

13. **Is a second dose of IMVAMUNE® now provided?**

Given the epidemiology of infection in individuals who have received one dose of IMVAMUNE and reassessment of national vaccine supply, BC is now recommending two doses of pre-exposure IMVAMUNE for maximum protection. The second dose will be available via SC route with at least 28 days after the first dose.

Pre-exposure

Imvamune preexposure vaccination is now offered as a two-dose primary series, with at least 28 days between doses, to individuals at highest risk of Mpox.

Post-exposure

Only one dose of vaccine is required for post exposure prophylaxis, unless the contact is also eligible for IMVAMUNE based on at risk PrEP eligibility criteria (See *'Individuals who meet eligibility criteria for Pre Exposure Vaccination'*.

- Post-exposure vaccine dose should be offered as soon as possible, preferably within 4 days of last exposure but can be considered up to 14 days of last exposure. It should not be offered to individuals who are symptomatic and who meet the definition of suspect, probable or confirmed case.

* Individuals who are moderately or severely immunocompromised as per provincial criteria (see BCCDC IMVAMUNE Biological Product page Appendix A)

14. Is there efficacy data on IMVAMUNE® vaccinations? What about intradermal route administration?

There are no data indicating the efficacy or effectiveness of IMVAMUNE® vaccination against preventing Mpox infection or disease in the context of PrEP or PEP (NACI, 2022). We understand that studies are underway to assess efficacy of Imvamune in this context.

Past data from Africa suggests that the earlier generations of smallpox vaccines are approximately 85% effective in preventing Mpox (CDC, 2022). The effectiveness of IMVAMUNE® against Mpox was concluded from a clinical study on the immunogenicity of IMVAMUNE® and efficacy data from animal studies.

Similarly, there are no data examining protection from subcutaneous (SC) or intradermal (ID) route, however, clinical trials indicate that both routes produce a similar antibody response.

If you get IMVAMUNE® after contact with Mpox virus, the vaccine can reduce your chances of getting a Mpox infection, or it can make the infection milder. For IMVAMUNE® to work, you need to get it before Mpox symptoms start. If you have a weak immune system, the vaccine may not work as well.

IMVAMUNE® administered prior to contact with Mpox takes approximately 14 days to reach peak effectiveness. Like other vaccines, IMVAMUNE® is not 100% effective in preventing disease.

15. What if someone has previously been vaccinated against smallpox using an earlier generation vaccine?

Eligible individuals previously vaccinated against smallpox (product other than IMVAMUNE®) should receive 1 dose for either pre or post-exposure prophylaxis, unless moderately or severely immunocompromised.

- For immunocompetent individuals who have received a live replicating 1st or 2nd generation smallpox vaccine in the past, a single dose of IMVAMUNE® may be offered (i.e. as a booster dose).
- Moderately or severely immunocompromised individuals who are currently eligible for two dose series as per provincial criteria (see BCCDC IMVAMUNE Biological Product page Appendix A) will be offered two doses of IMVAMUNE® irrespective of prior history of smallpox vaccination.

16. What side effects can an individual expect after receiving IMVAMUNE® vaccine?

Mild-moderate side effects may develop a day or two after receiving the IMVAMUNE® vaccine. Most reported side effects resolve within 7 days of vaccine receipt.

Local (at the injection site): pain, redness, induration, swelling, pruritus
Systemic: fatigue, headache, myalgia, arthralgia, fever, chills, nausea, loss of appetite

17. Will IMVAMUNE® leave a scar like previous smallpox vaccines?

IMVAMUNE® will not leave a scar like previous smallpox vaccines. It is administered through the subcutaneous route* which does not scar the skin. Previous generations of vaccine were given through scarification where the skin was punctured multiple times rapidly in a circular area.

*** How does the reaction profile of a dose of IMVAMUNE® administered ID differ from that when given SC?**

* IMVAMUNE® provided by intradermal route can result in more frequent severe (>3cm) and long lasting (>30 days) local reactions compared to subcutaneous injection.

There is only one trial that compares reaction rates when both doses are given SC versus when given ID. This trial found that the frequency of moderate to severe reactions following first dose SC vs ID is 14% versus 22%; and that following second dose is 58% vs 95% respectively. That is most individuals tend to have a local reaction after the second dose.

There are a couple of caveats that should be considered:

1. Rates of reactions reported in trials are generally greater than that reported or experienced in programs. However, the trend is reliable and we can expect a slightly greater rate of local reaction from ID as compared to SC dose.

2. The trial does not provide us information on reaction rate when the first dose is given SC and second given ID. Our sense is that the rate of reaction for this ID dose will be somewhere between the ranges reported above.

The trial also reported that while the second dose produces local reactions regardless of how it's administered, the frequency of moderate to severe systematic reactions are low (<20%) and do not differ among the two groups.

18. When should an individual report side effects to their health care provider?

While mild-moderate side effects are expected, if you experience any unusual, persistent or serious side effects including allergic reactions, these should be reported to your local public health unit. See BCCDC adverse event map to find local public health unit.

If you have concerns about the symptoms you develop after receiving the vaccine, contact your health care provider for advice.

Serious side effects are rare. Should you develop any serious symptoms or symptoms that could be an allergic reaction, call 9-1-1 right away.
Symptoms of allergic reaction include: Hives; Swelling of face, tongue, throat; Difficulty breathing

19. How is the IMVAMUNE® vaccine stored?

Once thawed, the vaccine can be stored in the refrigerator at +2°C to +8°C for up to 8 weeks (record the new expiry date on the vial prior to commencing refrigeration storage) and should be kept in the original packaging and protected from light.

20. Where can staff learn more about the vaccine?

Please visit the following websites for more information on Mpox and the IMVAMUNE vaccine and how to protect yourself, your family and your community:

- BCCDC Mpox Health Professionals: http://www.bccdc.ca/health-professionals/clinical-resources/monkeypox
- BCCDC Biological Products Page: Monkeypox.pdf (bccdc.ca)
- IMVAMUNE Product Monograph: https://pdf.hres.ca/dpd_pm/00063755.PDF

Client Handouts

- BCCDC Patient Handout
- BCCDC Factsheet for the 2SGBTQ+ community