

# JYNNEOS Smallpox/Monkeypox Vaccine Fact Sheet

<b>Brand Name and Manufacturer</b>	JYNNEOS™/Imvamune/Imvanex (Smallpox/Monkeypox Vaccine, Live, Non-replicating) Bavarian Nordic A/S
<b>NDC</b>	50632-001-02 (carton) and 50632-001-01 (vial)
<b>Indication(s) and Intended Population(s)</b>	Indicated for prevention of smallpox or monkeypox disease for these populations if patient is determined to be at high risk for smallpox or monkeypox infection: <ul style="list-style-type: none"> <li>• 18 years and older: <ul style="list-style-type: none"> <li>◦ FDA-approved as a two-dose series administered subcutaneously</li> <li>◦ EUA for intradermal administration</li> </ul> </li> <li>• under 18 years: authorized under EUA as a 2-dose series administered subcutaneously</li> </ul>
<b>Dosing Schedule</b>	2-dose vaccine series (full protection is anticipated 2 weeks following 2 <sup>nd</sup> dose)
<b>Minimum Intervals</b>	28 days apart
<b>Co-administration</b>	<ul style="list-style-type: none"> <li>• May be given at the same time as other vaccines.</li> <li>• People at increased risk of myocarditis (swelling of the heart muscle), including adolescent or young adult males, might consider waiting 4 weeks after JYNNEOS™ vaccination before getting an mRNA COVID-19 vaccine.</li> </ul>
<b>Safety &amp; Warnings</b>	<p><b>Severe Allergic Reactions:</b> Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS.</p> <p><b>Altered Immunocompetence:</b> Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.</p>
<b>Precautions</b>	People who have had a severe allergic reaction to gentamicin, ciprofloxacin or egg protein: discuss risks and benefits of vaccination. May be vaccinated with a 30-min observations period. Alternatively, vaccination can be delayed until an allergist-immunologist is consulted, but the impact of delaying vaccination should be considered.
<b>Contraindications</b>	People who had a severe allergic reaction to a prior dose of JYNNEOS: <b>do NOT vaccinate.</b>
<b>Post-Exposure Prophylaxis (PEP)</b>	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.
<b>Efficacy</b>	The efficacy of JYNNEOS to prevent monkeypox is inferred from seroconversion and immunogenicity that is noninferior as compared with replicating orthopoxvirus vaccines.
<b>Administration &amp; Dosing Volume</b>	<p>Allow vaccine to thaw and reach room temperature before use. See package insert.</p> <p><b>Intradermal injection, 0.1 mL (one-fifth vial):</b></p> <ul style="list-style-type: none"> <li>• People 18 years of age and older</li> </ul> <p><b>Subcutaneous, 0.5 mL (1 vial):</b></p> <ul style="list-style-type: none"> <li>• People less than 18 years old</li> <li>• People of any age who have a history of developing keloid scars</li> </ul>
<b>Adverse Reactions</b>	Injection site reactions such as pain, swelling, and redness.
<b>PPE</b>	Standard for immunization
<b>Reconstitution</b>	Do not dilute
<b>Packaging</b>	(20) 0.5 mL vials; ancillary supplies are not provided with vaccine
<b>Storage: Unpunctured Vials</b>	<ul style="list-style-type: none"> <li>• 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 carton, or lookup here: <a href="https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx">https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx</a></li> <li>• <b>Can also be stored at 2-8°C for up to 8 weeks</b> (this differs from the package insert, see provider letter: <a href="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</a>)</li> <li>• Once thawed, do not refreeze.</li> </ul>

<b>Punctured Vials</b>	Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture.
<b>FDA EUA Factsheet</b>	<a href="https://www.fda.gov/media/160774/download">https://www.fda.gov/media/160774/download</a>
<b>CDC intradermal how-to video</b>	<a href="https://www.youtube.com/watch?v=TLv1mR6mECQ">https://www.youtube.com/watch?v=TLv1mR6mECQ</a>
<b>CDC Interim clinical guidance</b>	<a href="https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html">https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html</a>
<b>Package Insert</b>	<a href="https://www.fda.gov/media/131078/download">https://www.fda.gov/media/131078/download</a>
<b>Storage and Handling</b>	<a href="https://www.cdc.gov/poxvirus/monkeypox/pdf/Storage-and-Handling-Summary.pdf">https://www.cdc.gov/poxvirus/monkeypox/pdf/Storage-and-Handling-Summary.pdf</a>
<b>EUA Fact Sheet for Recipients &amp; Caregiver; VIS</b>	Distribute before vaccination. For intradermal and for people <18 under EUA: <a href="https://www.fda.gov/media/160773/download">https://www.fda.gov/media/160773/download</a> . Vaccine Information Statement (for subcutaneous injection in ages 18+): <a href="https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf">https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf</a>
<b>CVX Code</b>	206