Information on JYNNEOS® (modified vaccinia Ankara – Bavarian Nordic, MVA-BN) vaccine

Version 4: 13 February 2023

What is mpox (monkeypox)?

Mpox virus is a DNA virus related to the virus that causes smallpox. Mpox is less severe than smallpox. Mpox can be spread from infected animals to people, or from person to person. Mpox does not spread easily between people. Transmission between people can occur through:

- close contact with rashes, blisters or sores on the skin
- body fluids, including respiratory droplets from coughing or sneezing (this is less common and usually only happens if there is prolonged face-to-face contact)
- contaminated objects such as linen and towels.

Mpox is usually not life-threatening. Infection with the mpox virus usually causes a mild illness and most people recover within a few weeks. Mpox can be associated with more significant clinical features such as painful rash/sores in the throat or rectum.

Some people can get severely unwell and suffer complications, and potentially death. People at higher risk of severe disease and complications with mpox include people with immunocompromise, young children and pregnant women.

Complications include secondary infection, scarring, sepsis (infection of the blood stream), pneumonia (lung infection) and encephalitis (inflammation of the brain).

About the vaccine

JYNNEOS® (modified vaccinia virus Ankara – Bavarian Nordic, MVA-BN) is a vaccine used to prevent infection with smallpox and mpox viruses. It is also known as IMVAMUNE® and IMVANEX®.

The vaccine is made using weakened live vaccinia virus and cannot cause smallpox or mpox.

A primary vaccination course with JYNNEOS® requires two doses, given at least 28 days apart. Standard administration of JYNNEOS® is by subcutaneous injection (under the skin).

People at high risk of mpox virus infection who have received a smallpox vaccine dose more than ten years ago are recommended to receive only one dose of JYNNEOS®.

People who have had mpox virus infection during the 2022 outbreak are not recommended to be vaccinated at this time as their immunity will be boosted by natural infection.

There are no studies directly assessing the effectiveness of JYNNEOS® in people infected with the smallpox virus or the mpox virus. However, studies have shown that people given JYNNEOS® produced antibodies to a level expected to provide protection against smallpox.

Maximum protection occurs around 2 weeks after the second dose of this vaccine.

JYNNEOS® is most effective when it is used to vaccinate a person before they are exposed to mpox. JYNNEOS® may also be given to a person soon after they have been exposed to a person infected with mpox, preferably as soon as possible. Vaccination within 14 days after first exposure is expected to reduce severity of the disease.

JYNNEOS® is not registered for use in Australia and has not been formally assessed by the Therapeutic Goods Administration (TGA) but has been made available via a special emergency pathway under section 18A of the *Therapeutic Goods Act 1989 (Commonwealth)*. JYNNEOS® is licensed in the United States of America for adults aged 18 years and older and the equivalent product with the same formulation and strength of JYNNEOS® is registered for use in adults in Europe as IMVANEX® and in Canada as IMVAMUNE®. All currently available information on the safety and efficacy of JYNNEOS® has been evaluated by the Australian Technical Advisory Group on Immunisation (ATAGI).

Who can get this vaccine?

Individuals 18 years and older:

JYNNEOS® is indicated for use in adults aged 18 years and older at high risk for mpox infection.

Individuals under 18 years:

JYNNEOS® has not been formally studied in children aged under 18 years and is not currently registered for use in this age group in countries where JYNNEOS® is licensed. However, there are clinical study data on safety in children on MVA (the active substance in this vaccine), which has been used as a vaccine component in a small number of childhood vaccines. ATAGI advises that vaccination with JYNNEOS® in children can be considered, especially for individuals in high-risk groups aged 16 years and older, after discussing the risks and benefits of vaccination with their immunisation provider.

JYNNEOS® has not been studied in pregnant or breastfeeding women however, there are no expected safety concerns. Based on animal studies, JYNNEOS® is considered safe to use in people who are pregnant or breastfeeding. However, vaccination should only be considered when the potential benefits outweigh any potential risk to the mother and baby.

What you need to know before you receive the vaccine

You **must not** receive JYNNEOS® if:

- you have had a sudden life-threatening allergic reaction to a previous dose or to any ingredient of JYNNEOS® (active substance: modified vaccinia Ankara – Bavarian Nordic live virus; other ingredients: trometamol, sodium chloride; contains small amounts of chicken host-cell DNA, chicken protein, benzonase, gentamicin, and ciprofloxacin). In people with confirmed anaphylaxis to egg, there is a possible risk of allergic reaction.

- you are unwell with a high temperature (>38.5°C). In this case, your immunisation provider will postpone the vaccination until you are feeling better.

Talk to your immunisation provider before receiving JYNNEOS® if you:

- have had anaphylaxis (severe allergic reaction) to any vaccine or medicine

- have had a known or possible exposure to mpox in the last 14 days
- have atopic dermatitis (eczema)
- are living with HIV or another condition or treatment leading to a weakened immune system
- are pregnant or breastfeeding
- have had a COVID-19 vaccine in the past month
- have had a previous smallpox vaccine dose ever
- have had a smallpox or mpox vaccine recently (e.g., overseas)
- have previously had mpox virus infection
- have a new rash.

People who have previously had a smallpox vaccine, including any doses of JYNNEOS® may still get mpox if they are exposed to a mpox case. If you develop any symptoms of mpox, you must still follow all health advice you are given by your state or territory public health staff.

JYNNEOS is considered safe to use in people with atopic dermatitis (eczema) and in people with weakened immune systems.

People who have received one dose of JYNNEOS® (or equivalent vaccine) overseas should wait at least 28 days before they get a second dose of JYNNEOS®.

What to expect after vaccination

As with any vaccine, you may have some side effects after receiving this vaccine. Most side effects are mild, short-lived and occur within a few days of receiving the vaccine.

There are no notable serious adverse events based on available data from clinical studies in over 7,800 people.

Common side effects reported in clinical studies after receiving JYNNEOS® vaccine include:

- injection site pain, redness, swelling, induration (hardening) or itch
- muscle aches
- headache
- fatigue
- nausea
- chills
- fever

People with atopic dermatitis (eczema) may be more likely to have side effects after vaccination compared to those without this condition.

Clinical studies show that there are similar levels of side effects experienced by people who have previously had a smallpox vaccine compared with those who have not.

JYNNEOS® may be given at the same time as other vaccines.

It is not known if JYNNEOS® is associated with a risk of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining of the heart). Spacing JYNNEOS® and a COVID-19 vaccine apart by several weeks may be considered for people with increased risk of myocarditis and/or pericarditis after mRNA COVID-19 vaccine, such as young adult males.

You should seek medical attention after vaccination if you:

- **Think you are having an allergic reaction. Call 000 if you experience severe symptoms, such as difficulty breathing, wheezing, or collapsing.**
- **Have chest pain, pressure or discomfort, irregular heartbeat, skipped beats or 'fluttering', fainting, or shortness of breath**
- **Are worried about a potential side effect or have new or unexpected symptoms**

Tell your health care provider if you have any side effects after vaccination that you are worried about. You or your immunisation provider should report adverse events to your state or territory health department or to the TGA. More information is available on the TGA website.

You may be contacted by SMS or email in the week after you have received the vaccine to see if you have had any side effects, as part of vaccine safety surveillance.

Reporting serious side effects in Western Australia

Anyone who experiences a significant reaction following vaccination should first seek medical attention from a health professional.

The Western Australian Vaccine Safety Surveillance (WAVSS) system is the central reporting service in Western Australia (WA) for any significant side effects (adverse events) following vaccination.

You should report:

- any significant event following immunisation.
- any reaction to a vaccine which requires assessment by a doctor or nurse
- any reaction that has affected you or your family's confidence in future immunisation.

If you have experienced any significant side effect to a vaccine, you can report it either:

- Online at https://www.safevac.org.au/, or
- Over the phone, by calling WAVSS on (08) 6456 0208 (8.30am to 4.30pm Mon to Fri).

By reporting serious side effects, you can help provide more information on the safety of this vaccine.

You can call HealthDirect on 1800 022 222 (24 hours) for non-urgent advice on managing side effects if needed.

Australian Immunisation Register

The person giving your vaccination should record it on the Australian Immunisation Register (AIR). Collection of your personal information for this purpose meets the requirements of the *Privacy Act 1988 (Cth)*. You can view your vaccination record through your Medicare Online account via:

- Express Plus Medicare mobile app
- MyGov
- My Health Record (you can register for this with a Medicare number or an individual healthcare identifier).

Collection of your vaccination information on the AIR ensures that you have a complete vaccination record. This means you and your health care provider can keep track of vaccines you have received and when you are due for any subsequent doses. Your immunisation provider can also report other mpox or smallpox vaccines that you may have received overseas to the AIR.

Further information

- WA mpox information – HealthyWA
- ATAGI clinical guidance on vaccination against mpox
- Australian Government Department of Health and Aged Care
- JYNNEOS® United States drug label
- European Medicines Agency IMVANEX product information and medicine overview
- ASCIA Guidelines: Vaccination of the egg-allergic individual - Australasian Society of Clinical Immunology and Allergy (ASCIA)

This document can be made available in alternative formats.