



BAVARIAN NORDIC

October 2024

IMPORTANT PRESCRIBING INFORMATION

Subject: Extension of expiration dates for JYNNEOS® (Smallpox and Monkeypox Vaccine, Live, Non-replicating)

Dear Healthcare Provider:

The purpose of this letter is to inform you of an extension to the expiration dates for lots FDP00017, FDP00018, FDP00019, FDP00020 of JYNNEOS® (Smallpox and Monkeypox Vaccine, Live, Non-replicating).

The expiration date printed on the carton label for four lots of JYNNEOS® (FDP00017, FDP00018, FDP00019 and FDP00020) is 31-Oct-2024, when stored at -25°C to -15°C (-13°F to +5°F). The expiration date for these lots has been extended to 31-Aug-2026 when stored at -25°C to -15°C (-13°F to +5°F).

As described in the current USPI, storage conditions are as follows:

Keep frozen at -25°C to -15°C (-13°F to +5°F).

Store in the original package to protect from light.

Do not re-freeze a vial once it has been thawed.

Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 4 weeks.

Healthcare Provider Action

Providers should include the revised expiration date on cartons of JYNNEOS® lots FDP00017, FDP00018, FDP00019, FDP00020, and include the revised expiration dates in their inventory management system.

Reporting Adverse Events

Report adverse events following JYNNEOS® to Bavarian Nordic at 1-800-675-9596 or to VAERS at 1-800-822-7967 and <https://vaers.hhs.gov>.

If you require further guidance regarding the information contained in this letter, please contact medical.information_us@bavarian-nordic.com or call 1-800-675-9596.

This letter is not intended as a complete description of the benefits and risks related to the use of JYNNEOS®; please refer to the enclosed full prescribing information.

Sincerely,

Victoria Jenkins, PhD
Vice President, Regulatory Affairs
Bavarian Nordic