

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

## 1. NAME OF THE MEDICINAL PRODUCT

COVID-19 Vaccine Janssen suspension for injection  
COVID-19 vaccine (Ad26.COVS-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.COVS-S), not less than 8.92 log<sub>10</sub> infectious units (Inf.U).

\* Produced in the PER.C6 TetR Cell Line and by recombinant DNA technology.

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 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.

### 4.2 Posology and method of administration

#### Posology

##### *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  $\geq 65$  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.

### **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**

#### 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.

#### 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.

#### 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.

#### 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.

#### Thrombocytopenia and coagulation disorders

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.

### 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.

## **4.5 Interaction with other medicinal products and other forms of interaction**

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**

### Pregnancy

There is limited experience with the use of COVID-19 Vaccine Janssen in pregnant women. Animal studies with COVID-19 Vaccine Janssen do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or postnatal development (see section 5.3).

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

### Breast-feeding

It is unknown whether COVID-19 Vaccine Janssen is excreted in human milk.

### Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

## **4.7 Effects on 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 Undesirable effects

### 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  $\geq 38.0^{\circ}\text{C}$ ) 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  $\geq 65$  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 ( $\geq 1/10$ );

Common ( $\geq 1/100$  to  $< 1/10$ );

Uncommon ( $\geq 1/1\ 000$  to  $< 1/100$ );

Rare ( $\geq 1/10\ 000$  to  $< 1/1\ 000$ );

Not known (cannot be estimated from the available data).

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 ( $\geq 1/10$ )	Common ( $\geq 1/100$ to $< 1/10$ )	Uncommon ( $\geq 1/1\ 000$ to $< 1/100$ )	Rare ( $\geq 1/10\ 000$ to $< 1/1\ 000$ )	Not known (cannot be estimated from the available data)
Immune system disorders				Hypersensitivity <sup>a</sup> ; urticaria	Anaphylaxis <sup>b</sup>
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		

<sup>a</sup> Hypersensitivity refers to allergic reactions of the skin and subcutaneous tissue.

<sup>b</sup> Cases received from an ongoing open-label study in South Africa.

### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the national reporting system listed in [Appendix V](#) and include batch/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.

## 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 efficacy

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  $\geq$ 30 kg/m<sup>2</sup> (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  $\leq$ 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<sup>b</sup> in SARS-CoV-2 seronegative adults - primary efficacy analysis population**

Subgroup	COVID-19 Vaccine Janssen N=19 630		Placebo N=19 691		% Vaccine Efficacy (95% CI) <sup>c</sup>
	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	
<b>14 days post-vaccination</b>					
All subjects <sup>a</sup>	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)
75 years and older	0	107.37	8	99.15	100 (45.90; 100.00)
<b>28 days post-vaccination</b>					
All subjects <sup>a</sup>	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)
75 years and older	0	106.42	3	98.06	–

<sup>a</sup> Co-primary endpoint as defined in the protocol.

<sup>b</sup> 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.

<sup>c</sup> 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<sup>a</sup> in SARS-CoV-2 seronegative adults - primary efficacy analysis population**

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

<sup>a</sup> Final determination of severe COVID-19 cases was made by an independent adjudication committee, who also assigned disease severity according to the definition per FDA guidance.

<sup>b</sup> 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<sub>2</sub>) criterion for severe disease ( $\leq 93\%$  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**

	Onset	Severity	
		COVID-19 point estimate (95% CI)	Severe COVID-19 point estimate (95% CI)
US	at least <b>14 days</b> after vaccination	74.4% (65.00; 81.57)	78.0% (33.13; 94.58)
	at least <b>28 days</b> after vaccination	72.0% (58.19; 81.71)	85.9% (-9.38; 99.69)
Brazil	at least <b>14 days</b> after vaccination	66.2% (51.01; 77.14)	81.9% (17.01; 98.05)
	at least <b>28 days</b> after vaccination	68.1% (48.81; 80.74)	87.6% (7.84; 99.72)
South Africa	at least <b>14 days</b> after vaccination	52.0% (30.26; 67.44)	73.1% (40.03; 89.36)
	at least <b>28 days</b> 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 ( $\geq 65$  years) and younger individuals (18-64 years).

#### Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with COVID-19 Vaccine Janssen in one or more subsets of the paediatric population in prevention of COVID-19 (see section 4.2 for information on paediatric use).

#### Conditional approval

This medicinal product has been authorised under a so-called ‘conditional approval’ scheme. **This means that further evidence on this medicinal product is awaited.** The European Medicines Agency will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

### **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.

#### Reproductive toxicity and fertility

Female reproductive toxicity and fertility were assessed in a combined embryo-foetal and pre- and post-natal development study in the rabbit. In this study a first vaccination of COVID-19 Vaccine Janssen was administered intramuscularly to female rabbits 7 days prior to mating, at a dose equivalent to 2-fold above the recommended human dose, followed by two vaccinations at the same dose during the gestation period (i.e., at gestational days 6 and 20). There were no vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development. The parental females as well as their foetuses and offspring exhibited SARS-CoV-2 S protein-specific antibody titers, indicating that maternal antibodies were transferred to the foetuses during gestation. No COVID-19 Vaccine Janssen data are available on vaccine excretion in milk.

In addition, a conventional (repeat-dose) toxicity study in rabbits with COVID-19 Vaccine Janssen did not reveal any effects on male sex organs that would impair male fertility.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

2-hydroxypropyl- $\beta$ -cyclodextrin (HBCD)  
Citric acid monohydrate  
Ethanol  
Hydrochloric acid  
Polysorbate-80  
Sodium chloride  
Sodium hydroxide  
Trisodium 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

#### Unopened vial

2 years when stored at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ .

Once removed from the freezer, the unopened vaccine may be stored refrigerated at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ , protected from light, for a single period of up to 3 months, not exceeding the printed expiry date (EXP).

Once thawed, the vaccine should not be re-frozen.

For special precautions for storage, see section 6.4.

#### Opened vial (after first puncture of the vial)

Chemical and physical in-use stability of the vaccine has been demonstrated for 6 hours at  $2^{\circ}\text{C}$  to  $25^{\circ}\text{C}$ . 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  $2^{\circ}\text{C}$ - $8^{\circ}\text{C}$  for a maximum of 6 hours or remain at room temperature (maximally  $25^{\circ}\text{C}$ ) up to 3 hours after first puncture of the vial. Beyond these times, in-use storage is the responsibility of the user.

### 6.4 Special precautions for storage

Store and transport frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ . The expiry date for storage at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$  is printed on the vial and outer carton after "EXP".

When stored frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ , the vaccine can be thawed either at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  or at room temperature:

- at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ : 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  $25^{\circ}\text{C}$ ): 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  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  for a single period of up to 3 months, not exceeding the original expiry date (EXP). Upon moving the product to  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  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. It 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**

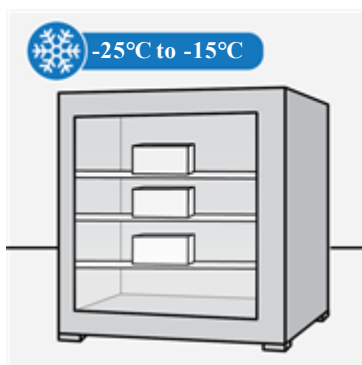
### Handling instructions and administration

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

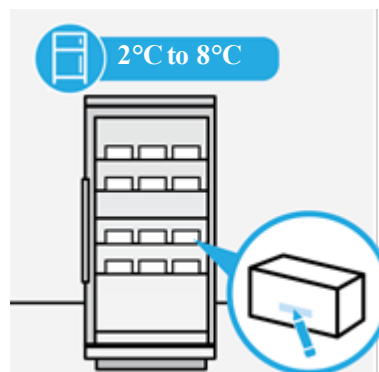
- The vaccine comes ready to use once thawed.
- The vaccine may be supplied frozen at -25°C to -15°C or thawed at 2°C to 8°C.
- Do not re-freeze vaccine once thawed.
- Keep the vials in the original carton in order to protect from light and to record the expiry for the different storage conditions, if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

### a. Storage upon receipt of vaccine

IF YOU RECEIVE YOUR VACCINE FROZEN AT  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$  you may:



OR



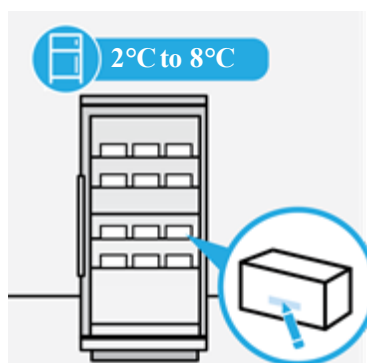
#### Store in a freezer

- The vaccine can be stored and transported frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ .
- 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  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  for a single period of **up to 3 months**, not exceeding the original expiry date (EXP).
- Upon moving the product to a **refrigerator at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$** , 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).

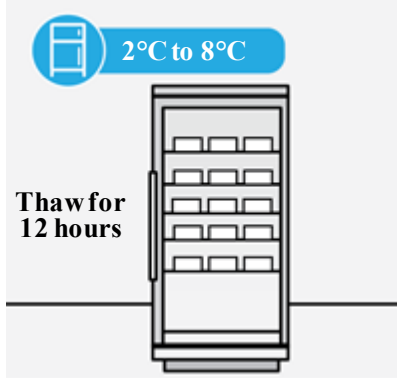
IF YOU RECEIVE YOUR VACCINE THAWED AT  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  you should store in a refrigerator:



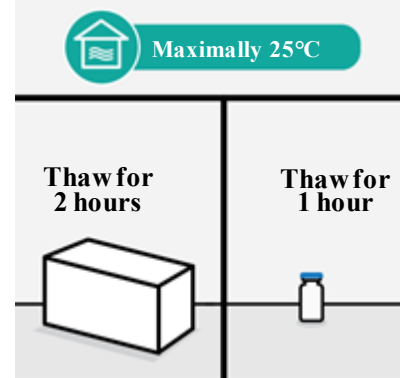
**!** **Do not** re-freeze if the product is received already thawed at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ .

**Note:** If the vaccine is received refrigerated at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ , 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).

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



OR



**Thaw in refrigerator**

- When stored frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ , a carton of 10 vials will take approximately 12 hours to thaw or individual vials will take approximately 2 hours to thaw **at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$** .
- 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  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ , a carton of 10 vials or individual vials should be thawed at room temperature maximally  **$25^{\circ}\text{C}$** .
- 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  $9^{\circ}\text{C}$  to  $25^{\circ}\text{C}$** . It 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.

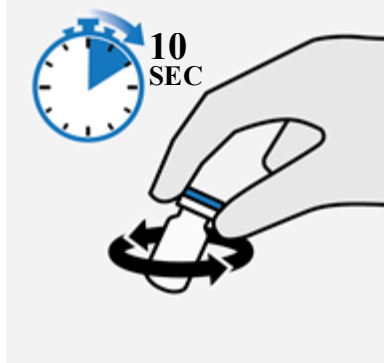
**!** Do not re-freeze once thawed.

**c. Inspect vial and vaccine**

- COVID-19 Vaccine Janssen is a colorless 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.

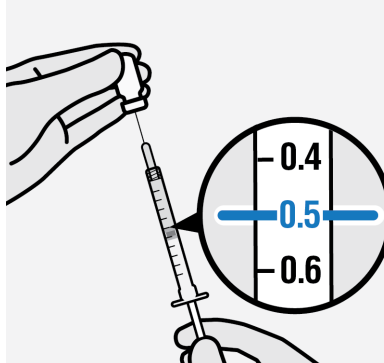
If any of these should exist, do not administer the vaccine.

#### d. Prepare and administer vaccine



##### Swirl the vial gently

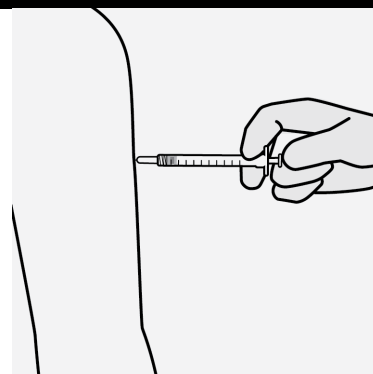
- Before administering a dose of vaccine, swirl the vial gently **in an upright position for 10 seconds**.
- **Do not** shake.



##### 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).

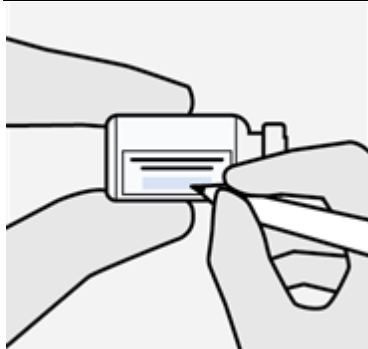
**!** A maximum of 5 doses can be withdrawn from the multi-dose vial. Discard any remaining vaccine in the vial after 5 doses have been extracted.



##### Inject 0.5 mL

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

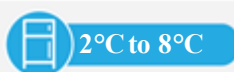
#### e. Storage after first puncture



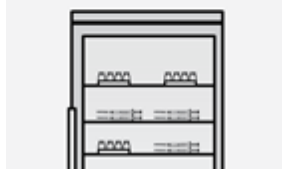
##### Record date and time the vial should be discarded

- 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.



Store up to 6 hours



- 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



Store up to 3 hours



- 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.

## **f. Disposal**

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. MARKETING AUTHORISATION HOLDER**

Janssen-Cilag International NV  
Turnhoutseweg 30  
B-2340 Beerse  
Belgium

### **8. MARKETING AUTHORISATION NUMBER(S)**

EU/1/20/1525/001

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation:

### **10. DATE OF REVISION OF THE TEXT**

Detailed information on this medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

## **ANNEX II**

- A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**
- D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**
- E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION**



**A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND  
MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturers of the biological active substance

Janssen Vaccines & Prevention B.V.  
Archimedesweg 4-6,  
2333 CN Leiden,  
The Netherlands

Janssen Biologics B.V.  
Einsteinweg 101  
2333 CB Leiden  
The Netherlands

Emergent Manufacturing  
Operations Baltimore LLC  
5901 East Lombard Street  
Baltimore, MD 21224  
United States (USA)

Name and address of the manufacturers responsible for batch release

Janssen Biologics B.V.  
Einsteinweg 101  
2333 CB Leiden  
The Netherlands

Janssen Pharmaceutica NV  
Turnhoutseweg 30  
2340 Beerse  
Belgium

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

In view of the declared Public Health Emergency of International Concern and in order to ensure early supply this medicinal product is subject to a time-limited exemption allowing reliance on batch control testing conducted in the registered site(s) that are located in a third country. This exemption ceases to be valid on 30 June 2021. Implementation of EU based batch control arrangements, including the necessary variations to the terms of the marketing authorisation, has to be completed by 30 June 2021 at the latest, in line with the agreed plan for this transfer of testing.

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Medicinal product subject to medical prescription.

• **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

### C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

### D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

### E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional comparability and validation data.	15 August 2021  Interim report: 31 March 2021
In order to confirm the efficacy and safety of Ad26.COVS.2 COVID-19 Vaccine, the MAH should submit the final Clinical Study Report for the randomised, placebo-controlled, observer-blind study VAC31518COV3001.	31 December 2023

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON-PACK SIZE OF 10 MULTI-DOSE VIALS**

**1. NAME OF THE MEDICINAL PRODUCT**

COVID-19 Vaccine Janssen suspension for injection  
COVID-19 vaccine (Ad26.COVS2-S [recombinant])

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

One dose (0.5 mL) contains not less than 8.92 log<sub>10</sub> infectious units

Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad26.COVS2-S)

This medicine contains genetically modified organisms (GMOs).

**3. LIST OF EXCIPIENTS**

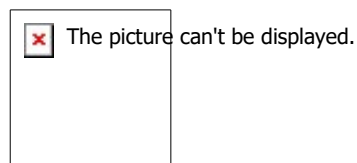
Excipients: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections. See leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
10 multi-dose vials  
Each vial contains 5 doses of 0.5 mL

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use  
Read the package leaflet before use  
For more information, scan this QR code or go to [www.covid19vaccinejanssen.com](http://www.covid19vaccinejanssen.com).



**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP when stored at -25°C to -15°C.

Write new expiry date at 2°C to 8°C (maximum 3 months): \_\_\_\_\_. Make former expiry date unreadable.

**9. SPECIAL STORAGE CONDITIONS**

Store and transport frozen at -25°C to -15°C.

Can also be stored at 2°C to 8°C for 3 months. Write new expiry date.

Do not refreeze once thawed.

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

For information on the shelf life after first opening and additional storage information, see the package leaflet.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Dispose of in compliance with the local guidance for pharmaceutical waste.

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Janssen-Cilag International NV  
Turnhoutseweg 30  
B-2340 Beerse  
Belgium

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/20/1525/001

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY****15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

Justification for not including Braille accepted.

**17. UNIQUE IDENTIFIER – 1D & 2D BARCODE**

2D barcode carrying the unique identifier included.

**18. UNIQUE IDENTIFIER - HUMAN READABLE DATA**

PC  
SN  
NN

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS  
MULTI-DOSE VIAL LABEL (5 DOSES OF 0.5 ML)**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

COVID-19 Vaccine Janssen injection  
COVID-19 vaccine (Ad26.COV2-S [recombinant])  
IM

**2. METHOD OF ADMINISTRATION**

Intramuscular use

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

5 doses of 0.5 mL

**6. OTHER**

Discard date/time



**B. PACKAGE LEAFLET**

## Package leaflet: Information for the user

### COVID-19 Vaccine Janssen suspension for injection COVID-19 vaccine (Ad26.COVS-S [recombinant])

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **Read all of this leaflet carefully before you are vaccinated because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What COVID-19 Vaccine Janssen is and what it is used for
2. What you need to know before you are given COVID-19 Vaccine Janssen
3. How COVID-19 Vaccine Janssen is given
4. Possible side effects
5. How to store COVID-19 Vaccine Janssen
6. Contents of the pack and other information

#### **1. What COVID-19 Vaccine Janssen is and what it is used for**

COVID-19 Vaccine Janssen is a vaccine used for preventing COVID-19 caused by the SARS-CoV-2 virus.

COVID-19 Vaccine Janssen is given to adults aged 18 years and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and specialised white blood cells that work against the virus, so giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

#### **2. What you need to know before you are given COVID-19 Vaccine Janssen**

##### **Do not have the vaccine if:**

- You are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before you are given COVID-19 Vaccine Janssen if:

- you have ever had a severe allergic reaction after injection of any other vaccine,
- you have ever fainted following any needle injection,
- you have a severe infection with a high temperature (over 38°C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold,
- you have a problem with bleeding or bruising, or if you are taking an anticoagulant medicine (to prevent blood clots),
- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines).

As with any vaccine, vaccination with COVID-19 Vaccine Janssen may not fully protect all those who receive it. It is not known how long you will be protected.

### **Children and adolescents**

COVID-19 Vaccine Janssen is not recommended for children aged below 18 years. Currently there is not enough information available on the use of COVID-19 Vaccine Janssen in children and adolescents younger than 18 years of age.

### **Other medicines and COVID-19 Vaccine Janssen**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or vaccines.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

### **Driving and using machines**

Some of the side effects of COVID-19 Vaccine Janssen listed in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

### **COVID-19 Vaccine Janssen contains sodium**

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

### **COVID-19 Vaccine Janssen contains ethanol**

This medicine contains 2 mg of alcohol (ethanol) in each dose of 0.5 mL. The amount of ethanol in this medicine is equivalent to less than 1 mL beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

## **3. How COVID-19 Vaccine Janssen is given**

Your doctor, pharmacist or nurse will inject the vaccine into the muscle - usually in the upper arm.

### **How much vaccine will you receive**

A single-dose (0.5 mL) of COVID-19 Vaccine Janssen is injected.

After the injection your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all vaccines, COVID-19 Vaccine Janssen can cause side effects, although not everybody gets them. Most of the side effects occur in the 1 or 2 days of getting the vaccination.

Get **urgent** medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing

- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain.

The following side effects can happen with this vaccine.

**Very common:** may affect more than 1 in 10 people

- headache
- nausea
- muscle aches
- pain where the injection is given
- feeling very tired

**Common:** may affect up to 1 in 10 people

- redness where the injection is given
- swelling where the injection is given
- chills
- joint pain
- cough
- fever

**Uncommon:** may affect up to 1 in 100 people

- rash
- muscle weakness
- arm or leg pain
- feeling weak
- feeling generally unwell
- sneezing
- sore throat
- back pain
- tremor
- excessive sweating

**Rare:** may affect up to 1 in 1 000 people

- allergic reaction
- hives

**Unknown** (cannot be estimated from the available data)

- severe allergic reaction

Tell your doctor, pharmacist or nurse if you have any side effects that bother you or do not go away.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#) and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store COVID-19 Vaccine Janssen

Keep this vaccine out of the sight and reach of children.

Store vial in the original carton to protect from light.

Your doctor, pharmacist or nurse is responsible for storing this vaccine and disposing of any unused product correctly.

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”.

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.

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.

Do not re-freeze vaccine once thawed.

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.

## 6. Contents of the pack and other information

### What COVID-19 Vaccine Janssen contains

- The active substance is Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein\*(Ad26.COV2-S) not less than 8.92 log<sub>10</sub> infectious units (Inf.U) in each 0.5 mL dose.  
\* Produced in the PER.C6 TetR Cell Line and by recombinant DNA technology.

This product contains genetically modified organisms (GMOs).

- The other ingredients (excipients) are 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections (see section 2 COVID-19 Vaccine Janssen contains sodium and COVID-19 Vaccine Janssen contains ethanol).

### What COVID-19 Vaccine Janssen looks like and contents of the pack

Suspension for injection (injection). The suspension is colorless to slightly yellow, clear to very opalescent suspension (pH 6-6.4).

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

COVID-19 Vaccine Janssen is available in a pack containing 10 multi-dose vials.

**Marketing Authorisation Holder**

Janssen-Cilag International NV  
Turnhoutseweg 30  
B-2340 Beerse  
Belgium

**Manufacturer**

Janssen Biologics B.V.  
Einsteinweg 101  
2333 CB Leiden  
The Netherlands

Janssen Pharmaceutica NV  
Turnhoutseweg 30  
2340 Beerse  
Belgium

For the specific manufacturer of the vaccine you have received, check the Lot number on the carton or vial and please contact the local representative of the Marketing Authorisation Holder.

For any additional information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**België/Belgique/Belgien**

Janssen-Cilag NV  
Tel/Tél: +3233939323/0080056540088

**Lietuva**

UAB "JOHNSON & JOHNSON"  
Tel: +37052142002/0080056540088

**България**

„Джонсън & Джонсън България“ ЕООД  
Тел.: / +35928008028/080018192

**Luxembourg/Luxemburg**

Janssen-Cilag NV  
Tél/Tel:  
+35227302815/0080056540088

**Česká republika**

Janssen-Cilag s.r.o.  
Tel: +420225296622/0080056540088

**Magyarország**

Janssen-Cilag Kft.  
Tel.: +3614292336/0080056540088

**Danmark**

Janssen-Cilag A/S  
Tlf: +4535158573/0080056540088

**Malta**

AM MANGION LTD  
Tel: +35627780004/80065007

**Deutschland**

Janssen-Cilag GmbH  
Tel: +4932221863163/0080056540088

**Nederland**

Janssen-Cilag B.V.  
Tel: +31880030701/0080056540088

**Eesti**

UAB "JOHNSON & JOHNSON" Eesti filiaal  
Tel: +3728804474/8002642

**Norge**

Janssen-Cilag AS  
Tlf: +4723500417/0080056540088

**Ελλάδα**

Janssen-Cilag Φαρμακευτική Α.Ε.Β.Ε.  
Τηλ: +302119906006/0080056540088

**Österreich**

Janssen-Cilag Pharma GmbH  
Tel: +43720380110/0080056540088

**España**

Janssen-Cilag, S.A.  
Tel: +34912158005/0080056540088

**Polska**

Janssen-Cilag Polska Sp. z o.o.  
Tel.: +48225123915/0080056540088

**France**

Janssen-Cilag  
Tél: +33185169327/0080056540088

**Portugal**

Janssen-Cilag Farmacêutica, Lda.  
Tel: +351220608007/0080056540088

**Hrvatska**

Johnson & Johnson S.E. d.o.o.  
Tel: +38518848011/0800806027

**România**

Johnson & Johnson România SRL  
Tel: +40311305128/0800672516

**Ireland**

Janssen Sciences Ireland UC  
Tel: +353212356806/0080056540088

**Slovenija**

Johnson & Johnson d.o.o.  
Tel: +38616009336/0080056540088

**Ísland**

Janssen-Cilag AB  
c/o Vistor hf.  
Sími: +3545390674/0080056540088

**Slovenská republika**

Johnson & Johnson, s.r.o.  
Tel: +421250112534/0080056540088

**Italia**

Janssen-Cilag SpA  
Tel: +390699748520/0080056540088

**Suomi/Finland**

Janssen-Cilag Oy  
Puh/Tel:  
+358981710294/99080056540088

**Κόπος**

Βαρνάβας Χατζηπαναγής Λτδ  
Τηλ+35725654186/0080056540088

**Sverige**

Janssen-Cilag AB  
Tfn: +46851992561/0080056540088

**Latvija**

UAB "JOHNSON & JOHNSON" filiāle Latvijā  
Tel: +37163138821/0080056540088

**United Kingdom (Northern Ireland)**

Janssen Sciences Ireland UC.  
Tel: +442076602872/0080056540088

**This leaflet was last revised in**

This vaccine has been given ‘conditional approval’. This means that there is more evidence to come about this vaccine.

The European Medicines Agency will review new information on this vaccine at least every year and this leaflet will be updated as necessary.

Scan the QR code below (also available on the carton and QR card) to get the package leaflet in different languages.

 The picture can't be displayed.

Or visit the URL: [www.covid19vaccinejanssen.com](http://www.covid19vaccinejanssen.com)

### **Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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### **The following information is intended for healthcare professionals only:**

- As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of COVID-19 Vaccine Janssen. Individuals should be monitored by a healthcare professional after vaccination for at least 15 minutes.
- COVID-19 Vaccine Janssen must not be mixed with other medicinal products or diluted in the same syringe.
- COVID-19 Vaccine Janssen must not be administered by intravascular, intravenous, subcutaneous or intradermal injection under any circumstances.
- Immunisation should be carried out by intramuscular injection only, preferably in the deltoid muscle of the upper arm.
- Syncope (fainting) may occur with any injection, including COVID-19 Vaccine Janssen. Procedures should be in place to prevent injury from falling and to manage syncopal reactions.

### 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.

### Instructions for administration and handling

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

Store and transport frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ . The expiry date for storage at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$  is printed on the vial and outer carton after “EXP”.

The vaccine comes ready to use once thawed. The vaccine may be supplied frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$  or thawed at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ .

When stored frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ , the vaccine can be thawed either at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  or at room temperature:

- at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ : 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  $25^{\circ}\text{C}$ ): a carton of 10 vials will take approximately 2 hours to thaw, and a single vial will take approximately 1 hour to thaw.

Do not re-freeze vaccine once thawed.

The vaccine can also be stored in a refrigerator at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  for a single period of up to 3 months, not exceeding the original expiry date (EXP). Upon moving the product to  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  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  $2^{\circ}\text{C}$  -  $8^{\circ}\text{C}$  as long as the appropriate storage conditions (temperature, time) are applied.



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.

COVID-19 Vaccine Janssen is a colorless 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.

Before administering a dose of vaccine, swirl the vial gently in an upright position for 10 seconds. Do not shake. Use a sterile needle and sterile syringe to extract a single-dose of 0.5 mL from the multi-dose vial and administer by intramuscular injection only into the deltoid muscle of the upper arm.

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.

After the first puncture of the vial the vaccine (vial) can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximum 25°C) for a single period of up to 3 hours. Discard if vaccine is not used within this time. After the first puncture of the vial, record the date and time the vial should be discarded on each vial label.

#### Disposal

Any unused vaccine or waste material should be disposed of in compliance with the local guidance for pharmaceutical waste. Potential spills should be disinfected with agents with viricidal activity against adenovirus.

**ANNEX IV**

**CONCLUSIONS ON THE GRANTING OF THE CONDITIONAL MARKETING  
AUTHORISATION PRESENTED BY THE EUROPEAN MEDICINES AGENCY**

**Conclusions presented by the European Medicines Agency on:**

- **Conditional marketing authorisation**

The CHMP having considered the application is of the opinion that the risk-benefit balance is favourable to recommend the granting of the conditional marketing authorisation as further explained in the European Public Assessment Report.