▼ This vaccine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

COVID-19 VACCINE JANSSEN®

Ad26.COV2.S

AUSTRALIAN PRODUCT INFORMATION

1. NAME OF THE MEDICINE

COVID-19 Vaccine Janssen suspension for injection

COVID-19 vaccine (Ad26.COV2.S [recombinant])

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multi-dose vial which contains 5 doses of 0.5 mL

One dose (0.5 mL) contains:
Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein* (Ad26.COV2-S; SARS-CoV-2 spike (S) protein sequence from Wuhan/WIV04/2019; Genbank MN908947), 5×10^{10} virus particles (VP) (equivalent to not less than 8.92 $\log_{10}$ infectious units (Inf.U)).

*The vaccine was manufactured using material sourced from a human embryo (Human Embryonic Retinal cells: PER.C6 cells).

The product contains genetically modified organisms (GMOs).

Excipients with known effect
Each dose (0.5 mL) contains approximately 2 mg of ethanol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection (injection).

Colourless to slightly yellow, clear to very opalescent suspension (pH 6-6.4).

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

COVID-19 Vaccine Janssen has **provisional approval** for the indication:

COVID-19 Vaccine Janssen is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

The decision has been made on the basis of short term efficacy and safety data. Continued approval is dependent upon the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dosage

Individuals 18 years of age and older

COVID-19 Vaccine Janssen is administered as a single-dose of 0.5 mL by intramuscular injection only.

Paediatric population

The safety and efficacy of COVID-19 Vaccine Janssen in children and adolescents (less than 18 years of age) have not yet been established. No data are available.

Elderly

No dose adjustment is required in elderly individuals ≥65 years of age. See also sections 4.8 and 5.1.

Method of administration

COVID-19 Vaccine Janssen is for intramuscular injection only, preferably in the deltoid muscle of the upper arm.

Do not inject the vaccine intravascularly, intravenously, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see section 4.4.

For instructions on handling and disposal of the vaccine, see section 6.6.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Hypersensitivity and anaphylaxis

Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine. Close observation for at least 15 minutes is recommended following vaccination.

Concurrent illness

Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection. However, the presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombosis with thrombocytopenia syndrome

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine Janssen. This includes

severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis as well as arterial thrombosis concomitant with thrombocytopenia. Fatal outcomes have been reported. These cases occurred within the first three weeks following vaccination, and mostly in women under 60 years of age.

Cases have occurred in patients with and without other risk factors for thrombosis and thrombocytopenia. As a precautionary measure, administration of the COVID-19 Vaccine Janssen in patients with a history of cerebral venous sinus thrombosis with thrombocytopenia, or heparin induced thrombocytopenia (HIT) should only be considered when the benefit outweighs the potential risk.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches, seizures, mental status changes or blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

Thrombosis in combination with thrombocytopenia requires specialised clinical management. Healthcare professionals should consult applicable guidance and/or consult specialists (e.g., haematologists, specialists in coagulation) to diagnose and treat this condition.

Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.

Risk of bleeding with intramuscular administration

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

The efficacy, safety and immunogenicity of the vaccine have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COVID-19 Vaccine Janssen may be lower in immunosuppressed individuals.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Duration of protection

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

Limitations of vaccine effectiveness

Protection starts around 14 days after vaccination. As with all vaccines, vaccination with COVID-19 Vaccine Janssen may not protect all vaccine recipients (see section 5.1).

Excipients

Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per 0.5 mL dose, that is to say essentially 'sodium-free'.

Ethanol
This medicinal product contains 2 mg of alcohol (ethanol) per 0.5 mL dose. The small amount of alcohol in this medicinal product will not have any noticeable effects.

Use in the elderly

Please see section 4.2

Paediatric use

The safety and efficacy of COVID-19 Vaccine Janssen in children and adolescents (less than 18 years of age) have not yet been established. No data are available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No interaction studies have been performed. Concomitant administration of COVID-19 Vaccine Janssen with other vaccines has not been studied.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data are available on fertility in humans following the use of COVID-19 Vaccine Janssen. A conventional (repeat-dose) toxicity study in rabbits with COVID-19 Vaccine Janssen did not reveal any effects on male or female sex organs that would impair fertility.

Use in pregnancy – Pregnancy Category B1

There is limited experience with the use of COVID-19 Vaccine Janssen in pregnant women.

A combined embryo-fetal and pre- and postnatal development study with COVID-19 Vaccine Janssen in the rabbit, immunised with 1×10^{11} viral particles (2-fold the human dose per subject, or 26 times on a mg/kg basis) administered as 1 mL intramuscular injection on 3 occasions (7 days prior to mating and on gestation days 6 and 20), did not indicate any direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or postnatal development. Dams and their fetuses exhibited SARS-CoV-2 S protein-specific antibody titres, indicative of placental transfer of maternal antibodies during gestation.

Administration of COVID-19 Vaccine Janssen in pregnancy should only be considered when the potential benefits outweigh any potential risks to the mother and fetus.

Use in lactation

No COVID-19 Vaccine Janssen data are available on vaccine excretion in milk. It is unknown whether COVID-19 Vaccine Janssen is excreted in human milk.

There were no vaccine-related effects on offspring development in a combined embryofetal and pre- and postnatal development study in female rabbits (see Use in Pregnancy). SARS-CoV-2 S protein-specific antibodies were present in plasma of the offspring.

4.7 EFFECTS OF ABILITY TO DRIVE AND USE MACHINES

COVID-19 Vaccine Janssen has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Clinical trial data

Summary of safety profile

The safety of COVID-19 Vaccine Janssen was evaluated in an ongoing phase 3 study (COV3001). A total of 21 895 adults aged 18 years and older received COVID-19 Vaccine Janssen. The median age of individuals was 52 years (range 18-100 years). The safety analysis was performed once the median follow-up duration of 2 months after vaccination was reached. Longer safety follow-up of >2 months is available for 11 948 adults who received COVID-19 Vaccine Janssen.

In study COV3001, the most common local adverse reactions reported was injection site pain (48.6%). The most common systemic adverse reactions were headache (38.9%), fatigue (38.2%), myalgia (33.2%) and nausea (14.2%). Pyrexia (defined as body temperature ≥38.0°C) was observed in 9% of participants. Most adverse reactions occurred within 1-2 days following vaccination and were mild to moderate in severity and of short duration (1-2 days).

Reactogenicity was generally milder and reported less frequently in older adults (763 adults ≥65 years old and 150 adults ≥75 years old).

The safety profile was generally consistent across participants with or without prior evidence of SARS-CoV-2 infection at baseline; a total of 2 151 adults seropositive at baseline received COVID-19 Vaccine Janssen (9.8%).

Tabulated list of adverse reactions

Adverse drug reactions observed during study COV3001 are organised by MedDRA System Organ Class (SOC). Frequency categories are defined as follows:
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).

Adverse drug reactions (ADRs) include solicited adverse events (AEs), and unsolicited AEs which occurred with a frequency of at least 0.1%, that were not collected as solicited AEs and occurred at a higher frequency in the Ad26 group compared to placebo group based on clinical judgement. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 1: Adverse reactions reported following vaccination with COVID-19 Vaccine Janssen

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)
Immune system disorders				Hypersensitivity[a]; urticaria	Anaphylaxis[b]
Nervous system disorders	Headache		Tremor		
Respiratory, thoracic and mediastinal disorders		Cough	Sneezing; oropharyngeal pain		
Gastrointestinal disorders	Nausea				
Skin and subcutaneous tissue disorders			Rash; hyperhidrosis		
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia	Muscular weakness; pain in extremity; back pain		
General disorders and administration site conditions	Fatigue; injection site pain	Pyrexia; injection site erythema; injection site swelling; chills	Asthenia; malaise		

[a] Hypersensitivity refers to allergic reactions of the skin and subcutaneous tissue.
[b] Cases received from an ongoing open-label study in South Africa.

Postmarketing Data

In addition to the adverse reactions reported during clinical studies and listed above, the following adverse reactions have been reported during postmarketing experience. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Thrombosis involving large blood vessels, including the cerebral venous sinuses, portal vein, lower extremity veins, and pulmonary artery, combined with thrombocytopenia have been reported post-marketing following vaccination with COVID-19 Vaccine Janssen.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems and include batch or lot number if available.

4.9 OVERDOSE

No case of overdose has been reported. In phase 1/2 studies where a higher dose (up to 2-fold) was administered COVID-19 Vaccine Janssen remained well-tolerated, however vaccinated individuals reported an increase in reactogenicity (increased vaccination site pain, fatigue, headache, myalgia, nausea and pyrexia).

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Vaccines, other viral vaccines, ATC code: J07BX03

Mechanism of Action

COVID-19 Vaccine Janssen is a monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 vector that encodes a SARS-CoV-2 full-length spike (S) glycoprotein in a stabilised conformation. Following administration, the S glycoprotein of SARS-CoV-2 is transiently expressed, stimulating both neutralising and other functional S-specific antibodies, as well as cellular immune responses directed against the S antigen, which may contribute to protection against COVID-19.

Clinical trials

An ongoing, multicentre, randomised, double-blind, placebo-controlled phase 3 study (COV3001) is being conducted in the United States, South Africa and Latin American countries to assess the efficacy, safety, and immunogenicity of a single-dose of COVID-19 Vaccine Janssen for the prevention of COVID-19 in adults aged 18 years and older. The study excluded individuals with abnormal function of the immune system resulting from a clinical condition, individuals who are under immunosuppressive therapies within 6 months, as well as pregnant women. Participants with stable HIV infection under treatment were not excluded. Licensed vaccines, excluding live vaccines, could be administered more than 14 days before or more than 14 days after the vaccination in the study. Licensed live attenuated vaccines could be administered more than 28 days before or more than 28 days after the vaccination in the study.

A total of 44 325 individuals were randomised in parallel in a 1:1 ratio to receive an intramuscular injection of COVID-19 Vaccine Janssen or placebo. A total of 21 895 adults received COVID-19 Vaccine Janssen and 21 888 adults received placebo. Participants were followed for a median of 58 days (range: 1-124 days) after vaccination.

The primary efficacy analysis population of 39 321 individuals included 38 059 SARS-CoV-2 seronegative individuals at baseline and 1 262 individuals with an unknown serostatus.

Demographic and baseline characteristics were similar among individuals who received the COVID-19 Vaccine Janssen and those who received placebo. In the primary efficacy analysis population, among the individuals who received COVID-19 Vaccine Janssen, the median age was 52.0 years (range: 18 to 100 years); 79.7% (N=15 646) of individuals were 18 to 64 years old [with 20.3% (N=3 984) aged 65 or older and 3.8% (N=755) aged 75 or older]; 44.3% of individuals were female; 46.8% were from Northern America (United States), 40.6% were from Latin America and 12.6% were from Southern Africa (South Africa). A total of 7 830 (39.9%) individuals had at least one pre-existing comorbidity associated with increased risk of progression to severe COVID-19 at baseline (comorbidities included: obesity defined as BMI ≥30 kg/m^2 (27.5%), hypertension (10.3%), type 2 diabetes (7.2%), stable/well-controlled HIV infection (2.5%), serious heart conditions (2.4%) and asthma (1.3%)). Other comorbidities were present in ≤1% of the individuals.

COVID-19 cases were confirmed by a central laboratory based on a positive SARS-CoV-2 viral RNA result using a polymerase chain reaction (PCR)-based test. Vaccine efficacy overall and by key age groups are presented in Table 2.

Table 2: Analysis of vaccine efficacy against COVID-19[b] in SARS-CoV-2 seronegative adults - primary efficacy analysis population

	COVID-19 Vaccine Janssen N=19 630		Placebo N=19 691		
Subgroup	**COVID-19 Cases (n)**	**Person-Years**	**COVID-19 Cases (n)**	**Person-Years**	**% Vaccine Efficacy (95% CI)[c]**
14 days post-vaccination					
All subjects[a]	116	3 116.57	348	3 096.12	66.9 (59.03; 73.40)
18 to 64 years of age	107	2 530.27	297	2 511.23	64.2 (55.26; 71.61)
65 years and older	9	586.31	51	584.89	82.4 (63.90; 92.38)
28 days post-vaccination					
All subjects[a]	66	3 102.00	193	3 070.65	66.1 (55.01; 74.80)
18 to 64 years of age	60	2 518.73	170	2 490.11	65.1 (52.91; 74.45)
65 years and older	6	583.27	23	580.54	74.0 (34.40; 91.35)

[a] Co-primary endpoint as defined in the protocol.
[b] Symptomatic COVID-19 requiring positive RT-PCR result and at least 1 respiratory sign or symptom or 2 other systemic signs or symptoms, as defined in the protocol.
[c] Confidence intervals for 'All Subjects' were adjusted to implement type I error control for multiple testing. Confidence intervals for age groups are presented unadjusted.

Vaccine efficacy against severe COVID-19 is presented in Table 3 below.

Table 3: Analyses of vaccine efficacy against severe COVID-19[a] in SARS-CoV-2 seronegative adults - primary efficacy analysis population

	COVID-19 Vaccine Janssen N=19 630		Placebo N=19 691		
Subgroup	**COVID-19 Cases (n)**	**Person-Years**	**COVID-19 Cases (n)**	**Person-Years**	**% Vaccine Efficacy (95% CI)[b]**
14 days post-vaccination					
Severe	14	3 125.05	60	3 122.03	76.7 (54.56; 89.09)
28 days post-vaccination					
Severe	5	3 106.15	34	3 082.58	85.4 (54.15; 96.90)

[a] Severe/critical COVID-19 was defined based on the following criteria: the individual must have experienced any one of the following at any time during the course of observation: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths/minute, heart rate ≥125 beats/minute, oxygen saturation (SpO2) ≤93% on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO2/FiO2) <300 mmHg), respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]), evidence of shock (defined as systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors), significant acute renal, hepatic, or neurologic dysfunction, admission to

intensive care unit (ICU), death. Final determination of severe COVID-19 cases was made by an independent adjudication committee.

[b] Confidence intervals were adjusted to implement type I error control for multiple testing.

Of the 14 vs. 60 severe cases with onset at least 14 days after vaccination in the COVID-19 Vaccine Janssen group vs. placebo group, 2 vs. 6 were hospitalised. Three individuals died (all in the placebo group). The majority of the remaining severe cases fulfilled only the oxygen saturation (SpO_2) criterion for severe disease (≤93% on room air).

Prior to unblinding, supplementary analyses, considered post-hoc, of positive cases using PCR-based tests regardless of confirmation by the central laboratory generally support the results of the primary analysis.

Beyond 14 days after vaccination, 2 vs. 8 cases of molecularly confirmed COVID-19 were hospitalised, respectively in the COVID-19 Vaccine Janssen vs. placebo group. One case in the placebo group required Intensive Care Unit (ICU) admission and mechanical ventilation. The finding was supported by post-hoc analysis of all COVID-19 related hospitalisations implementing a broader search based on all available information from any source (2 vs. 29 cases in the extended data set).

Subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates for male and female participants, as well as for participants with and without medical comorbidities associated with high risk of severe COVID-19.

Exploratory subgroup analyses of vaccine efficacy against COVID-19 and severe COVID-19 for Brazil, South Africa, and the United States were conducted (see Table 4). For the subgroup analyses, all COVID-19 cases accrued up to the primary efficacy analysis data cut-off date, including cases confirmed by the central laboratory and cases with documented positive SARS-CoV-2 PCR from a local laboratory which are still awaiting confirmation by the central laboratory, were included.

Table 4: Summary of vaccine efficacy against COVID-19 and severe COVID-19 for countries with >100 reported cases

		Severity	
	Onset	**COVID-19 point estimate (95% CI)**	**Severe COVID-19 point estimate (95% CI)**
US	at least **14 days** after vaccination	74.4% (65.00; 81.57)	78.0% (33.13; 94.58)
	at least **28 days** after vaccination	72.0% (58.19;81.71)	85.9% (-9.38; 99.69)
Brazil	at least **14 days** after vaccination	66.2% (51.01; 77.14)	81.9% (17.01; 98.05)
	at least **28 days** after vaccination	68.1% (48.81; 80.74)	87.6% (7.84; 99.72)
South Africa	at least **14 days** after vaccination	52.0% (30.26; 67.44)	73.1% (40.03; 89.36)
	at least **28 days** after vaccination	64.0% (41.19; 78.66)	81.7% (46.18; 95.42)

Samples from 71.7% of central laboratory confirmed primary analysis cases had been sequenced [United States (73.5%), South Africa (66.9%) and Brazil (69.3%)]. Of the sequenced samples there is an imbalance in the completeness of the dataset between COVID-19 Vaccine Janssen and placebo. In the United States, 96.4% of strains were identified as the Wuhan-H1 variant D614G; in South Africa, 94.5% of strains were identified as the 20H/501Y.V2 variant (B.1.351 lineage); in Brazil, 69.4% of strains were identified to be a variant of the P.2 lineage and 30.6% of strains were identified as the Wuhan-H1 variant D614G.

Elderly population

COVID-19 Vaccine Janssen was assessed in individuals 18 years of age and older. The efficacy of COVID-19 Vaccine Janssen was consistent between elderly (≥65 years) and younger individuals (18-64 years).

5.2 PHARMACOKINETIC PROPERTIES

Not applicable.

5.3 PRECLINICAL SAFETY DATA

Non-clinical data reveal no special hazards for humans based on conventional studies of repeat-dose toxicity and local tolerance, and reproductive and developmental toxicity.

Genotoxicity and Carcinogenicity

COVID-19 Vaccine Janssen has not been evaluated for its genotoxic or carcinogenic potential. The components of the vaccine are not expected to have genotoxic or carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Hydroxypropylbetadex
Citric acid monohydrate
Ethanol absolute
Hydrochloric acid
Polysorbate-80
Sodium chloride
Sodium hydroxide
Sodium citrate dihydrate
Water for injections

6.2 INCOMPATIBILITIES

This medicinal product must not be mixed with other medicinal products or diluted.

6.3 SHELF LIFE

Please also see sections 6.4 and 6.6 for special precautions for storage and detailed instructions for storage and handling.

Unopened vial

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

Opened vial (after first puncture of the vial)

Chemical and physical in-use stability of the vaccine has been demonstrated for 6 hours at 2°C to 25°C. From a microbiological point of view, the product should preferably be used immediately after first puncture of the vial; however, the product can be stored between 2°C-8°C for a maximum of 6 hours or remain at room temperature (maximally 25°C) up to 3 hours after first puncture of the vial.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Please also see section 6.6 for detailed instructions for storage and handling.

Storage Prior to Use

Store and transport frozen at -25°C to -15°C. The expiry date for storage at -25°C to -15°C is printed on the vial and outer carton after “EXP”.

When stored frozen at -25°C to -15°C, the vaccine can be thawed either at 2°C to 8°C or at room temperature:

- at 2°C to 8°C: a carton of 10 vials will take approximately 12 hours to thaw, and a single vial will take approximately 2 hours to thaw.
- at room temperature (maximally 25°C): a carton of 10 vials will take approximately 2 hours to thaw, and a single vial will take approximately 1 hour to thaw.

The vaccine can also be stored in a refrigerator at 2°C to 8°C for a single period of up to 3 months, not exceeding the original expiry date (EXP). Upon moving the product to 2°C to 8°C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable. The vaccine can also be transported at 2°C -8°C as long as the appropriate storage conditions (temperature, time) are applied.

Once thawed, the vaccine cannot be re-frozen.

Keep the vials in the original carton in order to protect from light.

Unopened COVID-19 Vaccine Janssen is stable for a total of 12 hours at 9°C to 25°C. This is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions during the 3 month storage at 2°C -8°C.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 NATURE AND CONTENTS OF CONTAINER

A 2.5 mL suspension in a multi-dose vial (Type I glass) with a rubber stopper (chlorobutyl with fluoropolymer coated surface), aluminium crimp and blue plastic cap. Each vial contains 5 doses of 0.5 mL.

Pack size of 10 multi-dose vials.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Handling instructions and administration

This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

- The vaccine comes ready to use once thawed.
- The vaccine may be supplied frozen at -25°C to -15°C or thawed at 2°C to 8°C.
- Do not re-freeze vaccine once thawed.
- Keep the vials in the original carton in order to protect from light and to record the expiry for the different storage conditions, if applicable.

1. Storage upon receipt of vaccine

IF YOU RECEIVE YOUR VACCINE FROZEN AT -25°C to -15°C you may:

OR

Store in a freezer

- The vaccine can be stored and transported frozen at **-25°C to -15°C**.
- The expiry date for storage is printed on the vial and outer carton after "EXP" (see section 6.4).

Store in a refrigerator

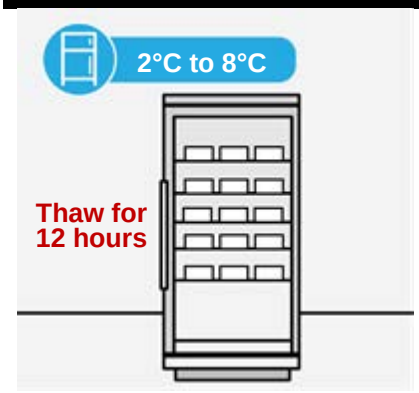
- The vaccine can also be stored and transported at **2°C to 8°C** for a single period of **up to 3 months**, not exceeding the original expiry date (EXP).
- Upon moving the product **to a refrigerator at 2°C to 8°C**, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. **The original expiry date should be made unreadable** (see section 6.4).

IF YOU RECEIVE YOUR VACCINE THAWED AT 2°C to 8°C you should store in a refrigerator:

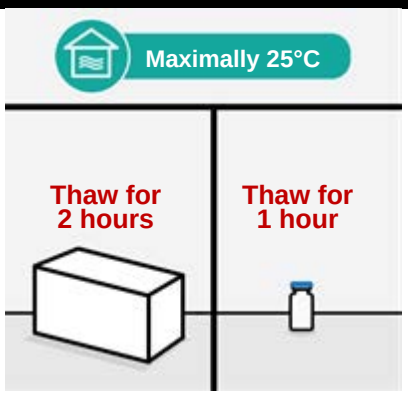
Do not re-freeze if the product is received already thawed at 2°C to 8°C.

Note: If the vaccine is received refrigerated at 2°C to 8°C, check that the expiry date has been updated by the local supplier upon receipt. If you cannot find the new EXP date, contact the local supplier to confirm the refrigerated EXP date. Write the **new expiry date** on the outer carton before the vaccine is stored in the refrigerator. **The original expiry date should be made unreadable** (see section 6.4).

2. If stored frozen, thaw vial(s) either in a refrigerator or at room temperature before administration



OR



Thaw in refrigerator

- When stored frozen at -25°C to -15°C, a carton of 10 vials will take approximately 12 hours to thaw or individual vials will take approximately 2 hours to thaw **at 2°C to 8°C**.
- If the vaccine is not used immediately, refer to the instructions in section 'Store in a refrigerator'.
- The vial must be kept in the original carton in order to protect from light and to record the expiry for the different storage conditions, if applicable.

⚠ Do not re-freeze once thawed.

Thaw at room temperature

- When stored frozen at **-25°C to -15°C**, a carton of 10 vials or individual vials should be thawed at room temperature maximally **25°C**.
- A carton of 10 vials will take approximately **2 hours** to thaw.
- Individual vials will take approximately **1 hour** to thaw.
- The vaccine is stable for a total of **12 hours at 9°C to 25°C**. This is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.
- If the vaccine is not used immediately, refer to the instructions in section Store in a refrigerator.

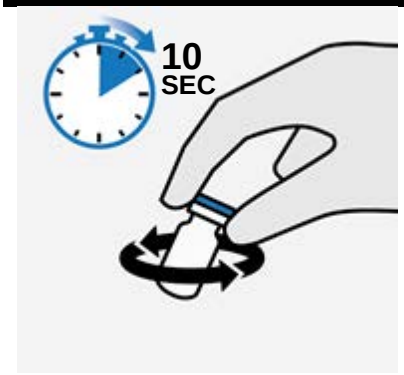
⚠ **Do not** re-freeze once thawed.

3. Inspect vial and vaccine

- COVID-19 Vaccine Janssen is a colourless to slightly yellow, clear to very opalescent suspension (pH 6-6.4).
- The vaccine should be inspected visually for particulate matter and discoloration prior to administration.
- The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering prior to administration.

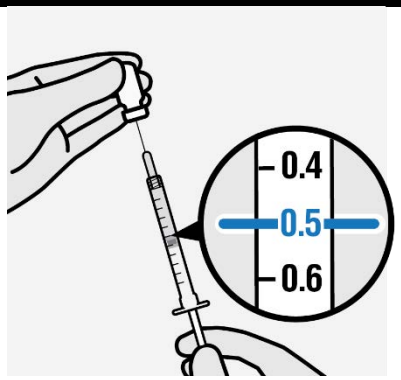
If any of these should exist, do not administer the vaccine.

4. Prepare and administer vaccine



Swirl the vial gently

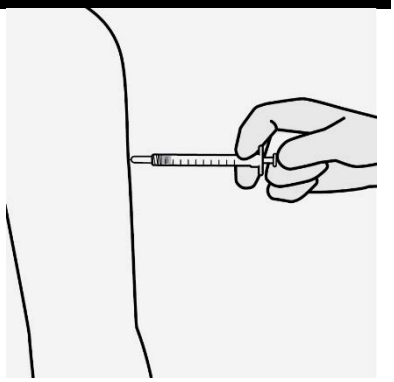
- Before administering a dose of vaccine, swirl the vial gently **in an upright position for 10 seconds**.
- **Do not** shake.



Withdraw 0.5 mL

- Use a sterile needle and sterile syringe to extract a single dose of **0.5 mL** from the multi-dose vial (see section 4.2).

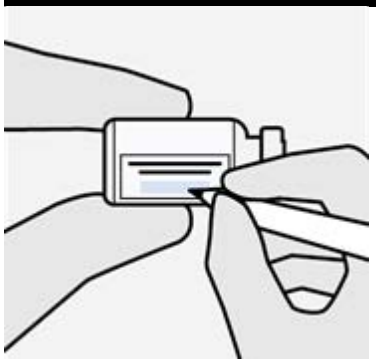
A maximum of 5 doses can be withdrawn from the multi-dose vial. Discard any remaining vaccine in the vial after 5 doses have been extracted.



Inject 0.5 mL

- Administer by **intramuscular injection only** into the deltoid muscle of the upper arm (see section 4.2).

5. Storage after first puncture



Record date and time the vial should be discarded

- After first puncture of the vial record the date and time the vial should be discarded on each vial label.

⚠ Preferably, use immediately after first puncture.

- After the first puncture of the vial, the vaccine can be held at **2°C to 8°C** for **up to 6 hours**.
- Discard if vaccine is not used within this time.

OR

- After the first puncture of the vial, the vaccine can be held at **room temperature (maximally 25°C)** for a single period of **up to 3 hours**.
(see section 6.3).
- Discard if vaccine is not used within this time.

6. Disposal

COVID-19 Vaccine Janssen contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in compliance with local guidance for pharmaceutical waste. Potential spills should be disinfected with agents with viricidal activity against adenovirus.

7. MEDICINE SCHEDULE (POISON STANDARD)

S4 Prescription Medicine

8. SPONSOR

Janssen-Cilag Pty Ltd
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Macquarie Park,
NSW, 2113, AUSTRALIA
Telephone: 1800 226 334

9. DATE OF FIRST APPROVAL

25 June 2021