

Provided by:

Pilot Medical Solutions, Inc.  
www.LeftSeat.com  
800-699-4457

## **FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)**

### **EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

#### **SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS**

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Janssen COVID-19 Vaccine is a suspension for intramuscular injection administered as a **single dose** (0.5 mL).

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com).

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine for active immunization against COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### **DESCRIPTION OF COVID-19**

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

#### **DOSAGE AND ADMINISTRATION**

**The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.**

##### **Storage and Handling**

###### Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Revised: Feb/27/2021

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

#### Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

#### **Dosing and Schedule**

The Janssen COVID-19 Vaccine is administered intramuscularly as a **single dose** (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.

#### **Dose Preparation**

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each 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.**
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

#### **Administration**

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Janssen COVID-19 Vaccine intramuscularly.

## **CONTRAINDICATION**

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine (*see Full EUA Prescribing Information*).

## **WARNINGS**

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

## **ADVERSE REACTIONS**

Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following the administration of the Janssen COVID-19 Vaccine (*see Full EUA Prescribing Information*).

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Janssen COVID-19 Vaccine.

## **USE WITH OTHER VACCINES**

There is no information on the co-administration of the Janssen COVID-19 Vaccine with other vaccines.

## **INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS**

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com) to obtain the Fact Sheet) prior to the individual receiving the Janssen COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Janssen COVID-19 Vaccine.

Revised: Feb/27/2021

- The significant known and potential risks and benefits of the Janssen COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine to prevent COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Provide a vaccination card to the recipient or their caregiver with the name of the vaccine (“Janssen COVID-19 Vaccine”) and date of administration to document vaccination.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

## **MANDATORY REQUIREMENTS FOR JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION**

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Janssen COVID-19 Vaccine, the following items are required. Use of unapproved Janssen COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements must be met):

1. The Janssen COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Janssen COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving the Janssen COVID-19 Vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
  - vaccine administration errors whether or not associated with an adverse event,
  - serious adverse events\* (irrespective of attribution to vaccination),
  - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
  - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words “Janssen COVID-19 Vaccine EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine to recipients.

\* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

**OTHER ADVERSE EVENT REPORTING TO VAERS AND JANSSEN BIOTECH, INC.**

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Janssen Biotech, Inc. using the contact information below or by providing a copy of the VAERS form to Janssen Biotech, Inc:

<b>e-mail</b>	<b>Fax number</b>	<b>Telephone numbers</b>
<a href="mailto:JNJvaccineAE@its.jnj.com">JNJvaccineAE@its.jnj.com</a>	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

**ADDITIONAL INFORMATION**

For general questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com) or call the telephone numbers provided below.

<b>QR Code</b>	<b>Fact Sheets Website</b>	<b>Telephone numbers</b>
	<a href="http://www.janssencovid19vaccine.com">www.janssencovid19vaccine.com</a>	US Toll Free: 1-800-565-4008 US Toll: 1-908-455-9922

## AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

## AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on Janssen Biotech, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Janssen COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the Full EUA Prescribing Information.

This EUA for the Janssen COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

## THE COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp), email [cicp@hrsa.gov](mailto:cicp@hrsa.gov), or call: 1-855-266-2427.

Manufactured by:  
Janssen Biotech, Inc.  
a Janssen Pharmaceutical Company of Johnson & Johnson  
Horsham, PA 19044, USA



© 2021 Janssen Pharmaceutical Companies

END SHORT VERSION FACT SHEET  
Long Version (Full EUA Prescribing Information) Begins On Next Page

Revised: Feb/27/2021

Revised: Feb/27/2021

---

# FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

## JANSSEN COVID-19 VACCINE

### FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION: CONTENTS\*

- 1 AUTHORIZED USE**
- 2 DOSAGE AND ADMINISTRATION**
  - 2.1 Preparation for Administration
  - 2.2 Administration
  - 2.3 Dosing and Schedule
- 3 DOSAGE FORMS AND STRENGTHS**
- 4 CONTRAINDICATIONS**
- 5 WARNINGS AND PRECAUTIONS**
  - 5.1 Management of Acute Allergic Reactions
  - 5.2 Altered Immunocompetence
  - 5.3 Limitations of Vaccine Effectiveness
- 6 OVERALL SAFETY SUMMARY**
  - 6.1 Clinical Trials Experience
- 8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS**

- 10 DRUG INTERACTIONS**
- 11 USE IN SPECIFIC POPULATIONS**
  - 11.1 Pregnancy
  - 11.2 Lactation
  - 11.3 Pediatric Use
  - 11.4 Geriatric Use
- 13 DESCRIPTION**
- 14 CLINICAL PHARMACOLOGY**
  - 14.1 Mechanism of Action
- 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA**
- 19 HOW SUPPLIED/STORAGE AND HANDLING**
- 20 PATIENT COUNSELING INFORMATION**
- 21 CONTACT INFORMATION**

\*Sections or subsections omitted from the full prescribing information are not listed.

Revised: Feb/27/2021

## FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

### 1 AUTHORIZED USE

Janssen COVID-19 vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

### 2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

#### 2.1 Preparation for Administration

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each 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.**
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

#### 2.2 Administration

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Janssen COVID-19 Vaccine intramuscularly.

#### 2.3 Dosing and Schedule

The Janssen COVID-19 Vaccine is administered intramuscularly as a **single dose** (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.

### **3 DOSAGE FORMS AND STRENGTHS**

Janssen COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

### **4 CONTRAINDICATIONS**

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine [*see Description (13)*].

### **5 WARNINGS AND PRECAUTIONS**

#### **5.1 Management of Acute Allergic Reactions**

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

#### **5.2 Altered Immunocompetence**

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.

#### **5.3 Limitations of Vaccine Effectiveness**

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

### **6 OVERALL SAFETY SUMMARY**

**It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Janssen COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Janssen Biotech, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS or Janssen Biotech, Inc.**

In study COV3001, the most common local solicited adverse reaction ( $\geq 10\%$ ) reported was injection site pain (48.6%). The most common systemic adverse reactions ( $\geq 10\%$ ) were headache (38.9%), fatigue (38.2%), myalgia (33.2%), and nausea (14.2%) (see Tables 1 to 4).

Severe allergic reactions, including one case of anaphylaxis in an ongoing open-label study in South Africa, have been reported following the Janssen COVID-19 vaccine administered in clinical studies.

## 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of the Janssen COVID-19 Vaccine has been assessed in an ongoing Phase 3 Study (COV3001). A total of 43,783 individuals were enrolled in this study, of whom 21,895 adults aged 18 years and older received the Janssen COVID-19 Vaccine [Full Analysis Set (FAS)]. This study is being conducted in the United States (n=19,302), Brazil (n=7,278), South Africa (n=6,576), Colombia (n=4,248), Argentina (n=2,996), Peru (n=1,771), Chile (n=1,133), Mexico (n=479). In this study, 45.0% were female, 54.9% were male, 58.7% were White, 19.4% were Black or African American, 45.3% were Hispanic or Latino, 3.3% were Asian, 9.5% were American Indian/Alaska Native and 0.2% were Native Hawaiian or other Pacific Islander, 5.6% were from multiple racial groups and 1.4% were unknown races (see Table 5). The median age of individuals was 52.0 years (range: 18-100). There were 4,217 (9.6%) individuals who were SARS-CoV-2 seropositive at baseline and who were included in the study. In the United States, 838 of 19,302 (4.3%) individuals were SARS-CoV-2 seropositive. Demographic characteristics were similar among individuals who received the Janssen COVID-19 Vaccine and those who received saline placebo.

The safety subset includes 6,736 individuals (3,356 from the Janssen COVID-19 Vaccine group, 3,380 from the placebo group). The demographic profile in the safety subset was similar in terms of age and gender compared to the FAS. A larger percentage of individuals in the safety subset were White (83.4%) compared to the FAS (58.7%). Geographically, the safety subset was limited to individuals from the United States (51.4%), Brazil (38.5%) and South Africa (10.2%). Fewer individuals in the safety subset compared to the FAS were SARS-CoV-2 seropositive at baseline, 4.5% vs. 9.6%, and had at least one comorbidity 34.1% vs 40.8%.

Safety monitoring in the clinical study consisted of monitoring for: (1) solicited local and systemic reactions occurring in the 7 days following vaccination in a subset of individuals (safety subset), (2) unsolicited adverse events (AEs) occurring in the 28 days following vaccination in the safety subset, (3) medically-attended AEs (MAAEs) occurring in the 6 months following vaccination in the entire study population (FAS), (4) serious AEs (SAEs) and AEs leading to study discontinuation for the duration of the study in the entire study population.

### *Solicited adverse reactions*

Shown below are the frequencies of solicited local adverse reactions (Tables 1 and 2) and systemic adverse reactions (Tables 3 and 4) reported in adults by age group in the ongoing Phase 3 clinical trial (COV3001) in the 7 days following vaccination.

**Table 1: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age**

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

<sup>a</sup> Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

<sup>b</sup> Grade 3 injection site swelling and erythema: Defined as >100 mm.

**Table 2: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 60 Years of Age and Older**

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

<sup>a</sup> Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

<sup>b</sup> Grade 3 injection site swelling and erythema: Defined as >100 mm.

**Table 3: Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age**

<b>Adverse Reactions</b>	<b>Janssen COVID-19 Vaccine N=2,036 n(%)</b>	<b>Placebo N=2,049 n(%)</b>
<b>Headache</b>		
Any	905 (44.4)	508 (24.8)
Grade 3 <sup>a</sup>	18 (0.9)	5 (0.2)
<b>Fatigue</b>		
Any	891 (43.8)	451 (22.0)
Grade 3 <sup>b</sup>	25 (1.2)	4 (0.2)
<b>Myalgia</b>		
Any	796 (39.1)	248 (12.1)
Grade 3 <sup>b</sup>	29 (1.4)	1 (<0.1)
<b>Nausea</b>		
Any	315 (15.5)	183 (8.9)
Grade 3 <sup>b</sup>	3 (0.1)	3 (0.1)
<b>Fever<sup>c</sup></b>		
Any	261 (12.8)	14 (0.7)
Grade 3	7 (0.3)	0
<b>Use of antipyretic or pain medication</b>	538 (26.4)	123 (6.0)

- <sup>a</sup> 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.
- <sup>b</sup> 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.
- <sup>c</sup> Fever of any grade: Defined as body temperature  $\geq 38^{\circ}\text{C}/100.4^{\circ}\text{F}$ . Grade 3 fever: Defined as  $39.0^{\circ}\text{C} - 40.0^{\circ}\text{C}$  ( $102.1^{\circ}\text{F} - 104.0^{\circ}\text{F}$ ).

**Table 4: 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(%)
<b>Headache</b>		
Any	401 (30.4)	294 (22.1)
Grade 3 <sup>a</sup>	5 (0.4)	4 (0.3)
<b>Fatigue</b>		
Any	392 (29.7)	277 (20.8)
Grade 3 <sup>b</sup>	10 (0.8)	5 (0.4)
<b>Myalgia</b>		
Any	317 (24.0)	182 (13.7)
Grade 3 <sup>b</sup>	3 (0.2)	5 (0.4)
<b>Nausea</b>		
Any	162 (12.3)	144 (10.8)
Grade 3 <sup>b</sup>	3 (0.2)	3 (0.2)
<b>Fever<sup>c</sup></b>		
Any	41 (3.1)	6 (0.5)
Grade 3	1 (0.1)	0
<b>Use of antipyretic or pain medication</b>	130 (9.8)	68 (5.1)

- <sup>a</sup> 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
- <sup>b</sup> 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.
- <sup>c</sup> Fever of any grade: Defined as body temperature  $\geq 38^{\circ}\text{C}/100.4^{\circ}\text{F}$ . Grade 3 fever: Defined as  $39.0^{\circ}\text{C} - 40.0^{\circ}\text{C}$  ( $102.1^{\circ}\text{F} - 104.0^{\circ}\text{F}$ ).

Solicited local and systemic adverse reactions reported following administration of the Janssen COVID-19 Vaccine had a median duration of 1 to 2 days.

### *Unsolicited adverse events*

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%).

### **Serious Adverse Events (SAEs) and other events of interest**

In study COV3001, up to a cut-off date of January 22, 2021, 54.6% of individuals had follow-up duration of 8 weeks. The median follow-up duration for all individuals was 58 days. SAEs, excluding those related to confirmed COVID-19, were reported by 0.4% (n=83) of individuals who received the Janssen COVID-19 Vaccine (N= 21,895) and 0.4% (n=96) of individuals who received placebo (N= 21,888).

Additional adverse events of interest, including but not limited to allergic, neurologic, inflammatory, vascular, and autoimmune disorders, were analyzed among all adverse events collected through protocol-specified safety monitoring procedures as well as unsolicited reporting.

Urticaria (all non-serious) was reported in five vaccinated individuals and 1 individual who received placebo in the 7 days following vaccination. In addition, an SAE of hypersensitivity, not classified as anaphylaxis, was reported in 1 vaccinated individual with urticaria beginning two days following vaccination and angioedema of the lips with no respiratory distress beginning four days following vaccination. The event was likely related to the vaccine.

An SAE of severe pain in the injected arm, not responsive to analgesics, with immediate onset at time of vaccination, and that was ongoing 74 days following vaccination was reported in an individual who received the Janssen COVID-19 Vaccine. An SAE of severe generalized weakness, fever, and headache, with onset on the day following vaccination and resolution three days following vaccination was reported in an individual who received the Janssen COVID-19 Vaccine. Both SAEs are likely related to the vaccine.

Numerical imbalances, with more events in vaccine than placebo recipients, were observed for the following serious and other adverse events of interest in individuals receiving the vaccine or placebo, respectively:

- Thromboembolic events:
  - Deep vein thrombosis: 6 events (2 serious; 5 within 28 days of vaccination) vs. 2 events (1 serious; 2 within 28 days of vaccination).
  - Pulmonary embolism: 4 events (3 serious; 2 within 28 days of vaccination) vs. 1 event (serious and within 28 days of vaccination).
  - Transverse sinus thrombosis: 1 event (serious and within 28 days of vaccination) vs. 0.
- Seizures: 4 events (1 serious; 4 within 28 days of vaccination) vs. 1 event (0 serious and 0 within 28 days following vaccination).
- Tinnitus: 6 events (0 serious; 6 within 28 days of vaccination, including 3 within 2 days of vaccination) vs. 0.

For these events, a causal relationship with the Janssen COVID-19 vaccine cannot be determined. The assessment of causality was confounded by the presence of underlying medical conditions that may have predisposed individuals to these events.

There were no additional notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and cardiovascular events) that would suggest a causal relationship to the Janssen COVID-19 Vaccine.

## **8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS**

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Janssen COVID-19 Vaccine administration to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event,
  - Serious adverse events\* (irrespective of attribution to vaccination),
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults,
  - Cases of COVID-19 that result in hospitalization or death.
- \* Serious Adverse Events are defined as:
- Death;
  - A life-threatening adverse event;
  - Inpatient hospitalization or prolongation of existing hospitalization;
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
  - A congenital anomaly/birth defect;
  - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

#### Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to [info@vaers.org](mailto:info@vaers.org).

**IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:**

- Patient demographics, (e.g., patient name, date of birth),
- Pertinent medical history,
- Pertinent details regarding admission and course of illness,
- Concomitant medications,
- Timing of adverse event(s) in relationship to administration of Janssen COVID-19 vaccine,
- Pertinent laboratory and virology information,
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Janssen COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
  - a. Write “Janssen COVID-19 Vaccine EUA” as the first line.
  - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
  - a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
  - b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
  - c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

#### Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Janssen Biotech, Inc. using the contact information below or by providing a copy of the VAERS form to Janssen Biotech, Inc:

<b>e-mail</b>	<b>Fax number</b>	<b>Telephone numbers</b>
<a href="mailto:JNJvaccineAE@its.jnj.com">JNJvaccineAE@its.jnj.com</a>	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

## **10 DRUG INTERACTIONS**

There are no data to assess the concomitant administration of the Janssen COVID-19 Vaccine with other vaccines.

## **11 USE IN SPECIFIC POPULATIONS**

### **11.1 Pregnancy**

#### 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>.

### Risk Summary

All Pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Available data on Janssen COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive developmental toxicity study female rabbits were administered 1 mL of the Janssen COVID-19 Vaccine (a single human dose is 0.5 mL) by intramuscular injection 7 days prior to mating and on Gestation Days 6 and 20 (i.e., one vaccination during early and late gestation, respectively). No vaccine related adverse effects on female fertility, embryo-fetal or postnatal development up to Postnatal Day 28 were observed.

## **11.2 Lactation**

### Risk Summary

Data are not available to assess the effects of Janssen COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

## **11.3 Pediatric Use**

Emergency Use Authorization of the Janssen COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

## **11.4 Geriatric Use**

Clinical studies of Janssen COVID-19 Vaccine included individuals 65 years of age and older and their data contributes to the overall assessment of safety and efficacy [*see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18)*]. Of the 21,895 individuals who received a single-dose of the Janssen COVID-19 Vaccine in COV3001, 19.5% (n=4,259) were 65 years of age and older and 3.7% (n=809) were 75 years of age and older. No overall differences in safety or efficacy were observed between individuals 65 years of age and older and younger individuals.

## **13 DESCRIPTION**

The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection. It contains no visible particulates. The vaccine consists of a replication-incompetent recombinant adenovirus type 26 (Ad26) vector expressing the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike (S) protein in a stabilized conformation.

The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6 TetR cells, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is

processed through several purification steps, formulated with inactive ingredients and filled into vials.

Each 0.5 mL dose of Janssen COVID-19 Vaccine is formulated to contain  $5 \times 10^{10}$  virus particles (VP) and the following inactive ingredients: citric acid monohydrate (0.14 mg), trisodium citrate dihydrate (2.02 mg), ethanol (2.04 mg), 2-hydroxypropyl- $\beta$ -cyclodextrin (HBCD) (25.50 mg), polysorbate-80 (0.16 mg), sodium chloride (2.19 mg). Each dose may also contain residual amounts of host cell proteins ( $\leq 0.15$  mcg) and/or host cell DNA ( $\leq 3$  ng).

Janssen COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

## **14 CLINICAL PHARMACOLOGY**

### **14.1 Mechanism of Action**

The Janssen COVID-19 Vaccine is composed of a recombinant, replication-incompetent human adenovirus type 26 vector that, after entering human cells, expresses the SARS-CoV-2 spike (S) antigen without virus propagation. An immune response elicited to the S antigen protects against COVID-19.

## **18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA**

An ongoing, multicenter, randomized, double-blind, placebo-controlled Phase 3 Study (COV3001) (NCT04505722) 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 the 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.

A total of 44,325 individuals were randomized equally to receive Janssen COVID-19 Vaccine or saline placebo. Individuals are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The primary efficacy analysis population of 39,321 individuals (19,630 in the Janssen COVID-19 Vaccine group and 19,691 in the placebo group) included 38,059 SARSCoV-2 seronegative individuals at baseline and 1,262 individuals with an unknown serostatus. Demographic and baseline characteristics were similar among individuals who received the Janssen COVID-19 Vaccine and those who received placebo (see Table 5).

**Table 5: Summary of Demographics and Baseline Characteristics - Primary Efficacy Analysis Population**

	<b>Janssen COVID-19 Vaccine (N=19,630) n (%)</b>	<b>Placebo (N=19,691) n (%)</b>
<b>Sex</b>		
Male	10,924 (55.6)	10,910 (55.4)
Female	8,702 (44.3)	8,777 (44.6)
<b>Age (years)</b>		
Mean (SD)	51.1 (15.0)	51.2 (15.0)
Median	52.0	53.0
Min, max	(18; 100)	(18; 94)
<b>Age group</b>		
≥18 to 59 years of age	12,830 (65.4)	12,881 (65.4)
≥60 years of age	6,800 (34.6)	6,810 (34.6)
≥65 years of age	3,984 (20.3)	4,018 (20.4)
≥75 years of age	755 (3.8)	693 (3.5)
<b>Race<sup>a</sup></b>		
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 <sup>b</sup>	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)
<b>Ethnicity</b>		
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)
<b>Region</b>		
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)
<b>Comorbidities<sup>c</sup></b>		
Yes	7,830 (39.9)	7,867 (40.0)
No	11,800 (60.1)	11,824 (60.0)

<sup>a</sup> Some individuals could be classified in more than one category.

<sup>b</sup> Including 175 individuals in the United States, which represents 1% of the population recruited in the United States.

<sup>c</sup> 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<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%), 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.

## Efficacy Against COVID-19

The co-primary endpoints evaluated the first occurrence of moderate to severe/critical COVID-19 with onset of symptoms at least 14 days and at least 28 days after vaccination. Moderate to severe/critical COVID-19 was molecularly confirmed by a central laboratory based on a positive SARS-CoV-2 viral RNA result using a polymerase chain reaction (PCR)-based test.

- Moderate COVID-19 was defined based on the following criteria: the individual must have experienced any one of the following new or worsening signs or symptoms: respiratory rate

$\geq 20$  breaths/minute, abnormal saturation of oxygen (SpO<sub>2</sub>) 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 ( $\geq 38.0^{\circ}\text{C}$  or  $\geq 100.4^{\circ}\text{F}$ ), heart rate  $\geq 90$  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 individual must have experienced any one of the following at any time during the course of observation: clinical signs at rest indicative of severe systemic illness (respiratory rate  $\geq 30$  breaths/minute, heart rate  $\geq 125$  beats/minute, oxygen saturation (SpO<sub>2</sub>)  $\leq 93\%$  on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO<sub>2</sub>/FiO<sub>2</sub>)  $< 300$  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 median length of follow up for efficacy for individuals in the study was 8 weeks post-vaccination. 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 (see Table 6).

**Table 6: Analyses of Vaccine Efficacy Against Centrally 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	
<b>14 days post-vaccination</b>					
All subjects <sup>a</sup>	116	3116.6	348	3096.1	66.9 (59.0; 73.4)
18 to 59 years of age	95	2106.8	260	2095.0	63.7 (53.9; 71.6)
60 years and older	21	1009.8	88	1001.2	76.3 (61.6; 86.0)
<b>28 days post-vaccination</b>					
All subjects <sup>a</sup>	66	3102.0	193	3070.7	66.1 (55.0; 74.8) <sup>b</sup>
18 to 59 years of age	52	2097.6	152	2077.0	66.1 (53.3; 75.8)
60 years and older	14	1004.4	41	993.6	66.2 (36.7; 83.0)

<sup>a</sup> Co-primary endpoint.

<sup>b</sup> The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions.

Vaccine efficacy against severe/critical COVID-19 at least 14 days after vaccination was 76.7% (95% CI: 54.6; 89.1) and 85.4% (95% CI: 54.2; 96.9) at least 28 days after vaccination (see Table 7).

**Table 7: Analyses of Vaccine Efficacy: Secondary Endpoints of Centrally 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	
<b>14 days post-vaccination</b>					
Severe/critical	14	3125.1	60	3122.0	76.7 (54.6; 89.1) <sup>a</sup>
<b>28 days post-vaccination</b>					
Severe/critical	5	3106.2	34	3082.6	85.4 (54.2; 96.9) <sup>a</sup>

<sup>a</sup> The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions.

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 2 COVID-19 related hospitalizations in the vaccine group (with none after 28 days) and 29 in the placebo group (with 16 after 28 days).

As of the primary analysis cut-off date of January 22, 2021, 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.

Janssen COVID-19 Vaccine Efficacy in Countries With Different Circulating SARS-CoV-2 Variants.

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 (see Table 8). For the subgroup analyses, all COVID-19 cases accrued up to the primary efficacy analysis data cutoff 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. 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%.

**Table 8: 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)	Severe/Critical Point estimate (95% CI)
US	at least <b>14 days</b> after vaccination	74.4% (65.0; 81.6)	78.0% (33.1; 94.6)
	at least <b>28 days</b> after vaccination	72.0% (58.2;81.7)	85.9% (-9.4; 99.7)
Brazil	at least <b>14 days</b> after vaccination	66.2% (51.0; 77.1)	81.9% (17.0; 98.1)
	at least <b>28 days</b> after vaccination	68.1% (48.8; 80.7)	87.6% (7.8; 99.7)
South Africa	at least <b>14 days</b> after vaccination	52.0% (30.3; 67.4)	73.1% (40.0; 89.4)
	at least <b>28 days</b> after vaccination	64.0% (41.2; 78.7)	81.7% (46.2; 95.4)

Strain sequencing was conducted on available samples with sufficient viral load from centrally confirmed COVID-19 cases (one sequence per case). As of February 12, 2021, 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%)]. 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 B.1.1.7 or P.1 lineages were not found in any of the sequenced samples.

**19 HOW SUPPLIED/STORAGE AND HANDLING**

Janssen COVID-19 Vaccine is supplied in a carton of 10 multi-dose vials (NDC 59676-580-15). A maximum of 5 doses can be withdrawn from the multi-dose vial.

**The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.**

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

**20 PATIENT COUNSELING INFORMATION**

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at:

<https://www.cdc.gov/vaccines/programs/iis/about.html>.

**21 CONTACT INFORMATION**

For general questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com) or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	<a href="http://www.janssencovid19vaccine.com">www.janssencovid19vaccine.com</a> .	US Toll Free: 1-800-565-4008 US Toll: 1-908-455-9922

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com).

Manufactured by:  
Janssen Biotech, Inc.

Revised: Feb/27/2021

a Janssen Pharmaceutical Company of Johnson & Johnson  
Horsham, PA 19044, USA



Revised: Feb/27/2021

© 2021 Janssen Pharmaceutical Companies

## FACT SHEET FOR RECIPIENTS AND CAREGIVERS

### EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com).

## WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

### WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

### WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

## **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?**

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,

## **WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?**

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

## **WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?**

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

## **WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?**

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl- $\beta$ -cyclodextrin (HBCD), polysorbate-80, sodium chloride.

## **HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?**

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

## **HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?**

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

## **WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?**

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

## **WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?**

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing,
- Swelling of your face and throat,
- A fast heartbeat,
- A bad rash all over your body,
- Dizziness and weakness.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

## **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

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

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Janssen COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

<b>e-mail</b>	<b>Fax number</b>	<b>Telephone numbers</b>
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

**WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?**

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

**ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?**

Currently, there is no FDA approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

**CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Janssen COVID-19 Vaccine with other vaccines.

**WHAT IF I AM PREGNANT OR BREASTFEEDING?**

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

**WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?**

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

**KEEP YOUR VACCINATION CARD**

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

**ADDITIONAL INFORMATION**

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	<a href="http://www.janssencovid19vaccine.com">www.janssencovid19vaccine.com</a> .	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

**HOW CAN I LEARN MORE?**

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

Contact your local or state public health department.

**WHERE WILL MY VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

**WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp) or call 1-855-266-2427.

**WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:  
Janssen Biotech, Inc.  
a Janssen Pharmaceutical Company of Johnson & Johnson  
Horsham, PA 19044, USA



© 2021 Janssen Pharmaceutical Companies

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com)

Revised: Feb/27/2021



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 02/2021