

JYNNEOS Smallpox and Monkeypox Vaccine

Storage and Handling Summary

Storage Basics



Store vaccine preferably in a purpose-built refrigerator or freezer.



Use a digital data logger to monitor temperature of the storage unit.



Check and record storage unit temperatures daily.

What to do when vaccine is received

- Unpack vaccine immediately upon arrival at the clinic.
- Check the cold chain monitor, a device used to monitor vaccine temperatures during transport, for any indication of a temperature excursion during transit.
- Check the expiration date on the carton.
- Store vaccine in the original package in order to protect from light.

Important note: All vaccine, whether received refrigerated or frozen, is originally frozen from the manufacturer. If you receive refrigerated vaccine, it is thawed vaccine. Do NOT refreeze. Thawed vaccine must be used within 8 weeks from thawing.

Vaccine Storage

If vaccine is received refrigerated and requires storage before use, maintain:

- Refrigerator storage between 2°C and 8°C (between 36°F and 46°F).
- As specified in the note above, refrigerated vaccine is thawed vaccine and must be used within 8 weeks from thawing.
- DO NOT refreeze.

If vaccine is received frozen and requires storage before use, maintain:

- Freezer storage between -25°C and -15°C (between -13°F and +5°F), if freezer capacity is available, **OR** refrigerator storage between 2°C and 8°C (between 36°F and 46°F).
 - If storing vaccine that was received frozen **in the freezer**, the vaccine should be used within the printed expiration date on the carton. Please note that the expiration date is not shown on the individual vial. Expiration date by lot number can be found at <https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx>.
 - If storing vaccine that was received frozen **in the refrigerator**, it is thawed vaccine and must be used within 8 weeks from thawing. DO NOT refreeze once thawed. It takes about 10 minutes to thaw from -20°C (-4°F).

JYNNEOS may be stored refrigerated between 2°C and 8°C (between 36°F and 46°F) for up to 8 weeks from thawing. This updated information has been provided by the vaccine manufacturer based on available supportive stability data. Please note that this Beyond Use Date (BUD) guidance differs from the package insert guidance, which states that the vaccine may be kept at 2°C to 8°C (36°F to 46°F) for 12 hours (Section 2.2 Preparation and Administration and 16.2 Storage Conditions).

Temperature Monitoring

Storage unit temperatures must be monitored regularly and checked and recorded to determine if any excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature using a temperature log and one of the following options:

- **Minimum/Maximum Temperatures (preferred):** Most DDLs display minimum and maximum (min/max) temperatures. Check and record the min/max temperatures at the start and end of each workday.
- **Current Temperature:** If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.

Temperature Excursions

Any temperature reading outside the range as specified in this document is considered a temperature excursion. It is critical to identify temperature excursions quickly and take immediate action to correct them.

- Refer to the following guidance from the CDC's Vaccine Storage and Handling Toolkit for appropriate steps to determine whether vaccine is still likely to be viable: <https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temperature-excursion-508.pdf>.
- You may find it helpful to use a vaccine storage troubleshooting record to document temperature excursions. One can be found at <https://www.immunize.org/catg.d/p3041.pdf>.
- Questions about temperature excursions can be directed to Bavarian Nordic at medical.information_US@bavarian-nordic.com or U.S. Call Center at 1-844-422-8274. Bavarian Nordic responds to inquiries Monday through Friday from 8:00 am to 4:30 pm CST.

Vaccine Disposal

Once vaccine has reached its expiration date, contact the manufacturer for guidance on whether it can still be used. If instructed to dispose of vaccine, dispose as medical waste according to your local and state regulations. Contact your jurisdiction's immunization program for guidance on vaccine disposal regulations. Jurisdiction immunization program contact information can be found at www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html.

Storage and Handling Resources

- CDC's Vaccine Storage and Handling Toolkit at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- Best practice fact sheets on storage and temperature monitoring for both refrigerated and frozen vaccines in Fahrenheit and Celsius at: <https://www.cdc.gov/vaccines/hcp/admin/storage/>

Additional Resources

- JYNNEOS package insert at <https://www.fda.gov/media/131078/download>
- Manufacturer's product information at <https://jynneos.com/>