JYNNEOS®
(Smallpox and Monkeypox Vaccine, Live, Non-replicating)

POWER TO PROTECT AGAINST MPOX*

*Vaccination with JYNNEOS may not protect all recipients.

ANYONE CAN BE INFECTED BUT MOST US MPOX† CASES HAVE BEEN AMONG GROUPS AT RISK[1-3]

PERSONS AT RISK INCLUDE[4]:

- **Gay, bisexual, and other men who have sex with men, transgender or nonbinary people** who in the past 6 months have had one of the following:
  - A new diagnosis of ≥1 sexually transmitted diseases
  - More than one sexual partner
  - Sex at a commercial sex venue
  - Sex in association with a large public event in a geographic area where mpox transmission is occurring
- **Sexual partners** of persons with the risks described in above
- Persons who anticipate experiencing **any of the above**

THE ACIP RECOMMENDS MPOX VACCINATION FOR AT-RISK INDIVIDUALS AGED ≥18 YEARS OLD[4]

Mpox is a **vaccine-preventable**, viral disease that can cause symptoms such as a **painful rash**, fever, and swollen lymph nodes and **can result in serious complications**, including death[1]

Despite a decline in US cases since the 2022 outbreak, **clusters of mpox cases continue to pose a threat to at-risk groups**, such as travelers attending gatherings that may place them in close contact with someone who has mpox[5,6]

3 out of 4 at-risk individuals are **unvaccinated** or have **not completed the 2-dose series**[7‡]

THE RISK OF MPOX REMAINS IN THE US.[5] DON'T WAIT – VACCINATE.

INDICATION AND USAGE

JYNNEOS is approved for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

IMPORTANT SAFETY INFORMATION

Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS. Anyone who has experienced a severe allergic reaction following a previous dose of JYNNEOS or following exposure to any component of JYNNEOS may be at increased risk for severe allergic reactions.

Syncope (fainting) has been reported following vaccination with JYNNEOS. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.

Vaccination with JYNNEOS may not protect all recipients.

In smallpox vaccine-naïve healthy adults, the most common (>10%) solicited injection site reactions were pain (84.9%), redness (60.8%), swelling (51.6%), induration (45.4%), and itching (43.1%); the most common solicited systemic adverse reactions were muscle pain (42.8%), headache (34.8%), fatigue (30.4%), nausea (17.3%) and chills (10.4%).

In healthy adults previously vaccinated with a smallpox vaccine, the most common (>10%) solicited injection site reactions were redness (80.9%), pain (79.5%), induration (70.4%), swelling (67.2%), and itching (32.0%); the most common solicited systemic adverse reactions were fatigue (33.5%), headache (27.6%), and muscle pain (21.5%).

The frequencies of solicited local and systemic adverse reactions among adults with HIV infection and adults with atopic dermatitis were generally similar to those observed in healthy adults.

Please see additional Important Safety Information throughout and full Prescribing Information or visit https://bavariannordic.io/uploads/jynneos-pi.pdf.

†The CDC, HHS, and WHO adopted "mpox" as the term used to refer to monkeypox disease on November 28, 2022.[8]

‡US mpox vaccine administration data no longer being tracked as of January 10, 2024.[7]

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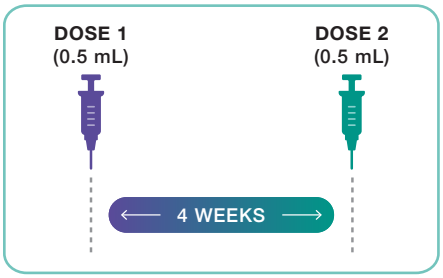
HELP PROTECT YOUR PATIENTS AGAINST MPOX IN 2 SHOTS[9]



JYNNEOS IS THE ONLY FDA-APPROVED AND ACIP-RECOMMENDED MPOX VACCINE[4,10]

- **JYNNEOS is administered subcutaneously, preferably into the upper arm, in 2 doses given 4 weeks apart[9]**
- **Store JYNNEOS frozen at -13°F to 5°F (-25°C to -15°C) and in the original package to protect from light; once thawed, the vaccine may be kept at 36°F to 46°F (2°C to 8°C) for 4 weeks[9]**

Vaccine effectiveness against mpox was inferred from the immunogenicity of JYNNEOS in a clinical study and from efficacy data from animal challenge studies.[9] Animals were administered JYNNEOS or a saline placebo on day 0 and day 28.[9] On day 63, animals were challenged with MPXV delivered by aerosol, intravenous or intratracheal route.[9] Across all studies, 80-100% of JYNNEOS-vaccinated animals survived compared to 0-40% of control animals.[9] The immunogenicity trial was a randomized, open-label study conducted at US military facilities in South Korea to compare the immunogenicity of JYNNEOS (N=220) to ACAM2000® (N=213) (95% CI) in healthy smallpox vaccine-naïve adults 18 through 42 years of age.[9] The results found that vaccinia neutralizing antibodies increased from a titer of 10.1 (9.9, 10.2) pre-vaccination to 152.8 (133.3, 175.0) at post-vaccination peak visit (2 weeks after second dose) in those administered JYNNEOS compared to 10.0 (10.0, 10.0) pre-vaccination and 84.4 (73.4, 97.0) at post-vaccination peak visit (4 weeks after single dose) in those receiving ACAM2000.[9]

REAL-WORLD DATA

EFFICACY

Data from 3 case-control studies suggest the **vaccine effectiveness against mpox ranges from 66-89% for full (2 doses) vaccination** with JYNNEOS[11,12]

LIMITATIONS: These case-control studies included individuals vaccinated via subcutaneous, intradermal, and heterologous routes of administration.* The studies were at risk for selection bias, confounding bias, and misclassification bias. Additional studies are needed.

SAFETY

Data collected from multiple CDC vaccine safety monitoring systems have identified **no new or unexpected safety concerns** with JYNNEOS[11,13]

LIMITATIONS: Data based on voluntary reports through safety monitoring systems; not all potential reactions are captured. Estimations of frequency or establishment of causation may not be possible.

*Approved route of administration for JYNNEOS is subcutaneous. Emergency Use Authorization for intradermal administration was issued by FDA on August 9, 2022.[10]

VACCINATION IS ONE OF THE MOST IMPORTANT WAYS TO HELP PROTECT PATIENTS AGAINST MPOX[6]

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IMPORTANT SAFETY INFORMATION (CONT.)

Across all studies, a causal relationship to JYNNEOS could not be excluded for 4 serious adverse events (SAEs), all non-fatal, which included Crohn's disease, sarcoidosis, extraocular muscle paresis and throat tightness.

Cardiac adverse events of special interest (AESIs) considered causally related to study vaccination were reported in 0.08% of subjects who received JYNNEOS and included tachycardia, electrocardiogram T wave inversion, electrocardiogram abnormal, electrocardiogram ST segment elevation, electrocardiogram T wave abnormal, and palpitations. None of the cardiac AESIs considered causally related to study vaccination were considered serious.

To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic at 1-844-4BAVARIAN or the US Department of Health and Human Services by either visiting www.vaers.hhs.gov/reportevent.html or calling 1-800-822-7967.

Please see full Prescribing Information or visit https://bavariannordic.io/uploads/jynneos-pi.pdf.

ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; FDA, US Food and Drug Administration; HHS, Health and Human Services; MPXV, monkeypox virus; WHO, World Health Organization.

References

1. WHO. Fact sheets. Mpox (monkeypox). Accessed January 10, 2024. https://www.who.int/news-room/fact-sheets/detail/monkeypox **2.** CDC. 2022-2023 outbreak cases and data. Accessed January 10, 2024. https://www.cdc.gov/poxvirus/mpox/response/2022/index.html **3.** Pollock ED, et al. *MMWR Morb Mortal Wkly Rep*. 2023;72:568-573. **4.** CDC. ACIP recommendations. Accessed January 10, 2024. https://www.cdc.gov/vaccines/acip/recommendations.html **5.** CDC. CDC urges mpox vaccination for those eligible given continued U.S. mpox cases. Accessed March 1, 2024. https://emergency.cdc.gov/newsletters/coca/2024/021224.html **6.** CDC. Travelers' health. Mpox. Accessed March 1, 2024. https://wwwnc.cdc.gov/travel/diseases/mpox **7.** CDC. Mpox vaccine administration in the U.S. Accessed January 10, 2024. https://www.cdc.gov/poxvirus/mpox/response/2022/vaccines_data.html **8.** CDC. CDC changes monkeypox terminology to mpox. Accessed January 10, 2024. https://www.cdc.gov/nchhstp/dear_colleague/2022/dcl-changes-monkeypox-terminology.html **9.** JYNNEOS Prescribing Information. Bavarian Nordic; 2023. **10.** CDC. JYNNEOS vaccine. Accessed January 10, 2024. https://www.cdc.gov/poxvirus/mpox/interim-considerations/jynneos-vaccine.html **11.** CDC. 2022/2023 Mpox outbreak: situational awareness and updates (October 25, 2023, ACIP meeting presentation). Accessed January 10, 2024. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-10-25-26/02-MPOX-Minhaj-508.pdf **12.** CDC. JYNNEOS vaccine effectiveness (February 22, 2023, ACIP meeting presentation). Accessed January 10, 2024. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-22/mpox-04-chard-508.pdf **13.** CDC. CDC WONDER. Accessed February 23, 2024. https://wonder.cdc.gov/vaers.html

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