

Monkeypox: JYNNEOS

Vaccine Fact Sheet for Clinicians



General Information

- **Vaccine** JYNNEOS™ (Smallpox/Monkeypox Vaccine, Live, Non-replicating) Bavarian Nordic A/S
- **NDC** 50632-001-02 (carton) and 50632- 001-01 (vial)
- **Packaging** (20) single-dose vials ; ancillary supplies are not provided with vaccine https://www.drugs.com/pro/images/69fc3841-a461-4706-bdcb-1176c40bf486/carton_label.jpg
- **Efficacy** The efficacy of JYNNEOS to prevent monkeypox is inferred from seroconversion and immunogenicity that is noninferior as compared with replicating orthopoxvirus vaccines.
- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.



Indications

- Indicated for prevention of smallpox or monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection
- Use in younger populations requires submission of a single-use Expanded Access Investigational New Drug (EA-IND) (“Compassionate Use”) application



Post-Exposure Prophylaxis

- The sooner an exposed person gets the vaccine, the better. CDC recommends that vaccine be given within 4 days from date of exposure to prevent onset of disease.
- If given between 4–14 days after date of exposure, vaccination may reduce symptoms of disease, but may not prevent the disease.



Vaccine Storage

- Unpunctured vials: Shipped at -20°C and requires cold chain management; store frozen at -25°C to -15°C (13°F to +5°F) until expiration date on the carton (or look it up at <https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx>) or at 2-8°C for up to 8 weeks (this differs from the package insert – see [Provider Letter https://aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf](https://aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf))
- Punctured vials: N/A, single dose vials
- Use-by limits: Once thawed, hold at +2°C to +8°C (+36°F to +46°F) for up to 8 weeks; do not refreeze.



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Preparing the Vaccine

- Follow standard use of PPE (personal protective equipment)
- Do not dilute



Administration

- Administer in accordance with current CDC <https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html> and DHS guidelines <https://www.dhs.wisconsin.gov/disease/monkeypox.htm>
- **Vaccine information statement (VIS)** Distribute the VIS before vaccination <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf>
- **Dosing regimen** 2-dose vaccine series (full protection is anticipated 2 weeks following second dose)
- **Minimum interval** 28 days apart
- **Administration** Subcutaneous injection only; allow vaccine to thaw and reach room temperature before use (see [package insert](https://www.fda.gov/media/131078/download) for instructions for vaccine preparation and administration <https://www.fda.gov/media/131078/download>)
- **Dosing volume** 0.5 mL each dose



Adverse Reactions

- **Common side effects** Injection site reactions such as pain, swelling, and redness
- **Severe allergic reactions** Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS.



Resources

- **ACIP recommendations** <https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm>
- **Package insert** <https://www.fda.gov/media/131078/download>
- **Provider letter** <https://aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf>
- **Packaging image** https://www.drugs.com/pro/images/69fc3841-a461-4706-bdcb-1176c40bf486/carton_label.jpg
- **Vaccine information statement** <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf>
- **DHS Monkeypox Information** <https://www.dhs.wisconsin.gov/disease/monkeypox.htm>