PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

JANSSEN COVID-19 VACCINE

Ad26.COV2-S [recombinant]

Suspension for intramuscular injection

Multidose Vial, 5 × 10^{10} virus particles/0.5 mL

(contains 5 doses of 0.5 mL)

Active Immunizing Agent

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RECENT MAJOR LABEL CHANGES

SERIOUS WARNINGS AND PRECAUTIONS (3.0)	04/2021
CONTRAINDICATIONS (2.0)	08/2021
WARNINGS AND PRECAUTIONS (7.0)	04/2021
WARNINGS AND PRECAUTIONS (7.0)	07/2021
WARNINGS AND PRECAUTIONS (7.0)	08/2021
WARNINGS AND PRECAUTIONS (7.0)	11/2021
ADVERSE REACTIONS, Post Market Adverse Reactions (8.3)	07/2021
ADVERSE REACTIONS, Post Market Adverse Reactions (8.3)	08/2021
ADVERSE REACTIONS, Post Market Adverse Reactions (8.3)	11/2021
STORAGE, STABILITY AND DISPOSAL (11.0)	04/2021
STORAGE, STABILITY AND DISPOSAL (11.0)	11/2021

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Janssen COVID-19 Vaccine (Ad26.COV2-S [recombinant]) is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.

1.1 Pediatrics

The safety and efficacy of Janssen COVID-19 Vaccine in individuals younger 18 years of age have not yet been established.

1.2 Geriatrics

Clinical studies of the Janssen COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy (see **8 ADVERSE REACTIONS,** and **14 CLINICAL TRIALS**).

2 CONTRAINDICATIONS

Janssen COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active ingredient, any other adenovirus-based vaccines, or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. (see **6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).**

Janssen COVID-19 Vaccine is contraindicated in individuals with a history of Capillary Leak Syndrome (CLS).

3 SERIOUS WARNINGS AND PRECAUTIONS

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine (see **WARNINGS AND PRECAUTIONS, Hematologic).**

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Janssen COVID-19 Vaccine is a suspension for intramuscular injection that should be administered by a trained healthcare worker.

4.2 Recommended Dose and Dosage Adjustment

Janssen COVID-19 Vaccine should be administered intramuscularly, as a single dose of 0.5 mL. There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 Vaccine.

4.3 Reconstitution

Janssen COVID-19 Vaccine must not be reconstituted, mixed with other medicinal products, or diluted.

4.4 Administration

Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. 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, carefully mix the contents of the multi-dose vial by swirling 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. The preferred site is the deltoid muscle of the upper arm. A needle length of ≥1 inch should be used as needles <1 inch may be of insufficient length to penetrate muscle tissue in some adults. Do not administer this vaccine intravenously or subcutaneously.

Changing needles between extracting vaccine from a vial and injecting it into an individual is not necessary unless the needle has been damaged or contaminated. Discard any remaining vaccine in the multi-dose vial after 5 doses have been extracted. After the first puncturing of the vial, the vial/filled syringe can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximally 25°C) for up to 3 hours. Discard if vaccine is not used within this time.

5 OVERDOSAGE

No case of overdose has been reported. In Phase 1/2 studies, where a higher dose (up to 2-fold) was administered, Janssen COVID-19 Vaccine remained well-tolerated however vaccinated individuals reported an increase in reactogenicity.

In the event of a suspected overdose, monitoring of vital functions and symptomatic treatment are recommended. Contact your local poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Suspension, (5×10^{10} virus particles/0.5 mL), adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein in a stabilized confirmation Multi-dose vial (total fill volume 3.1 mL, containing 5 doses of 0.5 mL)	• 2-hydroxypropyl-β-cyclodextrin (HBCD) • Citric acid monohydrate • Ethanol • Hydrochloric acid • Polysorbate-80 • Sodium chloride • Sodium hydroxide • Trisodium citrate dihydrate • Water for injection

Janssen COVID-19 Vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection. Janssen COVID-19 Vaccine contains an Adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein in a stabilized conformation (replication-incompetent, recombinant) and the non-medicinal ingredients listed in **Table 1.** The product contains no preservatives.

The Adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein is produced in the PER.C6® TetR Cell Line and by recombinant DNA technology.

Janssen COVID-19 Vaccine is supplied as a suspension in a multi-dose Type I glass vial with a latex-free rubber stopper (chlorobutyl), aluminum seal and flip-off blue plastic cap. Vials are packaged in a carton containing a total of ten (10) Janssen COVID-19 Vaccine multi-dose vials per carton.

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

7 WARNINGS AND PRECAUTIONS

General

The clinical data available for the Janssen COVID-19 Vaccine are derived from the COV3001 Phase 3 study and from Phase 1 and Phase 2 studies. Serious and unexpected adverse events may occur that have not been previously reported with the Janssen COVID-19 Vaccine use.

As with any vaccine, vaccination with the Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

Janssen COVID-19 Vaccine is not intended to prevent diseases caused by coronaviruses other than SARS-CoV-2. Janssen COVID-19 Vaccine is not intended to treat COVID-19.

Hypersensitivity and Anaphylaxis

Anaphylaxis has been reported. As with all vaccines, training for immunizers, and appropriate medical treatment and supervision after immunization should always be readily available in case of rare anaphylactic reactions following administration of this vaccine. Vaccine recipients should be kept under observation for at least 15 minutes after immunization; 30 minutes is a preferred interval when there is a specific concern about a possible vaccine reaction.

Acute illness

Consideration should be given to postponing immunization in persons with severe febrile illness or severe acute infection. Persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved.

Hematologic

Coagulation disorders

Thrombosis and thrombocytopenia

A combination of thrombosis and thrombocytopenia, including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine during post-authorization use. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CVST) and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of cases occurred within three weeks following vaccination. Some cases had a fatal outcome. Thrombosis with thrombocytopenia, following administration of Janssen COVID-19 Vaccine has a clinical course that may resemble autoimmune heparin-induced thrombocytopenia (HIT).

Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive the Janssen COVID-19 vaccine if the potential benefits outweigh the potential risks.

Immune thrombocytopenia

Cases of immune thrombocytopenia with very low platelet levels (<20,000 per uL) have been reported very rarely after vaccination with Janssen COVID-19 Vaccine, usually within the first four weeks after receiving Janssen COVID-19 Vaccine. This included cases with bleeding and cases with fatal outcome. Some of these cases occurred in individuals with a history of immune thrombocytopenia (ITP). If an individual has a history of ITP, the risks of developing low platelet levels should be considered before vaccination, and platelet monitoring is recommended after vaccination.

Healthcare professionals should be alert to the signs and symptoms of thrombosis, 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 or swelling, or progressive abdominal pain following vaccination. Additionally, anyone with neurological symptoms after vaccination including sudden onset of severe headaches, persistent or worsening headaches, blurred vision, confusion or seizure, or who experiences spontaneous bleeding, unusual skin bruising or petechiae beyond the site of vaccination after a few days, should seek prompt medical attention.

Since medical management of a post-vaccine thrombosis, thromboembolism, and/or thrombocytopenia may be different than medical management of other thromboses, if patients present with thrombosis, thromboembolism, and/or thrombocytopenia, healthcare professionals should consult with current guidance and hematologic specialists to diagnose and treat this post-vaccine event.

Individuals diagnosed with thrombocytopenia following vaccination with the Janssen COVID-19 Vaccine should be actively investigated for signs of thrombosis, and similarly individuals who present with thrombosis following vaccination should be evaluated for thrombocytopenia.

Venous thromboembolism

Venous thromboembolism (VTE) has been observed rarely following vaccination with the Janssen COVID-19 Vaccine. In individuals with a pre-existing increased risk for thromboembolism, the possible increased risk of VTE with vaccine use should be considered. Healthcare professionals should be alert to the signs and symptoms of VTE.

Risk of bleeding with intramuscular administration

As with other intramuscular injections, the Janssen COVID-19 Vaccine should be given with caution in individuals with bleeding disorders, such as haemophilia, or individuals currently on anticoagulant therapy, to avoid the risk of haematoma following the injection, and when the potential benefit clearly outweighs the risk of administration.

Capillary Leak Syndrome

Cases of capillary leak syndrome (CLS) have been reported very rarely in the first days following vaccination with Janssen COVID-19 Vaccine during post-authorization use. Some of the reported cases had a history of CLS. Some cases had a fatal outcome. CLS is a very rare disease characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia. Patients with an acute episode of CLS following vaccination require prompt medical attention and treatment. Intensive supportive therapy is usually warranted. Individuals with a known history of CLS should not be vaccinated with this vaccine.

Immune

Adults with stable/well-controlled HIV infection or adults receiving chronic low-dose (less than 20 mg of prednisone or equivalent) immunosuppressive therapy were included in Janssen COVID-19 Vaccine Phase 3 clinical studies.

Immunocompromised individuals including those receiving substantial immunosuppressant therapy may have a diminished immune response to Janssen COVID-19 Vaccine.

Neurologic

Guillain-Barré syndrome

Very rare events of demyelinating disorders, such as Guillain-Barré syndrome (GBS) have been reported following vaccination with Janssen COVID-19 Vaccine during post-authorization use. Healthcare professionals should be alert to GBS signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment and to rule out other causes.

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 needle injection. It is important that precautions are in place to avoid injury from fainting.

Reproductive Health

No data are available on fertility in humans following the use of Janssen COVID-19 Vaccine.

7.1 Special Populations

7.1.1 Pregnant Women

The safety and efficacy of the Janssen COVID-19 Vaccine in pregnant women have not yet been established.

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Janssen COVID-19 Vaccine during pregnancy. Women who are vaccinated with Janssen COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com

7.1.2 Breast-feeding

It is not known whether the components of Janssen COVID-19 Vaccine or antibodies induced by Janssen COVID-19 Vaccine are excreted in human milk. Human data are not available to assess the impact of Janssen COVID-19 Vaccine on milk production or its effects on the breastfed child.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunization against COVID-19.

7.1.3 Pediatrics

The safety and efficacy of Janssen COVID-19 Vaccine in children under 18 years of age have not yet been established.

7.1.4 Geriatrics

Clinical studies of the Janssen COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy (see **8 ADVERSE REACTIONS**, and **14 CLINICAL TRIALS**).

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The safety profile presented below is based on an interim analysis of data generated from an ongoing Phase 3 placebo-controlled clinical study trial (COV3001) conducted in North America, South America and South Africa. At the time of the analysis, a total of 43,783 participants ≥18 years of age had been randomized and received either Janssen COVID-19 vaccine (n=21,895) or placebo (n=21,888). In the group who received the Janssen COVID-19 vaccine, 6,800 (34.6%) participants were ≥60 years of age. At the time of the analysis, median follow-up was 58 days, and 56.4% of participants had been followed for at least 8 weeks.

Solicited Adverse Events (AEs) and Unsolicited AEs to day 28 post-vaccination were measured in the Safety Subset, which consisted of a subset of 6,736 participants from the US, Brazil and South Africa. In this Safety Subset, 3,356 participants received Janssen COVID-19 Vaccine and 3,380 received the placebo.

In the Safety Subset, the most common solicited local adverse reaction (AR) reported was injection site pain (48.7%). The most common solicited systemic ARs reported were: headache (39.0%), fatigue (38.3%), myalgia (33.2%), and nausea (14.2%) (see **Tables 2 to 5**). Solicited ARs were generally more common in younger than in older age groups. Most adverse reactions occurred within 2 days following vaccination, were mild to moderate in severity, and of short duration (2 to 3 days).

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials, therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another vaccine. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

Solicited adverse reactions

Solicited ARs were collected from Day 1 to Day 7 and reported by participants in the Safety Subset via e-diary. Shown below are the frequencies of solicited local ARs (**Tables 2 and 3**) and systemic ARs (**Tables 4 and 5**) reported in adults by age group (≥18 to 59 years of age and ≥60 years of age) in the ongoing Phase 3 clinical trial (COV3001). There were no Grade 4 ARs.

Table 2: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n(%)	Placebo N=2,049 n(%)
Injection Site Pain		
Any	1,193 (58.6)	357 (17.4)
Grade 3[a]	8 (0.4)	0
Injection Site Erythema		
Any (≥25 mm)	184 (9.0)	89 (4.3)
Grade 3[b]	6 (0.3)	2 (0.1)
Injection Site Swelling		
Any (≥25 mm)	142 (7.0)	32 (1.6)
Grade 3[b]	5 (0.2)	2 (0.1)

[a] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.
[b] Grade 3 injection site swelling and erythema: Defined as diameter >100 mm.

Table 3: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 60 Years of Age and Older

Adverse Reactions	Janssen COVID-19 Vaccine N=1,320 n(%)	Placebo N=1,331 n(%)
Injection Site Pain		
Any	439 (33.3)	207 (15.6)
Grade 3[a]	3 (0.2)	2 (0.2)
Injection Site Erythema		
Any (≥25 mm)	61 (4.6)	42 (3.2)
Grade 3[b]	1 (0.1)	0
Injection Site Swelling		
Any (≥25 mm)	36 (2.7)	21 (1.6)
Grade 3[b]	2 (0.2)	0

[a] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.
[b] Grade 3 injection site swelling and erythema: Defined as diameter >100 mm.

Table 4: Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n(%)	Placebo N=2,049 n(%)
Headache		
Any	905 (44.4)	508 (24.8)
Grade 3[a]	18 (0.9)	5 (0.2)
Fatigue		
Any	891 (43.8)	451 (22.0)
Grade 3[b]	25 (1.2)	4 (0.2)
Myalgia		
Any	796 (39.1)	248 (12.1)
Grade 3[b]	29 (1.4)	1 (<0.1)

Nausea		
Any	315 (15.5)	183 (8.9)
Grade 3[b]	3 (0.1)	3 (0.1)
Fever[c]		
Any	261 (12.8)	14 (0.7)
Grade 3	7 (0.3)	0
Use of antipyretic or pain medication	538 (26.4)	123 (6.0)

[a] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F).

Table 5: Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 60 Years of Age and Older

Adverse Reactions	Janssen COVID-19 Vaccine N=1,320 n(%)	Placebo N=1,331 n(%)
Headache		
Any	401 (30.4)	294 (22.1)
Grade 3[a]	5 (0.4)	4 (0.3)
Fatigue		
Any	392 (29.7)	277 (20.8)
Grade 3[b]	10 (0.8)	5 (0.4)
Myalgia		
Any	317 (24.0)	182 (13.7)
Grade 3[b]	3 (0.2)	5 (0.4)
Nausea		
Any	162 (12.3)	144 (10.8)
Grade 3[b]	3 (0.2)	3 (0.2)
Fever[c]		
Any	41 (3.1)	6 (0.5)
Grade 3	1 (0.1)	0
Use of antipyretic or pain medication	130 (9.8)	68 (5.1)

[a] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F)

Unsolicited Adverse Events (AEs)

Individuals within the safety subset in study COV3001 (N=6,736) were monitored for unsolicited adverse events (AEs) for 28 days following vaccination with 99.9% (N= 6,730) of individuals completing the full 28 days of follow-up. The proportion of individuals who reported one or more unsolicited AEs was similar among those in the Janssen COVID-19 Vaccine group (13.1%) and those in the placebo group (12.0%)

Most of these AEs were of Grade 1 or Grade 2 severity, with 0.6% of participants in each group reporting an unsolicited AE of Grade 3 severity. The most common unsolicited AEs occurring within 28 days after vaccination were predominantly reactogenicity events, some of which overlapped with the solicited AEs.

Serious Adverse Events

In study COV3001, with a median follow-up of 8 weeks, SAEs were reported by 0.4% (n=90) of individuals who received Janssen COVID-19 Vaccine and 0.6% (n=137) of individuals who received placebo. When COVID-19-related SAEs were excluded, 0.4% (n=83) of participants in the Janssen COVID-19 Vaccine group and 0.4% (n=95) participants in the placebo group reported an SAE.

Three SAEs were considered likely related to the Janssen COVID-19 Vaccine: one case of fever, headache and asthenia that began in a 35-year-old male less than a day after vaccination and resolved with 3 days; one case of severe injection site pain nonresponsive to analgesics that began immediately following vaccination in a 30-year-old male, and symptoms were ongoing at 10 weeks; one case of Type IV hypersensitivity (rash, erythema) began 2 days post-vaccination in a 42-year-old male and progressed to generalized urticaria and lip angioedema 4 days post-vaccination; symptoms resolved within 5 weeks.

No deaths were considered related to the study vaccine.

Other events of interest

Imbalances in events between the vaccine and placebo group were noted for hypersensitivity, thromboembolic events, tinnitus, vertigo and seizures. The assessment of causality was confounded by the presence of underlying medical conditions that may have predisposed individuals to these events.

Hypersensitivity adverse events were reported in 0.4% of vaccine recipients and 0.3% of placebo recipients. Hypersensitivity events in the vaccine group included rash and urticaria, which are likely related to vaccination. Additional hypersensitivity events considered related to vaccination included 2 cases of facial swelling and the SAE of Type IV hypersensitivity. In addition, severe allergic reactions, including one case of anaphylaxis in an ongoing open-label study in South Africa (COV3012), have been reported following the Janssen COVID-19 vaccine administered in clinical studies.

Thromboembolic AEs occurred in 15 vaccine recipients and in 10 placebo recipients. Thromboembolic events where the vaccine could not be excluded as a contributing factor include: a case of transverse sinus thrombosis; 2 cases of deep vein thrombosis; one case of pulmonary embolism; and one case of hemiparesis.

Episodes of tinnitus were more common in the Janssen COVID-19 Vaccine group than in the placebo group (6 cases vs 0 cases), with 3 cases occurring within 3 days of vaccination. Vertigo was also more common in the vaccine group than in the placebo group (13 cases vs 7 cases), with 5 participants in the vaccine group of the Safety Subset experiencing vertigo in the first 28 days. Seizures occurred in 4 vaccine recipients and in one placebo recipient.

For these events, a causal relationship with the Janssen COVID-19 vaccine cannot be determined.

No imbalances in events were noted for Guillain-Barré syndrome or facial palsy (Bell's palsy).

8.3 Post Market Adverse Reactions

In addition to the adverse reactions listed above, the following adverse reactions have been reported during post-marketing 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.

Blood and lymphatic system disorders: Lymphadenopathy, Thrombocytopenia

Ear, nose, and throat disorders: Tinnitus

Gastrointestinal disorders: Diarrhea, Vomiting

Nervous system disorders: Paresthesia, Hypoesthesia, Guillain-Barré syndrome, Dizziness

Vascular disorders: A combination of thrombosis and thrombocytopenia, including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. (See **7 WARNINGS AND PRECAUTIONS**).

In addition, cases of capillary leak syndrome (CLS) have been observed very rarely following vaccination with Janssen COVID-19 Vaccine. (See **7 WARNINGS AND PRECAUTIONS**).

Rare cases of venous thrombosis and thromboembolism have been observed (See **7 WARNINGS AND PRECAUTIONS**).

9 DRUG INTERACTIONS

No interaction studies have been performed.

Do not mix Janssen COVID-19 Vaccine with any other vaccine in the same syringe.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

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

11 STORAGE, STABILITY AND DISPOSAL

Storage prior to use

The vaccine can be stored and/or transported frozen at -25°C to -15°C. The expiry date for storage at -25°C to -15°C is printed on the vial and carton after “EXP”. The vaccine can also be

transported at 2°C to 8°C as long as the appropriate storage conditions (temperature, time) are applied.

When stored frozen at -25°C to -15°C, a carton of 10 vials or an individual vial should be thawed overnight at 2°C to 8°C. At room temperature (maximally 25°C), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. **DO NOT REFREEZE ONCE THAWED.**

The vaccine can also be stored in a refrigerator at 2°C to 8°C for a single period of up to 6 months, not exceeding the original expiry date (EXP).

The vial must be kept in the original package in order to protect from light and to track the expiry for the different storage conditions, if applicable.

Janssen COVID-19 Vaccine 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.

The method of determining the expiry date differs with the type of packaging; four packaging types are available:

Global White Label - product supplied with all white carton panels:

- The expiry date for storage at -25°C to -15°C is printed on the vial and carton after "EXP".
- The expiry date at 2°C to 8°C after thaw is for a single period of up to 6 months, not exceeding the original expiry date (EXP) on the labels.
- Upon moving the product to a refrigerator at 2°C to 8°C, the updated expiry date must be written on the carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable.
- 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 carton before the vaccine is stored in the refrigerator. The original expiry date should be made unreadable.

Non-US Orange Label - product supplied with an orange panel sticker on carton:

- The expiry date for storage at 2°C to 8°C is printed on the orange panel of the carton.
- The expiry date on the vial label is not applicable to the storage conditions of this product in Canada and should be disregarded. Similarly, the information on the insert references non-Canadian information.

US White and Non-US White Label - product with all white carton panels:

- No expiry date is printed on the carton panels or vial label.
- The date printed on the carton is the product manufacture date (Mfg. date)
- To obtain the expiry date for storage at 2°C to 8°C, scan the QR code on the carton or carton insert by using a smart device,
- or go online to www.vaxcheck.jnj, or
- call: 1-800-565-4008 (toll-free) or 1-908-455-9922 (US toll).

For product with US and Non-US carton with all white panels, the expiry date should be written manually on the carton. The suggested format is YYYY-MMM-DD with the month written alphabetically e.g. 2021-APR-14.

As the expiry date approaches, check the expiry date again by:

- scanning the QR code on the carton or carton leaflet by using a smart device,
- by going to www.vaxcheck.jnj, or
- calling: 1-800-565-4008 (toll-free) or 1-908-455-9922 (US toll).

If the expiry date has been extended, the new expiry date should be written manually on the carton and the previous date struck through. The suggested format is YYYY-MMM-DD with the month written alphabetically e.g. 2021-APR-14.

The method of recording date and time on the vial label differs with the type of label:

- Global White Label (product with all white carton panels) and Non-US Orange Label (product with an orange panel sticker on the carton): The vial label includes a space for recording date and time to discard after puncture.
- US White and Non-US White Label (product with all white carton panels): The vial label includes a space for recording date and time of first use.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial/filled syringe can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximally 25°C) for up to 3 hours, after the first puncturing of the vial. The discard date and time should be recorded on each vial. Discard if vaccine is not used within this time.

12 SPECIAL HANDLING INSTRUCTIONS

Any unused product and waste material should be disposed of in accordance with local requirements.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Ad26.COV2-S [recombinant]

Product Characteristics:

Janssen COVID-19 Vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection. Janssen COVID-19 Vaccine contains an Adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein in a stabilized conformation (replication-incompetent, recombinant). The Adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein is produced in the PER.C6® TetR Cell Line and by recombinant DNA technology. Janssen COVID-19 Vaccine contains genetically modified organisms (GMOs). Janssen COVID-19 Vaccine does not contain a preservative.

Janssen COVID-19 Vaccine is supplied as a suspension in a multi-dose Type I glass vial with a latex-free rubber stopper (chlorobutyl), aluminum seal and blue plastic cap. Each vial contains

5 doses of 5 x 10^{10} viral particles/dose. Vials are packaged in a carton containing a total of ten (10) Janssen COVID-19 Vaccine multi-dose vials per carton.

14 CLINICAL TRIALS

14.1 Trial Design and Study Demographics

An ongoing, multicenter, randomized, double-blind, placebo-controlled Phase 3 study (COV3001) is being conducted in the United States, South Africa, Brazil, Chile, Argentina, Colombia, Peru, and Mexico to assess the efficacy, safety, and immunogenicity of a single dose of Janssen COVID-19 Vaccine for the prevention of COVID-19 in adults aged 18 years and older. Randomization was stratified by age (18-59 years, 60 years and older) and presence or absence of comorbidities associated with an increased risk of progression to severe COVID-19. The study allowed for the inclusion of individuals with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy during the 3 months preceding vaccination, as well as individuals with stable human immunodeficiency virus (HIV) infection. Participants who had previously received a coronavirus vaccine, pregnant women and participants with abnormal function of the immune system were ineligible. Participants were also excluded if they had known or suspected allergy or a history of anaphylaxis or serious adverse reactions to vaccines or their excipients.

A total of 44,325 participants were randomized in parallel in a 1:1 ratio to receive an IM injection of Janssen COVID-19 Vaccine (at a dose level of 5 × 10^{10} VP) or saline placebo. According to protocol, participants are to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The primary efficacy endpoint was defined as a symptomatic moderate to severe/critical COVID-19 case, confirmed by positive SARS COV-2 viral RNA results using a Polymerase Chain Reaction (PCR)-based test in a central laboratory.

Moderate COVID-19 was defined based on the following criteria:

- the participant must have experienced any one of the following new or worsening signs or symptoms: respiratory rate ≥20 breaths/minute, abnormal saturation of oxygen (SpO2) but still >93% on room air at sea level, clinical or radiologic evidence of pneumonia, radiologic evidence of deep vein thrombosis (DVT), shortness of breath or difficulty breathing
- OR any two of the following new or worsening signs or symptoms: fever (≥38.0°C or ≥100.4°F), heart rate ≥90 beats/minute, shaking chills or rigors, sore throat, cough, malaise, headache, muscle pain (myalgia), gastrointestinal symptoms, new or changing olfactory or taste disorders, red or bruised appearing feet or toes.

Severe/critical COVID-19 was defined based on the following criteria:

- the participant 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/critical COVID-19 cases were made by an independent adjudication committee.

The population for the analysis of the primary efficacy endpoint included participants who did not have evidence of prior infection with SARS-CoV-2 through 14 days after the first dose (co-primary efficacy endpoint), as well participants who did not have evidence of prior infection with SARS-CoV-2 through 28 days after the first dose (co-primary efficacy endpoint).

The primary efficacy analysis population of 39,321 individuals (19,630 in the Janssen COVID-19 Vaccine group and the 19,691 in the placebo group) included 38,059 SARS-CoV-2 seronegative individuals at baseline, and 1,262 individuals with an unknown serostatus. Table 6 presents the demographic characteristics in the studied population.

Table 6: Summary of Demographics and Baseline Characteristics - Primary Efficacy Analysis Population

	Janssen COVID-19 Vaccine (N=19,630) n (%)	**Placebo (N=19,691) n (%)**
Sex		
Male	10,924 (55.6)	10,910 (55.4)
Female	8,702 (44.3)	8,777 (44.6)
Age (years)		
Mean (SD)	51.1 (15.04)	51.2 (14.97)
Median	52.0	53.0
Min, max	(18; 100)	(18; 94)
Age group		
≥18 to 59 years of age	12,830 (65.4)	12,881 (65.4)
≥60 years of age of age	6,800 (34.6)	6,810 (34.6)
≥65 years of age of age	3,984 (20.3)	4,018 (20.4)
≥75 years of age of age	755 (3.8)	693 (3.5)
Race[a]		
White	12,200 (62.1)	12,216 (62.0)
Black or African American	3,374 (17.2)	3,390 (17.2)
Asian	720 (3.7)	663 (3.4)
American Indian/Alaska Native[b]	1,643 (8.4)	1,628 (8.3)
Native Hawaiian or other Pacific Islander	54 (0.3)	45 (0.2)
Multiple	1,036 (5.3)	1,087 (5.5)
Unknown	262 (1.3)	272 (1.4)
Not reported	341 (1.7)	390 (2.0)

	Janssen COVID-19 Vaccine (N=19,630) n (%)	Placebo (N=19,691) n (%)
Ethnicity		
Hispanic or Latino	8,793 (44.8)	8,936 (45.4)
Not Hispanic or Latino	10,344 (52.7)	10,259 (52.1)
Unknown	173 (0.9)	162 (0.8)
Not reported	319 (1.6)	333 (1.7)
Region		
Northern America (United States)	9,185 (46.8)	9,171 (46.6)
Latin America	7,967 (40.6)	8,014 (40.7)
Southern Africa (South Africa)	2,478 (12.6)	2,506 (12.7)
Comorbidities[c]		
Yes	7,830 (39.9)	7,867 (40.0)
No	11,800 (60.1)	11,824 (60.0)

[a] Some individuals could be classified in more than one category.

[b] Including 175 individuals in the United States, which represents 1% of the population recruited in the United States

[c] Number of individuals who have 1 or more comorbidities at baseline that increase the risk of progression to severe/critical COVID-19: 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%), asthma (1.3%) and in ≤1% of individuals: cancer, cerebrovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, cystic fibrosis, immunocompromised state (weakened immune system) from blood or organ transplant, liver disease, neurologic conditions, pulmonary fibrosis, sickle cell disease, thalassemia and type 1 diabetes, regardless of age.

14.2 Study Results

At the time of the final primary efficacy analysis (cut-off date of 22 January 2021), participants had been followed for symptomatic COVID 19 disease for a median of 8 weeks post-vaccination, corresponding to 3,143.7 person years for the Janssen COVID-19 Vaccine and 3,146.7 person years in the placebo group.

Vaccine efficacy for the co-primary endpoints against moderate to severe/critical COVID-19 in individuals who were seronegative or who had an unknown serostatus at baseline was 66.9% (95% CI: 59.0; 73.4) at least 14 days after vaccination and 66.1% (95% CI: 55.0; 74.8) at least 28 days after vaccination. Vaccine efficacy results against moderate to severe/critical COVID-19 are presented in Table 7.

Table 7 Analyses of Vaccine Efficacy Against Confirmed Moderate to Severe/Critical COVID-19 – With Onset at Least 14 Days and at Least 28 Days Post-Vaccination – Primary Efficacy Analysis Population

Subgroup	Janssen COVID-19 Vaccine N=19,630		Placebo N=19,691		% Vaccine Efficacy (95% CI)
	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	
14 days post-vaccination					
All subjects[a]	116	3116.57	348	3096.12	66.9 (59.03; 73.40) [b]
≥18-59 years old	95	2106.8	260	2095.0	63.7 (53.9; 71.6) [c]
≥60 years and older	21	1009.8	88	1001.2	76.3 (61.6; 86.0)[c]
28 days post-vaccination					
All subjects[a]	66	3102.00	193	3070.65	66.1 (55.01; 74.80)[b]
≥18-59 years old	52	2097.6	152	2077.0	66.1 (53.3; 75.8)[c]
≥60 years and older	14	1004.4	41	993.6	66.2 (36.7; 83.0)[c]

[a] Co-primary endpoint.
[b] The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions
[c] CI not adjusted for multiplicity

With onset at least 14 days (28 days) after vaccination, there were 4 (2) cases of mild COVID-19, 309 (220) cases of moderate COVID-19 and 74 (39) cases of severe/critical of COVID-19.

The findings of vaccine efficacy against severe/critical COVID-19 at least 14 days after vaccination and at least 28 days after vaccination are shown in Table 8.

Table 8: Analyses of Vaccine Efficacy: Secondary Endpoints of Confirmed Severe/Critical COVID-19 – in Adults 18 Years of Age and Older With Onset at Least 14 Days and at Least 28 Days Post-Vaccination – Primary Efficacy Analysis Population

Subgroup	Janssen COVID-19 Vaccine N=19,630		Placebo N=19,691		% Vaccine Efficacy (95% CI)
	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	
14 days post-vaccination					
Severe/critical	14	3125.05	60	3122.03	76.7 (54.56; 89.09)[a]
28 days post-vaccination					
Severe/critical	5	3106.15	34	3082.58	85.4 (54.15; 96.90)[a]

[a] The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions.

There were 2 COVID-19 related hospitalizations in the vaccine group and 29 in the placebo group among all COVID-19 cases with onset at least 14 days post vaccination, including cases diagnosed by a positive PCR from a local laboratory and still awaiting confirmation at the central laboratory. There were no COVID-19 related hospitalizations in the vaccine group and 16 in the placebo group, among all COVID-19 cases with onset at least 28 days post vaccination, including cases diagnosed by a positive PCR from a local laboratory and still awaiting confirmation at the central laboratory.

There were no COVID-19-related deaths reported in Janssen COVID-19 Vaccine recipients, compared to 5 COVID-19-related deaths reported in placebo recipients, who were SARS-CoV-2 PCR negative at baseline.

Strain sequencing was conducted on available samples with sufficient viral load from centrally confirmed COVID-19 cases (one sequence per case). 71.7% of central laboratory confirmed primary analysis cases have been sequenced [United States (73.5%), South Africa (66.9%) and Brazil (69.3%)]. 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. As of February 12, 2021, SARS-CoV-2 variants from the B1.1.7 or P.1 lineages were not found in any of the sequenced samples. Exploratory subgroup analyses of vaccine efficacy against moderate to severe/critical COVID-19 and severe/critical COVID-19 for Brazil, South Africa, and the United States were conducted. For these subgroup analyses, all COVID-19 cases (PCR-positive cases confirmed and pending confirmation by the central laboratory) accrued up to the primary efficacy analysis data cut-off date of 22 January 2021 were included. The concordance rate observed up to the data cut-off date between the PCR results from the local laboratory and the central laboratory was 90.3%. The results are shown in Table 9.

Table 9: Summary of Vaccine Efficacy against Moderate to Severe/Critical and Severe/Critical COVID-19 for Countries With >100 Reported Moderate to Severe/Critical Cases

		Severity	
	Onset	**Moderate to Severe/Critical Point estimate (95% CI)[a]**	**Severe/Critical Point estimate (95% CI)[a]**
US	at least **14 days** after vaccination	74.4% (65.0; 81.6)	78.0% (33.1; 94.6)
	at least **28 days** after vaccination	72.0% (58.2;81.7)	85.9% (-9.4; 99.7)
Brazil	at least **14 days** after vaccination	66.2% (51.0; 77.1)	81.9% (17.0; 98.1)
	at least **28 days** after vaccination	68.1% (48.8; 80.7)	87.6% (7.8; 99.7)
South Africa	at least **14 days** after vaccination	52.0% (30.3; 67.4)	73.1% (40.0; 89.4)
	at least **28 days** after vaccination	64.0% (41.2; 78.7)	81.7% (46.2; 95.4)

[a] CI's are not adjusted for multiplicity

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

General Toxicology: In a repeat-dose toxicity study, New Zealand White rabbits were administered Janssen COVID-19 Vaccine by intramuscular injection at a dose of $1x10^{11}$ vp/dose (in 1 mL), every two weeks for a total of 3 doses. Vaccine administration resulted in inflammation at the site of injection, as well as increased germinal centre cellularity in draining lymph nodes and spleen (correlating with enlargement of draining lymph nodes and increased spleen weights), transient increase in body temperature, increased white blood cell counts, and clinical chemistry changes indicative of an acute phase response. Full or partial recovery from all findings was observed following a 3-week recovery period. These changes are consistent with an expected immunostimulatory response following intramuscular administration of a vaccine and are not deemed adverse.

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

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

Reproductive and Developmental Toxicology: Female reproductive toxicity, fertility, and developmental toxicity were assessed in a combined embryo-fetal and pre- and postnatal development study in the rabbit. In this study a first vaccination of Janssen COVID-19 Vaccine was administered intramuscularly to female rabbits 7 days prior to mating at a dose ($1x10^{11}$ vp/dose in 1 mL) equivalent to 2-fold above the recommended human dose on an absolute basis, followed by two vaccinations at the same dose during the gestation period (i.e. on gestation days 6 and 20, respectively). There was no adverse effect of Janssen COVID-19 Vaccine on reproductive performance, fertility, ovarian and uterine examinations, or parturition; however, one female died on gestation day 23 from unknown causes. In addition, there was no adverse effect of vaccination on fetal body weights, external, visceral and skeletal evaluations, or on postnatal development of the offspring.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Janssen COVID-19 Vaccine

Ad26.COV2-S [recombinant]

Read this carefully before you start taking **Janssen COVID-19 Vaccine**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Janssen COVID-19 Vaccine**.

What is Janssen COVID-19 Vaccine used for?

Janssen COVID-19 Vaccine is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus. Janssen COVID-19 Vaccine can be given to protect people aged 18 years and older.

How does Janssen COVID-19 Vaccine work?

Janssen COVID-19 Vaccine uses a recombinant, replication-incompetent human adenovirus type 26 vector to stimulate the body's natural defenses (immune system) and produce its own protection (antibodies) against the virus.

The vaccine is given as a single dose, by injection with a needle, usually in the upper arm.

You cannot get COVID-19 from this vaccine.

As with any vaccine, Janssen COVID-19 Vaccine may not fully protect all those who receive it. Even after you have had the vaccine, continue to follow the recommendations of local public health officials to prevent spread of COVID-19.

What are the ingredients in Janssen COVID-19 Vaccine?

Medicinal ingredients: recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein 5×10^{10} virus particles (VP)*

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

Non-medicinal ingredients:

- 2-hydroxypropyl-β-cyclodextrin (HBCD)
- Citric acid monohydrate
- Ethanol
- Hydrochloric acid
- Polysorbate-80
- Sodium chloride
- Sodium hydroxide
- Trisodium citrate dihydrate
- Water for injection

Janssen COVID-19 Vaccine comes in the following dosage forms:

Colourless to slightly yellow, clear to very opalescent suspension provided in a multiple dose vial of 5 doses of 0.5 mL, each dose containing 5×10^{10} virus particles of adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein.

Do not use Janssen COVID-19 Vaccine if:

- you have previously had a severe allergic reaction to any of the active substance(s) or any of the other ingredients of Janssen COVID-19 Vaccine
- you have ever had a severe allergic reaction after a dose of any other 'adenovirus-based vaccine'
- you have ever had a diagnosis of capillary leak syndrome, a very rare, serious condition where fluid (plasma) leaks out of the small blood vessels into the body tissues. (see ***What are the possible side effects from using Janssen COVID-19 Vaccine***).
- you currently have symptoms that could be due to COVID-19. Talk to your healthcare professional about your symptoms and getting a COVID-19 test. Your healthcare professional will advise you when you are able to receive the vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Janssen COVID-19 Vaccine. Talk about any health conditions or problems you may have, including if you:

- Have ever had a severe allergic reaction after any type of vaccine
- Have had a history of venous sinus thrombosis in the brain with low platelets (thrombocytopenia), a history of heparin-induced thrombocytopenia (HIT), or a history of very low platelets (immune thrombocytopenia)
- Have previously experienced episodes of capillary leak syndrome (see ***What are possible side effects from using Janssen Covid-19 Vaccine?****).*
- Have a weakened immune system due to a medical condition or are on a medicine that affects your immune system
- Are pregnant, think you may be pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have a bleeding problem, bruise easily or use a blood thinning medication
- Have a high fever or severe infection
- Have any serious illness
- Have ever fainted following any needle injection

Do not drive or use machines if you are feeling unwell after vaccination.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Janssen COVID-19 Vaccine.
Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There is no information on the use of Janssen COVID-19 Vaccine with other vaccines. Tell your healthcare professional if you have recently taken or might take any other vaccine.

How Janssen COVID-19 Vaccine is given:

- Your doctor, pharmacist, or nurse will inject the vaccine into a muscle (intramuscular injection) - usually in your upper arm.
- During and after each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for at least 15 minutes to monitor for signs of an allergic reaction.

Usual dose:

A single dose (0.5 mL) of Janssen COVID-19 Vaccine should be administered.

Overdose:

In the event of suspected overdose with Janssen COVID-19 Vaccine, contact your regional poison control centre.

What are possible side effects from using Janssen COVID-19 Vaccine?

Like all vaccines, Janssen COVID-19 Vaccine can cause side effects. In clinical studies with the vaccine, most of the side effects, happened within 2 days of getting the injection, were mild to moderate in intensity, and resolved within 1-2 days.

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

A combination of blood clots and low level of platelets, in some cases together with bleeding, has been observed very rarely in unusual locations (e.g., brain, liver) following vaccination with Janssen COVID-19 Vaccine. Seek medical attention right away if any of the following symptoms occur within the first month following vaccination:

- new severe headaches, worsening or persistent headaches; blurred vision, confusion or seizures
- shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
- unexplained skin bruising or pinpoint round spots under the skin beyond the site of vaccination

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with Janssen COVID-19 Vaccine. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek medical attention right away if you develop these symptoms in the days following vaccination.

Guillain-Barré syndrome (GBS) is a neurological disorder where inflammation of peripheral nerves causes rapid muscle weakness and can sometimes lead to paralysis. This has been reported very rarely after vaccination with Janssen COVID-19 Vaccine. Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face.

Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have been reported very rarely, usually within the first four weeks following vaccination with Janssen COVID-19 Vaccine.

The following side effects may happen with this vaccine:

Very common (may affect more than 1 in 10 people):

- headache
- nausea
- muscle aches
- pain at injection site
- feeling very tired (fatigue)

Common (may affect up to 1 in 10 people):

- fever
- redness at injection site
- swelling at injection site
- chills
- joint pain

Uncommon (may affect up to 1 in 100 people):

- rash
- muscle weakness
- arm or leg pain
- feeling weak
- feeling generally unwell
- dizziness

Rare (may affect up to 1 in 1000 people):

- allergic reaction, including hives

  Should you develop any serious symptoms or symptoms that could be an allergic reaction, seek medical attention immediately. Symptoms of an allergic reaction include:

  - hives (bumps on the skin that are often very itchy)
  - swelling of the face, tongue or throat
  - difficulty breathing

Very rare (may affect up to 1 in 10000 people):

- persistent ringing in the ears (tinnitus)
- diarrhea
- unusual feeling in the skin, such as a persistent tingling feeling (paresthesia)
- swollen lymph nodes (lymphadenopathy)
- vomiting
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- serious nerve inflammation, which may cause paralysis and difficulty breathing (Guillain-Barré syndrome)
- unexplained bleeding

These may not be all the possible side effects of Janssen COVID-19 Vaccine. If you experience any side effects not listed here, tell your healthcare professional.

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

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Janssen Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

Storage:

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

Keep Janssen COVID-19 Vaccine out of reach and sight of children.

If you want more information about Janssen COVID-19 Vaccine:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (www.janssen.com/canada), or by calling Janssen Inc. at: 1-800-567-3331.

This leaflet was prepared by Janssen Inc.

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