



JYNNEOS Vaccine Information and Facts for Providers

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JYNNEOS Vaccine

- Approved in 2019 for 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.
- August 09, 2022, the FDA issues an emergency use authorization for JYNNEOS vaccine to allow healthcare providers to use the vaccine by intradermal injection for individuals 18 years and older who are determined to be at high risk for monkeypox infection.
- The EUA also allows for the use of the vaccine subcutaneously in individuals younger than 18 years of age determined to be at high risk of monkeypox infection.
- Could facilitate vaccination of entire current target population and allow for additional supply in the event of further spread.
- One fifth of the dose (0.1 ml) given intradermally on the same schedule produces similar efficacy to subcutaneous, albeit with more local redness.
- Live, attenuated, non-replicating orthopoxvirus.
- Also known as Imvamune or Imvanex.
- Indications:
 - High Risk contact of confirmed positive case
 - High risk exposure to an event or venue that has known monkeypox cases
 - MSM that has had 2 or more partners in the past 14 days
- Emergency Use Authorization:
 - Allows for a fraction of the JYNNEOS dose to be administered intradermally to those 18 years and older who are determined to be at high risk for monkeypox.
 - Authorizes two doses of JYNNEOS administered by subcutaneous route in individuals younger than 18 years of age.
- Post Exposure recommended within 4 days (4-14 days may reduce severity).
- Administration:
 - See EUA Guidelines.
 - Allow vaccine to thaw and reach room temperature before use. Once thawed, may be kept at +36° to +46° up to 8 weeks* – Do not refreeze.
 - Once punctured, use within 8 hours.
 - Keep refrigerated between doses from the same vial.
 - Swirl vial gently for 30 seconds before use.

Emergency Use Authorization

Vaccination Strategies

Strategy	Definition
Post-Exposure Prophylaxis (PEP)	Vaccination after known exposure to monkeypox
Expanded Post-Exposure Prophylaxis (PEP++)	Vaccination after known or presumed exposure to monkeypox
Pre-Exposure Prophylaxis (PrEP)	Vaccination before exposure to monkeypox

<https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination/overview.html>

Emergency Use Authorization

INDICATIONS	< 18 YEARS OF AGE	> 18 YEARS OF AGE
CRITERIA FOR ADMINISTRATION	See EAU	See EAU
DOSAGE AND ROUTE	0.5 ML SUBCUTANEOUS (SINGLE DOSE PER VIAL)	0.1 ML INTRADERMAL (5 DOSES PER VIAL)
NUMBER OF DOSES	2 DOSES	2 DOSES
INTERVAL BETWEEN DOSES	28 DAYS APART	28 DAYS APART
CONTRAINDICATIONS	Immunocompromised may have diminished immune response	Immunocompromised may have diminished immune response Persons with history of keloid scar formation should receive subcutaneous administration only
COMMON ADVERSE	Localized redness, induration, itching and pain at injection site Mild Fatigue, headache, muscle pain, nausea, chills and fever Cardiac AESI's less than 1% and none considered serious	Localized redness, induration, itching and pain at injection site Mild Fatigue, headache, muscle pain, nausea, chills and fever Cardiac AESI's less than 1% and none considered serious
STORAGE AND HANDLING	Allow vaccine to thaw and reach room temperature before use. Once thawed, may be kept at +36° to +46° up to 8 weeks* – Do not refreeze	Allow vaccine to thaw and reach room temperature before use. Once thawed, may be kept at +36° to +46° up to 8 weeks* – Do not refreeze *See Special Considerations

Administration of the JYNNEOS Vaccine

How to Administer a JYNNEOS Vaccine Intradermally

Step 1

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



STEP 1

Locate and clean a site for injection in the inner (volar) surface of the forearm.

www.cdc.gov/monkeypox




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Step 2

MONKEYPOX


How to administer a JYNNEOS vaccine intradermally



STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.

www.cdc.gov/monkeypox

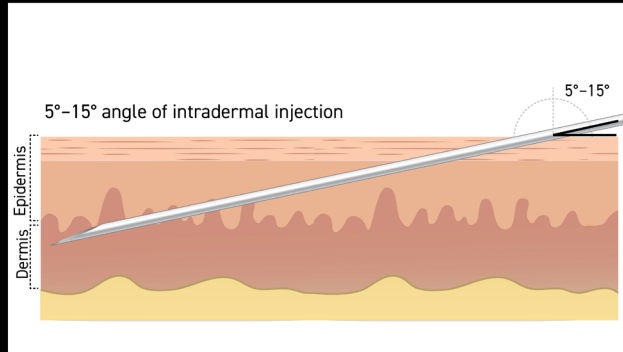


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➤ **Step 2 Continued**

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



www.cdc.gov/monkeypox

STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.



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➤ **Step 3**

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



www.cdc.gov/monkeypox

STEP 3

Slowly inject 0.1mL intradermally. This should produce a noticeable pale elevation of the skin (wheal).



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➤ **Step 4**

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



STEP 4

Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein.



www.cdc.gov/monkeypox


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➤ **Video Tutorial**

MONKEYPOX

How to administer a JYNNEOS vaccine intradermal

How to administer a vaccine intradermally.



From a national health authority
Learn how experts define health sources in a journal of the National Academy of Medicine

[How to administer a JYNNEOS vaccine intradermally - YouTube](#)

Interim Recommendation for JYNNEOS Vaccine Administration Errors and Deviations

TYPE	Administration error/deviation	Interim Recommendations
Intervals	Interval between first and second dose less than the recommended minimum interval. ¹	Repeat dose after the dose given in error by at least the recommended interval of 28 days if the patient is severely immunosuppressed. ² Otherwise, do not repeat dose. ¹
Intervals	Interval between first and second dose greater than the recommended minimum interval. Vaccine doses administered up to 4 days before the minimum interval may be counted and do not need to be repeated.	Do not restart the series and administer the second dose as soon as possible. While available clinical data show that the second dose may be given up to 7 days after the minimum interval of 28 days (i.e., 35 days after the first dose), there is no maximum interval and the second dose should be given as soon as possible to complete the series.
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)	Contact the manufacturer ² for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).
Storage and handling	Dose administered past the expiration/beyond-use date	Contact the manufacturer ² for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).

- Email: medical.information_US@bavarian-nordic.com
- U.S. phone number: 1-844-422-8274
- U.S. fax number: 1-843-422-8274

Dose Interval Considerations

Recommended Interval

- Dose 2 given 28 days following Dose 1
 - May be given up to 7 days later than the minimum interval of 28 days (*up to 35 days after Dose 1*)
 - If Dose 2 is not administered during the recommended interval, it should be administered as soon as possible.
 - There is no need to restart or add doses to the series if there is an extended interval between.

- Dose 2 may be administered 4 days before the minimum interval of 28 days (*may give as early as 24 days*)
 - If Dose 2 is inadvertently administered before the minimum interval, the dose may need to be repeated.

Special Considerations

- A person who presents for their second JYNNEOS vaccine dose who is still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) may have the second dose administered intradermally in the contralateral forearm.

- When necessary, a person aged 18 years or older who received one JYNNEOS vaccine dose with the standard subcutaneous regimen may receive a second dose with the alternative intradermal regimen at the recommended interval (i.e., 28 days) to complete the vaccination series.

- Exceptions to the recommended two-dose vaccine series.
 - A person who is diagnosed with monkeypox after their first dose of JYNNEOS is not recommended to receive the second dose at this time, because monkeypox infection likely confers additional immune protection.
 - A person who would be eligible for vaccination but has been diagnosed with monkeypox during this outbreak, which started in the United States on May 17, 2022, is not recommended to be vaccinated at this time, because monkeypox infection likely confers immune protection.
 - An immunocompromised person who is diagnosed with monkeypox after their first dose of JYNNEOS may be eligible to receive the second dose of JYNNEOS on a case-by-case shared decision-making basis based on the clinical judgment of the healthcare provider.

➤ **Concomitant Administration with other Vaccines**

- JYNNEOS typically may be administered without regard to timing of other vaccines. This includes simultaneous administration of JYNNEOS and other vaccines on the same day, but at different anatomic sites if possible.
- COVID19 Vaccines:
 - In the setting of PEP or PrEP, do not delay JYNNEOS because of receipt of mRNA or Novavax vaccines. No minimum interval necessary.
- Adolescents or young adult males might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving an mRNA or Novavax vaccine due to observed risk for myopericarditis after ACAM2000 vaccine and mRNA or Novavax vaccines and unknown risk for those complications after JYNNEOS.

➤ **Pre- and Post- Vaccination Counseling**

Pre-Vaccination Counseling

- Recipients should be informed of the risks and benefits of JYNNEOS prior to vaccination.
- Healthcare providers should ascertain the medical history of recipients to appropriately determine the route of vaccine administration.
- Recipients should be counseled about possible side effects from vaccination including injection site pain, redness, swelling, induration, itching, fatigue, headache, nausea, chills, and muscle aches, and be provided with a JYNNEOS vaccine information statement (VIS) or FDA JYNNEOS EUA Fact Sheet, as applicable.
- There have been reports of prolonged duration of induration or erythema following intradermal administration. Side effects are usually self-limiting.

Post-Vaccination Counseling

- Continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact with someone who has monkeypox.
- People with underlying heart disease or three or more major cardiac risk factors should be counseled about the theoretical risk for myopericarditis following vaccination with JYNNEOS given the uncertain etiology of myopericarditis associated with replication-competent smallpox vaccines such as ACAM2000.

➤ Other Vaccine Considerations

- People presenting with **minor illnesses**, such as a cold, may be vaccinated
- People who are **moderately or severely ill** should usually **wait** until they have recovered to their baseline state of health before vaccination
- A person offered JYNNEOS vaccine due to an exposure to monkeypox virus or disease should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system
- Vaccine providers, particularly when vaccinating adolescents, should consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until the symptoms resolve.

➤ Contraindications and Precautions

Medical condition or history	Interim guidance	Suggested action(s)
History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS	Contraindication	Do not vaccinate. Referral to an allergist-immunologist should be considered to assess the risks versus benefits of administering a dose.
History of severe allergic reaction (e.g., anaphylaxis) following gentamicin or ciprofloxacin ¹	Precaution	Discuss risks and benefits with potential recipients. They may be vaccinated with a 30-minute observation period. Alternatively, vaccination can be delayed until an allergist-immunologist is consulted, but the impact of delaying vaccination should be considered.
History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND are currently avoiding exposure to all chicken or egg products ¹	Precaution	Discuss risks and benefits with potential recipients. They may be vaccinated with a 30-minute observation period. Alternatively, vaccination can be delayed until an allergist-immunologist is consulted, but the impact of delaying vaccination should be considered.
Moderate or severe acute illness, with or without fever	Precaution	Consider deferring vaccination until the acute illness has improved.

Reporting Adverse Events

- Vaccination providers who are administering JYNNEOS under the EUA are required to report the following adverse events that occur after JYNNEOS vaccination.
 - Vaccine administration errors whether or not associated with an adverse event.
 - Serious adverse events (irrespective of attribution to vaccination).
 - Cases of cardiac events including myocarditis and pericarditis.
 - Cases of thromboembolic events and neurovascular events.
- Information on how to submit a report to VAERS is available at vaers.hhs.gov or by calling 1-800-822-7967

JYNNEOS Storage and Handling

- Store the vaccine in an appropriate refrigerator or freezer.
 - We advise you to NOT use any dorm-style fridge or freezer.
- Use a Digital Data Logger to continually monitor the temperature of the storage unit.
 - Check and record the temperatures daily.
- Jynneos can be stored in either a frozen or refrigerated state.
 - Freezer storage temps:
 - -25°C and -15°C (-13°F and +5°F)
 - Refrigerator storage temps:
 - 2°C and 8°C (36°F and 46°F)
- **Any temperatures outside of these ranges should be considered an excursion.**
 - If an excursion occurs download the temperatures.
 - Email kaypa@health.ok.gov with the downloaded temps and a note about the excursion.
- If you receive a refrigerated vaccine, it is considered thawed vaccine and must be used within 8 weeks.
- Beyond Use Date (BUD) stickers should be used when the vaccine is moved to refrigeration and is in a thawed state.
- If the vials are being used for intradermal injections, a thawed, punctured vial of vaccine is good for 8 hours.
 - Vaccine must be refrigerated at all times.
 - Vaccine should never be refrozen.

JYNNEOS in OSIIS

- Two ways to document the vaccine in OSIIS.
- When documenting the vaccine in OSIIS, intradermal is the default route and dosage.

Intradermal vaccination

PATIENT, TEST ID: 4110310 DOB: 01/24/1975 AGE: 47Y 6M 23D GENDER: M

Immunizations [Learn More](#) Cancel Links Update

Administer

Patient Level Eligibility * (01) NOT VFC ELIGIBLE

Vaccination Time HH:MM AM/PM (HH:MM A/P)

Administered By * TEST, TRAIN (-)

Refusal Reason *

Vaccine Smallpox Monkeypox TEST, TRAIN (-)

Did not Admin

Delete

Dose Level Eligibility * (01) NOT VFC ELIGIBLE

Mfg | Lot | Exp Date (MM/DD/YY) | Funding Src | Inv Loc | NDC | Brand *
(I) BN | TEST123 | 08/23/23 | 317 | IISTPROVIONE | 50632-0001-01 | JYNNEOS (SINGLE DOS

Body Site * Route * Dosage Refusal Reason
INTRADERMAL 0.10

Subcutaneous vaccination

Change the dosage to .5

PATIENT, TEST ID: 4110310 DOB: 01/24/1975 AGE: 47Y 6M 23D GENDER: M

Immunizations [Learn More](#) Cancel Links Update

Administer

Patient Level Eligibility * (01) NOT VFC ELIGIBLE

Vaccination Time HH:MM AM/PM (HH:MM A/P)

Administered By * TEST, TRAIN (-)

Refusal Reason *

Vaccine Smallpox Monkeypox TEST, TRAIN (-)

Did not Admin

Delete

Dose Level Eligibility * (01) NOT VFC ELIGIBLE

Mfg | Lot | Exp Date (MM/DD/YY) | Funding Src | Inv Loc | NDC | Brand *
(I) BN | TEST123 | 08/23/23 | 317 | IISTPROVIONE | 50632-0001-01 | JYNNEOS (SINGLE DOS

Body Site * Route * Dosage Refusal Reason
SUBCUTANEOUS .5



INTRADERMAL
INTRAMUSCULAR
INTRAVENOUS
NASAL
ORAL
OTHER/MISC
SUBCUTANEOUS
TRANSDERMAL


- Body site does not auto-populate and must be selected.
- The only way to see what dosage a patient previously received will be to look at the details of the vaccine on the patient's record in OSIIS.
 - Patient -> Immunizations -> Smallpox Monkeypox Vaccine -> Update

- Subcutaneous administration requires an inventory adjustment in OSIIS.
 - Once the shot is saved on the patient's record, go to inventory on-hand
 - Find the Smallpox Monkeypox vaccine
 - Action
 - Adjustment
 - Subtract out 4 doses with the reason being VTRCKS Other
 - In the comments, put "Used the whole vial for one patient"

Vaccine Inventory Adjustment Cancel Create

Add

Date/Time *	08/16/2022  02:38 PM (HH:MM A/P)
Inventory Location *	INV: ITSTESTING1
Vaccine Mfg NDC *	SMALLPOX MONKEYPOX BN 50632-0001-01
Lot Number *	TESTLOT
Expiration Date *	08/19/2022 
Funding Source *	317
Doses On-Hand *	19
Reason *	VTRCKS - OTHER
Modification *	SUBTRACT
Doses Adjusted *	4
Container Id	
Comments *	USED THE WHOLE VIAL FOR 1 PATIENT

Clear 

Smallpox/Monkeypox Vaccine (JYNNEOS™): *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Smallpox/monkeypox vaccine (JYNNEOS™) can help protect against smallpox, monkeypox, and other diseases caused by orthopoxviruses, including vaccinia virus.

Smallpox is a very serious disease caused by variola virus. Smallpox was declared eradicated in 1980 and no cases of naturally occurring smallpox have happened since 1977. Some people continue to be at risk of exposure to the virus that causes smallpox, including people who work in emergency preparedness and some laboratory workers. The virus can spread from person to person, causing symptoms including fever and a skin rash. Many people who had smallpox in the past recovered, but about 3 out of every 10 people with the disease died.

Monkeypox is a rare disease with symptoms that are similar to but milder than the symptoms of smallpox. Monkeypox can cause death. Monkeypox is an emerging infection in Africa and outbreaks of imported cases of monkeypox sometimes happen in other countries, including the United States.

Vaccinia virus can cause disease when people are exposed to infected people (such as exposure to someone who has recently been vaccinated against smallpox) or animals. People who work with vaccinia virus in laboratories can be accidentally exposed to the virus, and if they become infected, they can get sick. Most vaccinia infections resolve on their own without treatment.

2. Smallpox/monkeypox vaccine (JYNNEOS™)

Smallpox/monkeypox vaccine (JYNNEOS™) can prevent smallpox, monkeypox, vaccinia, and other diseases caused by orthopoxviruses. The vaccine is made using weakened live vaccinia virus and cannot cause smallpox, monkeypox, or any other disease.

JYNNEOS™ is approved by the Food and Drug Administration (FDA) for prevention of smallpox and monkeypox disease in **adults 18 years or older at high risk for smallpox or monkeypox infection.**

- CDC recommends JYNNEOS™ for certain laboratory workers and emergency response team members who might be exposed to the viruses that cause orthopoxvirus infections.
- CDC recommends consideration of the vaccine for people who administer ACAM2000®, another type of smallpox vaccine, or who care for patients infected with orthopoxviruses.

JYNNEOS™ is usually administered as a series of 2 injections, 4 weeks apart. People who have received smallpox vaccine in the past might only need 1 dose.

Booster doses are recommended every 2 or 10 years if a person remains at continued risk for exposure to smallpox, monkeypox, or other orthopoxviruses. Your health care provider can give you more information.

Smallpox/monkeypox vaccine (JYNNEOS™) may be given at the same time as other vaccines. Certain people at increased risk of a condition called 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.



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of smallpox vaccine**, or has any **severe, life-threatening allergies**
- Has a **weakened immune system**
- Is **pregnant** or thinks they might be pregnant or is **breastfeeding**

In some cases, your health care provider may decide to postpone routine (pre-exposure) smallpox/monkeypox vaccination with JYNNEOS™ until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting a routine (pre-exposure) dose of JYNNEOS™. **If you have been recommended to receive JYNNEOS™ due to an exposure to monkeypox virus, you should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.**

4. Risks of a vaccine reaction

- Redness, soreness, swelling, and itching where the shot is given are the most common things that happen after vaccination with JYNNEOS™.
- Fatigue (tiredness), headache, and muscle pain can also sometimes happen after vaccination with JYNNEOS™.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines. If you have been injured by smallpox/monkeypox vaccine, you can learn more about this Program by visiting the program's website at www.hrsa.gov/cicp, or calling **1-855-266-2427 (855-266-CICP)**.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/poxvirus/monkeypox.

