NEW ZEALAND DATA SHEET

1. PRODUCT NAME

JYNNEOS suspension for subcutaneous injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

JYNNEOS is a live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus. MVA-BN is grown in primary Chicken Embryo Fibroblast (CEF) cells suspended in a serum-free medium containing no material of direct animal origin, harvested from the CEF cells, purified and concentrated by several Tangential Flow Filtration (TFF) steps including benzonase digestion.

Each 0.5 mL dose is formulated to contain 0.5 x 10^8 to 3.95 x 10^8 infectious units of MVA-BN live virus in 10 mM Tris (tromethamine), 140 mM sodium chloride at pH 7.7.

Each 0.5 mL dose may contain residual traces of host-cell DNA (≤ 20 mcg), protein (≤ 500 mcg), benzonase (≤ 0.0025 mcg), gentamicin (≤ 0.400 mcg) and ciprofloxacin (≤ 0.005 mcg) (see section 4.3).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for subcutaneous injection.

When thawed, JYNNEOS (Smallpox and Mpox Vaccine, Live, Non-replicating) is a milky, light yellow to pale white coloured suspension for subcutaneous injection.

JYNNEOS is a sterile vaccine formulated without preservatives.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

JYNNEOS is indicated for prevention of mpox disease in adults 18 years of age and older:

- At risk of occupational exposure to mpox
- At risk of mpox infection during a local mpox outbreak
- At risk of mpox infection because they are
    - Gay, bisexual, men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following
        - A new diagnosis of a sexually transmitted disease
        - More than one sex partner
        - Sex at a commercial venue
        - Sex in association with a large public event in an area where mpox transmission is occurring

- Sexual partners of the people with the above risks
- People who anticipate experiencing any of the above.

4.2 Dose and method of administration

For subcutaneous injection only.
Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS.

Dose

Administer two doses (0.5 mL each) of JYNNEOS at least 4 weeks apart.

There is no information on the need for a booster dose.

Paediatric population
The safety and efficacy of JYNNEOS in children below 18 years have not been established.
No data are available.

Method of administration

Allow the vaccine to thaw and reach room temperature before use.

Swirl the vial gently before use for at least 30 seconds.
Withdraw a dose of 0.5 mL into a sterile syringe for injection.

Administer JYNNEOS by subcutaneous injection, preferably into the upper arm.

For instructions on handling of the medicine before administration, see section 6.6

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or trace residues (chicken protein, benzonase, gentamicin and ciprofloxacin).

4.4 Special warnings and precautions for use

Severe Allergic Reactions

Persons who experienced a severe allergic reaction following a previous dose of JYNNEOS or following exposure to any component of JYNNEOS may be at increased risk for severe allergic reactions after JYNNEOS. The risk for a severe allergic reaction should be weighed against the risk for mpox disease.

Concurrent illness

Immunisation should be postponed in individuals suffering from an acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever does not need to result in deferral of vaccination.

Anxiety-related reactions

Anxiety-related reactions including vasovagal reactions (syncope), hyperventilation or stress-related reactions have been reported following vaccination with JYNNEOS. Procedures should be in place to avoid injury from fainting.

Myo-/pericarditis

Smallpox vaccines have been associated with myo-/pericarditis. Vaccinees should be informed to seek immediate medical attention if they develop symptoms such as chest pain, shortness of breath, or palpitations following vaccination. Vaccinees presenting with symptoms should be urgently referred to specialists for diagnosis and treatment.

Altered Immunocompetence

Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.

Limitations of Vaccine Efficacy

The protective efficacy of JYNNEOS against mpox has not been studied in humans; see section 5.1. Vaccination with JYNNEOS may not protect all recipients.

Individuals with atopic dermatitis

Individuals with atopic dermatitis developed more local and general symptoms after vaccination see section 4.8.

Immunocompromised individuals

In HIV infected individuals with CD4 counts ≥ 100 cells/microlitre and ≤ 750 cells per microlitre lower immune responses have been observed. There are no data on the immune response in other immunosuppressed individuals.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies with other vaccines or medicinal products have been performed. Therefore, concomitant administration of JYNNEOS with other vaccines should be avoided.
The concomitant administration of the vaccine with any immunoglobulin including Vaccinia Immune Globulin (VIG) has not been studied and should be avoided.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data (less than 300 pregnancy outcomes) from use of JYNNEOS in pregnant people. Available human data on JYNNEOS administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

The effect of JYNNEOS on embryo-fetal and post-natal development was evaluated in four developmental toxicity studies conducted in female rats and rabbits. In two studies, rats were administered a single human dose of JYNNEOS (0.5 mL) once prior to mating and on one or two

occasions during gestation. In the third study, rats were administered a single human dose of JYNNEOS (0.5 mL) on two occasions during gestation. In the fourth study, rabbits were administered a single human dose of JYNNEOS (0.5 mL) once prior to mating and on two occasions during gestation. These animal studies revealed no evidence of harm to the fetus.

As a precautionary measure it is preferable to avoid the use of JYNNEOS in pregnancy. Administration in pregnancy should only be considered when the potential benefits to the mother outweigh the potential risks to the mother and fetus.

Breast-feeding

Risk Summary
It is not known whether JYNNEOS is excreted in human milk. Data are not available to assess the effects of JYNNEOS in the breastfed infant or on milk production/excretion.

Administration of JYNNEOS during breast-feeding should only be considered when the potential benefits outweigh any potential risks to the mother and baby.

Fertility

Animal studies did not reveal any evidence of impaired female or male fertility.

4.7 Effects on ability to drive and use machines

There is no information on the effect of JYNNEOS on the ability to drive or use machines. However, some of the undesirable effects mentioned in sections 4.4 and 4.8 may affect the ability to drive or use machines (e.g. dizziness).

4.8 Undesirable effects

Summary of the safety profile

The overall clinical trial program included 23 studies and a total of 8,988 individuals 18 through 80 years of age who received at least 1 dose of JYNNEOS (8,222 smallpox vaccine-naïve and 766 smallpox vaccine-experienced individuals). For the purpose of pooling safety data, a later study with freeze-dried formulation of JYNNEOS (>1,100 subjects) was added for completeness.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. There is the possibility that broad use of JYNNEOS could reveal adverse reactions not observed in clinical trials.

Table 1: Adverse Reactions Reported in Completed Clinical Trials[a] with MVA-BN (N = 8,988[b] subjects) and post-authorisation experience with MVA-BN

MedDRA System Organ Class	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Not known (cannot be estimated from the available data)
Infections and infestations	-	-	Nasopharyngitis, Upper respiratory tract infection	Sinusitis, Influenza, Conjunctivitis, Gastroenteritis	
Blood and lymphatic system disorders	-	-	Lymphadenopathy		
Metabolism and nutrition disorders	-	Appetite disorder	-		
Psychiatric disorders	-	-	Sleep disorder		
Nervous system disorders	Headache	-	Dizziness, Paresthesia	Migraine, Peripheral sensory neuropathy, Somnolence	Acute peripheral facial paralysis (Bell's palsy)
Ear and labyrinth disorders	-	-		Vertigo, Ear pain	
Cardiac disorders	-	-	-	Tachycardia	
Respiratory, thoracic and mediastinal disorders	-	-	Pharyngolaryngeal pain, Rhinitis, Cough	Oropharyngeal pain	
Gastrointestinal disorders	Nausea	-	Diarrhea, Vomiting, Dry mouth	Abdominal Pain	
Skin and subcutaneous tissue disorders	-	-	Rash, Pruritus, Dermatitis, Urticaria	Skin discolouration, Hyperhidrosis,	

MedDRA System Organ Class	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Not known (cannot be estimated from the available data)
				Ecchymosis, Night sweats, Subcutaneous nodule, Angioedema	
Musculoskeletal and connective tissue disorders	Myalgia	Pain in extremity, Arthralgia	Musculoskeletal stiffness, Neck pain	Back pain, Muscle spasms, Musculoskeletal pain, Muscular weakness	
General disorders and administration site conditions	Injection site pain, Injection site erythema, Injection site swelling, Injection site induration, Injection site pruritus, Fatigue	Rigor/Chills, Injection site nodule, Injection site discolouration, Injection site haematoma, Injection site warmth, Axillary pain	Underarm swelling, Malaise, Injection site haemorrhage, Injection site irritation, Flushing, Chest pain, Injection site bruising, Injection site vesicles,	Injection site exfoliation, Injection site inflammation, Injection site paraesthesia, Injection site reaction, Injection site rash, Oedema, peripheral Asthenia, Injection site anesthesia, Injection site dryness, Injection site movement impairment, Influenza like illness	
Investigations	-	Body temperature increased, Pyrexia	Troponin I increased, Hepatic enzyme increased,	White blood cell count increased	

MedDRA System Organ Class	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Not known (cannot be estimated from the available data)
			White blood cell count decreased, Mean platelet volume decreased		
Injury, poisoning and procedural complications	-	-	-	Contusion	

Note: The frequency groups for adverse drug reactions, and the naming conventions for these groups, are based on the WHO guidance for reporting adverse events following immunization (AEFI).

[a] POX-MVA-001, -002, -004, -005, -006, -007, -008, -009, -010, -011, -013, -023, -024, -027, -028, -029, -030, -031, -036, -037, -03X, HIV-NEF-004 and HIV-POL-002

[b] 8 subjects exposed but not included in analysis. 7 subjects in POX-MVA-009 received Dryvax either on the same day or within 7 days after MVA-BN administration and were therefore not included to avoid a potential bias in the adverse event reporting. 1 subject in POX-MVA-029 was not vaccinated according to the randomization, therefore removed from analysis set.

Serious Adverse Events

The integrated analyses of serious adverse events (SAEs) pooled safety data across 23 studies, which included a total of 8,222 smallpox vaccine-naïve subjects and 766 smallpox vaccine-experienced subjects who received at least 1 dose of JYNNEOS and 1,219 smallpox vaccine-naïve subjects who received placebo only. SAEs were monitored from the day of the first study vaccination through at least 6 months after the last study vaccination.

Overall, SAEs were reported to occur in 1.5% of JYNNEOS recipients and 1.1% of placebo recipients. Among the smallpox vaccine-naïve participants, SAEs were reported for 1.4% of JYNNEOS recipients and 1.1% of placebo recipients. Among the smallpox vaccine-experienced subjects enrolled in studies, SAEs were reported for 2.3% of JYNNEOS recipients. Across all studies, a causal relationship to JYNNEOS could not be excluded for 4 SAEs, all non-fatal, which included Crohn's disease, sarcoidosis, extraocular muscle paresis, and throat tightness.

Cardiac Adverse Events of Special Interest

Evaluation of cardiac adverse events of special interest (AESIs) included any cardiac signs or symptoms, ECG changes determined to be clinically significant, or troponin-I elevated above 2 times the upper limit of normal. In the 23 studies, subjects were monitored for cardiac-related signs or symptoms through at least 6 months after the last vaccination.

The numbers of JYNNEOS and placebo recipients, respectively, with troponin-I data were: baseline level (7,505 and 1,203); level two weeks after first dose (6,284 and 1,166); level two weeks after

second dose (1,684 and 193); unscheduled visit, including for clinical evaluation of suspected cardiac adverse events (501 and 60).

Overall, cardiac AESIs were reported to occur in 1.2% (112/8,988) of JYNNEOS recipients and 0.2% (3/1,2220) of placebo recipients. Cardiac AESIs were reported to occur in 2.1% (16/766) of JYNNEOS recipients who were smallpox vaccine-experienced. The higher proportion of JYNNEOS recipients who experienced cardiac AESIs was driven by 28 cases of asymptomatic post-vaccination elevation of troponin-I in two studies: Study 1 [NCT00316589], which enrolled 482 HIV-infected subjects and 97 healthy subjects, and Study 2 [NCT00316602], which enrolled 350 subjects with atopic dermatitis and 282 healthy subjects. An additional 127 cases of asymptomatic post-vaccination elevation of troponin-I above the upper limit of normal but not above 2 times the upper limit of normal were documented in JYNNEOS recipients throughout the clinical development program, 124 of which occurred in Study 1 and Study 2. Proportions of subjects with troponin-I elevations were similar between healthy and HIV-infected subjects in Study 1 and between healthy and atopic dermatitis subjects in Study 2. A different troponin assay was used in these two studies compared to the other studies, and these two studies had no placebo controls. The clinical significance of these asymptomatic post-vaccination elevations of troponin-I is unknown.

Among the cardiac AESIs reported, 6 cases (<0.1%) were considered to be causally related to JYNNEOS vaccination and included tachycardia, electrocardiogram T wave inversion, electrocardiogram abnormal, electrocardiogram ST segment elevation, electrocardiogram T wave abnormal, and palpitations.

None of the cardiac AESIs considered causally related to study vaccination were considered serious.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

No case of overdose has been reported.

In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines, other viral vaccines, ATC code: J07BX

Mechanism of Action

JYNNEOS is an attenuated, live, non-replicating smallpox and mpox vaccine that elicits humoral and cellular immune responses to orthopoxviruses. Vaccinia neutralizing antibody responses in humans were evaluated to establish the effectiveness of JYNNEOS for prevention of smallpox and mpox.

Clinical efficacy and safety

Clinical studies

Vaccine effectiveness

In real-world observational studies conducted in vaccine-eligible individuals (according to local recommendations), vaccine effectiveness against mpox disease was demonstrated at least 14 days after vaccination[a], with adjusted vaccine effectiveness estimates ranging from 35% (95% CI, -2-59) to 89% (95% CI, 76-95) after one MVA-BN dose and from 66% (95% CI, 47-78) to 90% (95% CI, 86-92) after two MVA-BN doses.

Table 2: Vaccine effectiveness at least 14 days after vaccination[a]

Country	**Study design Period**	**Vaccination strategy**	**1-dose effectiveness % [95% CI]**	**2-dose effectiveness % [95% CI]**
US	Case-control Aug 2022-Mar 2023	PrEP/PEP	77% (60-87)	89% (56-97)
	Case-control Aug 2022- Nov 2022	PrEP	36% (22-47)*	66% (47-78)*
	Retrospective cohort May 2022 – Dec 2022	PrEP/PEP	81% (64-90)*	83% (28-96)*
	Case-coverage Jul 2022-Oct 2022	PrEP/PEP	86% (83-89)*	90% (86-92)*
	Case-control Jun 2022-Dec 2022	PrEP/PEP	68% (25-87)*	89% (44-98)*
Spain	Retrospective cohort Jul 2022-Dec 2022	PrEP	79% (33-100)*,**	-
	Prospective cohort May 2022-Aug 2022	PEP	89% (76-95)[a]	-
Canada	Case-control Jun 2022-Sep 2022	PrEP	35% (-2-59) 65% (1-87)***	-
	Prospective cohort Jun 2022-Nov 2022	PrEP	59% (31-76)	-
UK	Case-coverage Jul 2022-Dec 2022	PrEP	78% (54-89)**	-
Netherlands	Case-coverage Aug 2022-Dec 2022	PrEP/PEP	-	68% (4-90)**

Note: all data are adjusted vaccine effectiveness, based on subcutaneous administration, unless indicated otherwise.

*Covers both subcutaneous and intradermal administrations,

**Crude vaccine effectiveness,

***Based on individual-level data supplemented with questionnaire responses on risk behaviour,

[a] PEP administered ≤ 14 days after exposure.

Impact on hospitalisation

In a surveillance study conducted from May 2022 to May 2023 in US, MVA-BN was shown to reduce the risks of mpox-related hospitalisation. Compared with unvaccinated mpox patients, the odds of hospitalisation were 0.27 (95% CI, 0.08-0.65) after one MVA-BN dose, and 0.20 (95% CI, 0.01-0.90) after two MVA-BN doses. The estimated relative risk reduction was 73% after one MVA-BN dose and 80% after two MVA-BN doses.

Immunogenicity

Study 3 [NCT01913353] (N=433) was a randomized, open-label study conducted at US military facilities in South Korea to compare the immunogenicity of JYNNEOS to ACAM2000 in healthy smallpox vaccine-naïve adults 18 through 42 years of age. Subjects were randomized to receive either two doses of JYNNEOS (N=220) administered 28 days apart or one dose of ACAM2000 (N=213). In the total study population, the mean age was 24 years and 23 years in subjects receiving JYNNEOS and ACAM2000, respectively; 82.3% and 86.4% of the subjects were men; 57.3% and 63.8% were white/Caucasian, 21.8% and 18.8% black/African American, 6.4% and 5.6% Asian, 3.6% and 2.8% American Indian/Alaska Native, 2.3% and 1.4% Native Hawaiian/Other Pacific, 8.6% and 7.5% other racial groups, and 24.5% and 18.8% of Hispanic/Latino ethnicity (JYNNEOS and ACAM2000, respectively).

The primary immunogenicity endpoint was geometric mean titer (GMT) of vaccinia neutralizing antibodies assessed by PRNT at "peak visits" defined as two weeks after the second dose of JYNNEOS and four weeks after the single dose of ACAM2000. Analyses of antibody responses were performed in the per-protocol immunogenicity (PPI) population, consisting of individuals who received all vaccinations and completed all visits up until the peak visit without major protocol violations pertaining to immunogenicity assessments. Table 3 presents the pre-vaccination and "peak visit" PRNT GMTs from Study 3.

Table 3: Comparison of Vaccinia-Neutralizing Antibody Responses Following Vaccination with JYNNEOS or ACAM2000 in Healthy Smallpox Vaccine-Naïve Adults 18 through 42 Years of Age, Study 3[x], Per Protocol Set for Immunogenicity[y]

Time Point	JYNNEOS[a] (N=185) GMT[b] [95% CI]	ACAM2000[a] (N=186) GMT[b] [95% CI]
Pre-Vaccination	10.1 [9.9, 10.2]	10.0 [10.0, 10.0]
Post-Vaccination "Peak Visit"[y]	152.8[c] [133.3, 175.0]	84.4[c] [73.4, 97.0]

[x] NCT01913353

[y] Per Protocol Set for Immunogenicity included subjects who received all vaccinations, completed all visits up until the specified "peak visits" (two weeks after the second dose of JYNNEOS or 4 weeks after the single dose of ACAM2000) without major protocol violations pertaining to immunogenicity assessments.

[a] JYNNEOS was administered as a series of two doses given 28 days apart, and ACAM2000 was administered as a single dose.

[b] GMT of vaccinia-neutralizing antibody titers assessed by plaque reduction neutralization test (PRNT) using the Western Reserve vaccinia strain. Values below the assay lower limit of quantitation (LLOQ) of 20 were imputed to a titer of 10; the proportions of subjects with pre-vaccination titers less than the assay lower limit of detection were 98.9% among subjects randomized to JYNNEOS and 97.8% among subjects randomized to ACAM2000, respectively.

[c] Non-inferiority of the "peak visit" PRNT GMT for JYNNEOS compared to ACAM2000 was demonstrated as the lower bound of the 1-sided 97.5% CI for the GMT ratio (JYNNEOS/ACAM2000) was > 0.5.

N: Number of subjects in the specified treatment group; GMT: Geometric Mean Titer; 95% CI: 95% confidence interval, lower limit and upper limit.

PRNT GMTs were also evaluated at pre-specified time points post-vaccination and prior to the "peak visits". The PRNT GMTs at two and four weeks after the first dose of JYNNEOS (prior to the second dose), were 23.4 (95% CI: 20.5, 26.7) and 23.5 (95% CI: 20.6, 26.9), respectively. The PRNT GMT at two weeks after the single dose of ACAM2000 was 23.7 (95% CI: 20.9, 26.8).

Paediatric population

The safety and efficacy of JYNNEOS in children below 18 years have not been established.

Elderly

Clinical studies of JYNNEOS did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Carcinogenesis, Mutagenesis, Impairment of Fertility

JYNNEOS has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Developmental toxicity studies conducted in rats and rabbits vaccinated with JYNNEOS revealed no evidence of impaired female fertility (see section 4.6 Fertility, pregnancy and lactation).

Animal Toxicology and/or Pharmacology

The efficacy of JYNNEOS to protect cynomolgus macaques (*Macaca fascicularis*) against a mpox virus (MPXV) challenge was evaluated in several studies. Animals were administered Tris-Buffered Saline (placebo) or JYNNEOS (1×10^8 $TCID_{50}$) subcutaneously on day 0 and day 28. On day 63, animals were challenged with MPXV delivered by aerosol (3×10^5 pfu), intravenous (5×10^7 pfu) or intratracheal (5×10^6 pfu) route. Across all studies, 80-100% of JYNNEOS-vaccinated animals survived compared to 0-40% of control animals.

*Reproductive and Developmental Toxicity*Developmental toxicity studies were conducted in female rats and rabbits. In one study, female rabbits were administered a single human dose of JYNNEOS (0.5 mL) by the subcutaneous route on three occasions: prior to mating, and on gestation days 0 and 14. Three studies were conducted in female rats administered a single human dose of JYNNEOS (0.5 mL) by the subcutaneous route on two or three occasions: prior to mating, and on gestation days 0 and 14; or prior to mating, and on gestation day 0; or on gestation days 0 and 6. No vaccine-related fetal malformations or variations and adverse effects on female fertility or pre-weaning development were reported in these studies

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trometamol
Sodium chloride
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years at -20°C +/-5°C
5 years at -50°C +/-10°C
9 years at -80°C +/-10°C

If the vaccine has been stored prior at -20°C, once thawed, it may be kept at +2°C to +8°C for 4 weeks.
If the vaccine has been stored prior at -50°C, once thawed, it may be kept at +2°C to +8°C for up to 24 weeks.
Do not re-freeze a vial once it has been thawed.

6.4 Special precautions for storage

Store in a freezer at -20°C +/-5°C or -50°C +/-10°C or -80°C +/-10°C. Expiry date depends on storage temperature.
For storage conditions after thawing of the medicine, see section 6.3.
Store in the original package to protect from light.
Do not re-freeze a vial once it has been thawed.

6.5 Nature and contents of container

Each dose 0.5 ml of suspension is supplied in a vial (Type I glass) with stopper (bromobutyl rubber). The vial stoppers are not made with natural rubber latex.

Pack sizes of 2, 5, 10 or 20 single-dose vials.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Allow the vaccine to thaw and reach room temperature before use. Swirl the vial gently before use for at least 30 seconds.

When thawed, JYNNEOS is a milky, light yellow to pale white coloured suspension.
The suspension should be visually inspected for particulate matter and discoloration before use. In the event of any damage to the vial, foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine.
A dose of 0.5 ml is withdrawn into a syringe for injection.
Each vial is for single use.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
Phone - +64 9 918 5100
Email: HNZvaccines@prnzl.co.nz
Website: www.hcl.co.nz

9. DATE OF FIRST APPROVAL

11 September 2024
Date of publication in the New Zealand Gazette of consent to distribute the medicine: 11 September 2024

10. DATE OF REVISION OF THE TEXT

25 July 2025

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Wording aligned to consistent naming of mpox instead of monkeypox
1. Product Name	Infections units removed from product name
2. Qualitative and Quantitative Composition	Correction of residual traces of host-cell DNA (≤ 20 mcg), **chicken protein** (≤ 500 mcg) to residual traces of host-cell DNA (≤ 20 mcg), **protein** (≤ 500 mcg)
4.3 Contraindications	Deletion of JYNNEOS is contraindicated in subjects with known hypersensitivity to eggs or to any other component of the vaccine
4.4 Special warnings and precautions	Added warning about myo-/pericarditis and recommendation to seek immediate medical attention for cardiac symptoms.
4.8 Undesirable effects	Adaption of the frequency category “not known (cannot be estimated from the available data) to the New Zealand Data Sheet Template Explanatory Guide
5.1 Pharmacodynamic properties	Addition of real-world vaccine effectiveness data from observational studies across the US, Spain, UK, Canada, Netherlands and Impact on hospitalisation.
5.3 Preclinical safety data	Subheading “Reproductive and Developmental Toxicity” added to clarify content on animal studies