Consent form for JYNNEOS® vaccination

Last updated: 12 December 2022

Before you fill out this form, make sure you understand the patient information sheet.

About JYNNEOS® vaccination against mpox (monkeypox)

JYNNEOS® (modified vaccinia virus Ankara – Bavarian Nordic, MVA-BN) is a vaccine used to prevent infection with smallpox and monkeypox viruses. It is manufactured by Bavarian Nordic. It 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). An alternative route of administration is intradermal injection (between the layers of the skin). The two doses do not need to be given by the same injection method.

Clinical studies suggest that people with weakened immune systems may have a lower immune response to JYNNEOS® compared to healthy individuals. For this reason, people with weakened immune systems should not receive JYNNEOS® via intradermal injection. Additionally, subcutaneous injection is the preferred method for the first dose of post-exposure prophylaxis.

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

People who have previously had a smallpox vaccine, including any doses of JYNNEOS® may still get mpox if they are exposed to an infected person. 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.

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

Who can get the vaccine?

Individuals 18 years and older:

JYNNEOS® vaccine is indicated for use in adults aged 18 years and older considered at 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 of MVA (the active substance in this vaccine) which was also for a vaccine component in a small number of childhood vaccines. The Australian Technical Advisory

Group on Immunisation (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® is considered safe to use in people who are pregnant or breastfeeding, in people with atopic dermatitis (eczema) and in people with weakened immune systems.

Co-administration with other vaccines

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 an mRNA COVID-19 vaccine, such as young adult males.

Who should not get this vaccine?

JYNNEOS® should not be given to people with anaphylaxis (severe allergic reaction) to a previous dose or to a component of the vaccine. JYNNEOS® contains modified vaccinia Ankara – Bavarian Nordic live virus (active substance), trometamol, sodium chloride, and small amounts of benzonase, gentamicin and ciprofloxacin (antibiotics), chicken host-cell DNA and chicken protein.

It is not known whether people who have had anaphylaxis (severe allergic reaction) to chicken eggs are at increased risk of a reaction after receiving the JYNNEOS® vaccine. Tell your health care provider if this is a concern.

People with very weakened immune systems, and people who have had keloid scarring (a specific type of wound scarring) in the past should receive JYNNEOS® by subcutaneous injection only. Subcutaneous injection is the preferred method for the first dose of post-exposure prophylaxis.

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.

Vaccine side effects

Safety data on JYNNEOS® is available from 22 clinical studies with a total of over 7,800 JYNNEOS® vaccine recipients. Most side effects are mild, short-lived and occur within a few days of receiving the vaccine. Common adverse events include injection site pain, redness, swelling, induration (hardness) and itch, muscle aches, headache, fatigue, nausea, chills and fever. There are no notable serious side effects from the clinical studies.

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

A clinical study comparing the safety of the intradermal route of administration to subcutaneous administration of this vaccine showed increased rates of injection site redness and hardening in those who received an intradermal injection.

Tell your health care provider if you have any side effects after vaccination that you are worried about. You or your vaccination provider should report adverse events to the state or territory health department or to the Therapeutic Goods Administration (TGA).

More information is available on the TGA website.

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

Further information

JYNNEOS® vaccine 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 (Cth)*. 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 ATAGI.

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 immunisation 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 vaccination provider can also report other mpox or smallpox vaccines that you may have received overseas to the AIR.

On the day of your vaccine

Before you get vaccinated, tell the person giving you the vaccination if you have had:

- A severe reaction to a previous dose of JYNNEOS® or to one of its ingredients*
- Anaphylaxis (severe allergic reaction) to any vaccine
- A known or possible exposure to mpox in the last 14 days
- A previous smallpox vaccine ever
- A smallpox or mpox vaccine recently (e.g. overseas)
- Have previously had mpox virus infection
- A current medical condition that lowers your immunity

- A history of keloid scarring
- A new rash.

*JYNNEOS® contains trace residues of benzonase, gentamicin and ciprofloxacin (antibiotics), chicken host-cell DNA and chicken egg protein. In people with confirmed anaphylaxis to egg, there is a possible risk of allergic reaction. See above for complete list.

Screening questionnaire

Yes	No	
		Have you ever had a severe reaction to a previous dose of JYNNEOS® or to one of its ingredients*?
		Have you ever had a severe reaction following any vaccine or medication (e.g., anaphylaxis)?
		Do you have any severe allergies (to anything)?
		Have you had a known or possible exposure to mpox in the last 14 days?
		Do you have a bleeding disorder or take any medicine to thin your blood (an anticoagulant therapy)?
		Do you have a condition that lowers immunity (e.g., leukaemia, cancer, HIV) or are you receiving treatment that lowers immunity?
		Have you ever had eczema (atopic dermatitis) or any other skin conditions?
		Have you ever had keloid scarring (a specific type of wound scarring)?
		Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)?
		Are you pregnant, planning to become pregnant or breastfeeding?
		Have you been sick with a fever or are feeling sick in another way?
		Do you currently have a rash (this could look like bumps, blisters or pimples) or any sores anywhere on your body, including in your mouth or your anus?
		Have you had a JYNNEOS® vaccine, or other mpox or smallpox vaccine before? If so, vaccine name (if known):____ Date: _____
		Have you had a COVID-19 vaccine in the last 4 weeks, or do you plan to receive one in the next 4 weeks?
		Have you received any other vaccination in the last 4 weeks?

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If you answered Yes to any of the above questions, you may still be able to receive JYNNEOS®, however you should talk to your immunisation provider first to discuss the best timing of vaccination and whether any additional precautions are needed.

Patient information

Name:										
Medicare number:										
Medicare Individual Reference Number										
Individual Health Identifier (IHI) if applicable:										
Date of birth:										
Phone contact number:										
Email address:										

Next of kin (in case of emergency):	
Name:	
Phone contact number:	

Consent to receive JYNNEOS® vaccine

I confirm I have received and understood information provided to me on JYNNEOS® vaccination.

I confirm that none of the above conditions apply to me, or I have discussed these conditions and any other special circumstances with my regular health care provider and/or vaccination provider.

I confirm that I understand the risks and benefits of the JYNNEOS® vaccine.

I agree to receive a course of JYNNEOS® vaccine / I agree to receive a booster of JYNNEOS® vaccine

Patient's name:	
Patient's signature:	
Date:	

I am the patient's parent, guardian or substitute decision-maker, and agree to JYNNEOS® vaccination of the patient named above.

Parent/guardian/substitute decision-maker's name:	
Parent/guardian/substitute decision maker's signature:	
Date:	

For provider use:

Dose 1:

Date vaccine administered:	
Time received:	
Batch no:	
Serial no:	
Site of vaccine injection:	
Route of vaccine injection (subcutaneous or intradermal):	
Name of vaccination service provider:	

Dose 2:

Date vaccine administered:	
Time received:	
Batch no:	
Serial no:	
Site of vaccine injection:	
Route of vaccine injection (subcutaneous or intradermal):	
Name of vaccination service provider:	

*See ATAGI clinical guidance on the use of vaccination against mpox in Australia: https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-monkeypox.