Ministry of Health

Imvamune® Vaccine Storage and Handling Guidance

Version 1.1 – August 18, 2022

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

The intended audience for this guidance document is public health units that are:

- Storing, distributing and/or administering Imvamune®;
- Involved in the assessment of temperature excursions, including the vaccine return process;
- Providing education for the storage and handling of ultra-low temperature (ULT) and frozen vaccines and the use of temperature monitoring devices, such as data loggers.

Vaccines are sensitive biological substances that can lose their potency and effectiveness if they are exposed to temperatures (heat and/or cold) outside of the required temperature range for the specific product (i.e., ultra-low or frozen temperatures) or when exposed to light.

Failure to adhere to vaccine handling and cold chain requirements may reduce vaccine potency and/or increase local reactions at the site of the vaccine administration.

The loss of vaccine effectiveness due to cold chain exposures to adverse conditions is cumulative, permanent, and irreversible.

At this time vaccine should be primarily stored by the public health unit. Where vaccines are not being stored and used by the public health unit, health care providers and organizations (e.g., clinics) should also follow the:

- Ontario Vaccine Storage Handling Guidelines;
- Imvamune® Product Monograph.

In addition, health care providers and organizations who have questions should contact their local public health unit.
Vaccine Storage Conditions

Imvamune® should be stored frozen at the following temperatures:

- -20°C ± 5°C (-25°C to –15°C)
- -50°C ± 10°C (-60°C to –40°C)
- -80°C ± 10°C (-90°C to –70°C)

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Approved Shelf Life (this differs from expiry date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-25°C to -15°C</td>
<td>2 years*</td>
</tr>
<tr>
<td>-60°C to -40°C</td>
<td>2 years</td>
</tr>
<tr>
<td>-90°C to -70°C</td>
<td>9 years</td>
</tr>
</tbody>
</table>

* Data is available to support a shelf-life extension to 3 years, the manufacturer should be contacted for further details.

Thawing

The product should be thawed at room temperature. Once thawed,

- The vaccine should be used immediately, or
- The vaccine can be stored between +2°C to +8°C for up to 2 weeks prior to use.

If taken from -80°C, thawing takes approximately 10 minutes.
If taken from -50°C or -20°C thawing takes approximately less than 10 minutes.

To ensure homogeneity upon thawing, the vial should be swirled gently (not shaken) for at least 30 seconds. After thawing, the vaccine should appear a pale milky coloured homogeneous suspension. The liquid vaccine should be visually inspected for any foreign particulate matter prior to administration. In case of foreign particulate matter being visible, the vaccine must not be used.

Do not re-freeze a vial once it has been thawed/moved to fridge +2°C to +8°C.

Store in original packaging to protect it from light.

Receipt of Vaccine

When receiving the vaccine, the receiving site should:

- Designate one person as the lead for the facility who will be an authorized receiver of the vaccine delivery. This individual should ensure that standard
operating policies and procedures related to vaccine storage and handling are in place and are followed.

- Designate and train alternate(s) to be responsible for the above if the lead is not available. The alternate(s) should be trained in routine and emergency policies and procedures related to vaccine storage and handling.

- Ensure that responsible staff are adequately trained and have knowledge of the requirements for vaccine storage and handling, product sensitivities, storage equipment, temperature monitoring devices, and inventory management procedures.

- Use the **Vaccine Storage Handling Guidelines**, 2018 (or as current) to educate and instruct health care providers who store publicly funded vaccines.

- Ensure that designated and trained staff or their alternate(s):
  - Are available to receive and store vaccines when they are expected to arrive.
  - Never leave vaccines in a shipping container, unpacked or unattended.
  - Understand that vaccine deliveries require immediate attention.

- Immediately open all of the transport containers and assess the digital temperature monitoring device(s).
  - Products should be quarantined until all necessary steps to confirm successful transport are complete (e.g., temperature during transport, condition of product received).

- Examine the shipment for evidence of damage. Quarantine the product immediately if damaged.

- The staff person who received the vaccine is responsible for:
  - Documenting their name, the date and time of receipt of the vaccines and sign the manifest to acknowledge the receipt of the vaccines.
  - Unpacking the shipment and placing the vaccines immediately in the appropriate storage unit.
  - Reviewing the order against the packing slip(s) to confirm that the order is correct.
  - Receiving and recording the vaccines into inventory for use (i.e., remove from quarantine) if the digital temperature monitoring device(s) indicates that the cold chain was maintained during shipping.
  - In the event of a temperature excursion, public health unit should initiate their investigation/assessment.
• Check vaccine expiry dates regularly and after every vaccine order.
  o Move vaccines with shorter expiry dates to the front of the storage unit so that they can be used first.
  o Check expiry dates before vaccines are used.
  o Remove expired vaccines and dispose of them appropriately.
  o **Imvamune® Lot P00021 has received a Health Canada approved extension of 4 years. The new expiry date is 2023-09-30.**

**Temperature Excursions**

If vaccine is not being stored at the public health unit, the site should contact their local public health unit to report the excursion through normal process. Public health units should have an established process in place to manage temperature excursions after hours and on weekends to ensure that vaccine is not held in quarantine for an extended period of time.

Email or fax the public health unit the following:

- The date, time, temperatures (maximum, minimum and current temperature) and the details on the excursion (e.g., length of time); and
- Attach the PDF file (if applicable).

The public health unit should contact the manufacture Bavarian-Nordic at medical.information_us@bavarian-nordic.com for vaccine assessment.

There is no syringe stability information available from the manufacturer. The product should be used immediately once drawn into a syringe.

**Transport and Packing**

Given the 2-week shelf-life of the vaccine at +2°C to +8°C, recommended shipping is at one of the frozen storage temperatures. If not possible or planned for specific clinic use, the vaccine can be transported at +2°C to +8°C.

For further information on how to pre-condition and pack an insulated container, see **Appendix G in the COVID-19 Vaccine Storage and Handling Guidance**.

The manufacturer has not provided any syringe stability information. Vaccines should be transported in their original vials, unopened, in any of the approved storage temperatures.
Vaccine Vial Disposal

- Vials, either empty or with vaccine remaining, should be disposed of per regulation and guidelines by the Ministry of the Environment and Climate Change:
  - [Environmental Protection Act, R.S.O. 1990, c. E.19, Regulation 347](#)
  - [C-4: The Management Of Biomedical Waste In Ontario](#)
  - [Registration Guidance Manual for Generators of Liquid Industrial and Hazardous Waste](#)

Additional Resources

Ontario - [Monkeypox Virus (gov.on.ca)](#)

World Health Organization – [Monkeypox information](#)

World Health Organization - [Monkeypox Q&A (who.int)](#)

European Centre for Disease Prevention and Control - [Factsheet for health professionals on monkeypox (europa.eu)](#)

United States Centres for Disease Control - [Monkeypox | Poxvirus | CDC](#)

Public Health Ontario – [Monkeypox Case and Contact Management](#)