# FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT JYNNEOS (SMALLPOX AND MONKEYPOX VACCINE, LIVE, NON-REPLICATING) TO PREVENT MONKEYPOX DISEASE IN INDIVIDUALS DETERMINED TO BE AT HIGH RISK FOR MONKEYPOX INFECTION

You or your child is being offered JYNNEOS to prevent monkeypox disease. This Fact Sheet contains information to help you understand the risks and benefits of receiving JYNNEOS, which you or your child may receive because there is an outbreak of monkeypox.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to:

- Allow use of JYNNEOS given between layers of the skin for prevention of monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection; and
- Allow use of JYNNEOS given beneath the skin for prevention of monkeypox disease to individuals younger than 18 years of age determined to be at high risk for monkeypox infection.

For more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document. JYNNEOS is not approved for use in individuals under 18 years of age in the United States. For individuals 18 years of age and older, JYNNEOS given between layers of skin (intradermally) is not approved in the United States. Read this Fact Sheet for information about JYNNEOS. Talk to your healthcare provider about your options or if you have any questions. Under the EUA, there is an option to accept or refuse JYNNEOS.

## WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

### WHAT IS MONKEYPOX?

Monkeypox is a disease caused by infection with the monkeypox virus. Monkeypox virus is part of the same family of viruses as the virus that causes smallpox. Monkeypox symptoms are similar to smallpox symptoms, but milder, and monkeypox is rarely fatal. The monkeypox virus can spread to anyone through close skin-to-skin contact. It can also spread through touching objects, fabrics, and surfaces that have been used by someone with monkeypox or by contact with respiratory secretions. People with monkeypox get a rash that may be located anywhere on the body. The rash will go through several stages, including scabs, before healing. The rash can initially look like pimples or blisters and may be painful or itchy. Other symptoms of monkeypox can include:

- Fever
- Chills
- Swollen lymph nodes
- Exhaustion
- Muscle aches and backache
- Headache
- Respiratory symptoms such as sore throat, nasal congestion, or cough

## WHAT IS JYNNEOS?

JYNNEOS is a vaccine FDA-approved 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. In these individuals, JYNNEOS is approved to be given beneath the skin (subcutaneously).

The FDA has authorized the emergency use of JYNNEOS to prevent monkeypox disease in individuals under 18 years of age determined to be at high risk for monkeypox infection. In these individuals, JYNNEOS is authorized to be given beneath the skin (subcutaneously).

There is a limited supply of JYNNEOS. FDA has authorized the emergency use of JYNNEOS given between the layers of the skin (intradermally) to prevent monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection. When given intradermally less vaccine is needed per dose, increasing the vaccine supply.

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

## WHAT SHOULD I TELL MY VACCINATION PROVIDER BEFORE I OR MY CHILD TAKES JYNNEOS?

**Tell your vaccination provider if you or your child:**

- Had an allergic reaction after a previous dose of JYNNEOS or another smallpox vaccine
- Have any allergies
- Have a weakened immune system
- Are pregnant

## HOW IS JYNNEOS GIVEN?

For individuals 18 years of age and older, JYNNEOS will be given as an injection between the layers of the skin (intradermally).

For individuals under 18 years of age, JYNNEOS will be given as an injection beneath the skin (subcutaneously).

For all age groups, JYNNEOS is administered as a two-dose series, 4 weeks apart.

## WHAT ARE THE INGREDIENTS IN JYNNEOS?

JYNNEOS is a live virus vaccine. JYNNEOS contains Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), a weakened, non-replicating orthopoxvirus. It also contains Tris (tromethamine) and sodium chloride, and may contain small amounts of DNA and protein from the Chicken Embryo Fibroblast cells used to grow the vaccine virus, benzonase, gentamicin, and ciprofloxacin.

## HAS JYNNEOS BEEN USED BEFORE?

In clinical trials, approximately 7,800 individuals 18 through 80 years of age received at least one dose of JYNNEOS. Almost all of these individuals received JYNNEOS subcutaneously, which is the FDA-approved way to administer the vaccine.

In a clinical trial, approximately 190 individuals 18 years of age or older received at least one dose of the vaccine given between the layers of the skin (intradermally.

JYNNEOS is not approved for use in individuals under 18 years of age. JYNNEOS has not been studied in individuals under 18 years of age.

**WHAT ARE THE RISKS OF JYNNEOS?**
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported in clinical trials with JYNNEOS include muscle pain, headache, fatigue, nausea, chills, and fever, along with pain, redness, swelling, firmness, and itching at the site of injection.

In some people who received JYNNEOS between the layers of the skin (intradermally), minimal redness or firmess at the injection site lasted for up to several months. Some people who received JYNNEOS between the layers of the skin (intradermally) also reported small, firm lumps or discoloration of the skin at the injection site.

These may not be all the possible side effects of JYNNEOS. Serious and unexpected side effects may occur. The possible side effects of JYNNEOS are being monitored during postmarketing use.

**WHAT SHOULD I DO ABOUT SIDE EFFECTS?**
If you or your child experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or you/your child's healthcare provider if you/your child have any side effects that bother you/your child or do not go away.

Report vaccine side effects to FDA/CDC **Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "JYNNEOS" in the first line of box #18 of the report form.

In addition, you can report side effects to Bavarian Nordic A/S at 1-844-4BAVARIAN.

**WHAT IF I DECIDE NOT TO GET JYNNEOS OR NOT TO HAVE MY CHILD GET JYNNEOS?**
Under the EUA, there is an option to accept or refuse JYNNEOS. Should you decide not to receive it or for your child not to receive it, it will not change your standard medical care.

**ARE OTHER CHOICES AVAILABLE FOR PREVENTING MONKEYPOX?**
JYNNEOS is the only vaccine approved or authorized for the prevention of monkeypox in the United States.

**CAN I RECEIVE JYNNEOS AT THE SAME TIME AS OTHER VACCINES?**
Data have not been submitted to FDA on administration of JYNNEOS at the same time as other vaccines. If you are considering receiving or having your child receive JYNNEOS with other vaccines, discuss your options with your/your child's healthcare provider.

**WHAT ABOUT PREGNANCY AND BREASTFEEDING?**
If you or your child is pregnant or breastfeeding or if your child is being breastfed, discuss the options with the healthcare provider.

**WILL JYNNEOS GIVE ME OR MY CHILD MONKEYPOX?**
No. JYNNEOS does not contain the monkeypox virus and cannot give you monkeypox.

**ADDITIONAL INFORMATION**
If you have questions or to access the most recent JYNNEOS Fact Sheets, please visit https://www.fda.gov/media/160773/download.

**WHERE WILL MY VACCINATION INFORMATION BE RECORDED?**
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

**HOW CAN I LEARN MORE?**
- Ask the vaccination provider or your healthcare provider
- Visit CDC at https://www.cdc.gov/poxvirus/monkeypox/about.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your local or state public health department.

**CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF JYNNEOS?**
At this time, the vaccine provider cannot charge you for the vaccine dose and the vaccine provider must administer the vaccine regardless of your ability to pay administration fees. Vaccine providers may seek appropriate reimbursement from a program or plan that covers Monkeypox vaccine administration fees for the vaccine recipient (vaccine recipient's private insurance company or Medicare/Medicaid reimbursement).

**WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**
Individuals becoming aware of suspected fraudulent activities related to emergency use of Jynneos are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

**WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?**
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

**WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**
An EUA is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current monkeypox outbreak. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of vaccines during the monkeypox outbreak. The unapproved uses of an approved product that are authorized under EUA have not undergone the same type of review by FDA as FDA approved uses.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the unapproved use of the product may be effective to prevent monkeypox during the monkeypox outbreak and that the known and potential benefits of the use outweigh the known and potential risks of the use. All of these criteria must be met to allow for such use of the product during the monkeypox outbreak.

An EUA is in effect for the duration of the monkeypox EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used under emergency use).

Manufactured by: Bavarian Nordic A/S
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To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

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