

## VACCINE INFORMATION STATEMENT

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

## 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. 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. However, 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 with ACAM2000®, another type of smallpox vaccine) 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. However, most vaccinia virus infections resolve on their own without treatment.

## 2. Smallpox/monkeypox vaccine (JYNNEOS™)

Smallpox/monkeypox vaccine (JYNNEOS™) is made using weakened live vaccinia virus and cannot cause smallpox, monkeypox, or any other infectious disease.

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

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®, 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.

## 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 she 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.



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CONTROL AND PREVENTION**

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.**

JYNNEOS™ may typically be given without regard to timing of other vaccines. However, 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 certain COVID-19 vaccines. **If you have been recommended to receive JYNNEOS™ due to an exposure to monkeypox virus, you should be vaccinated even if you have recently received a COVID-19 vaccine.**

## 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.

You can enroll in v-safe after receiving any dose of JYNNEOS™ vaccine by using your smartphone and going to [vsafe.cdc.gov](https://v-safe.cdc.gov). V-safe is a safety monitoring system that lets you share with CDC how you, or your dependent, feel after getting a JYNNEOS™ vaccine. For more information visit [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe).

## 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](http://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](http://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](http://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](http://www.cdc.gov/poxvirus/monkeypox).

