The Janssen COVID-19 Vaccine

Storage, Dosage and Administration Guide

The Janssen COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized by FDA through an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. The emergency use of this product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the FD&C Act, unless the declaration is terminated or authorization revoked sooner.

AUTHORIZATION OF USE

The 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).

- Primary vaccination regimen for the Janssen COVID-19 Vaccine is a single-dose (0.5 mL) administered to individuals 18 years of age and older.
- A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after the primary vaccination with the Janssen COVID-19 Vaccine, to individuals 18 years of age and older.
- A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

FD&C=Federal Food, Drug, and Cosmetic Act.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- **Severe Allergic Reactions:** 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.
- **Thrombosis with Thrombocytopenia:** Do not administer the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccines (e.g., AstraZeneca's COVID-19 vaccine which is not authorized or approved in the United States).

Please read additional Important Safety Information throughout.
Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including full EUA Prescribing Information available at www.JanssenCOVID19Vaccine.com/EUA-factsheet.

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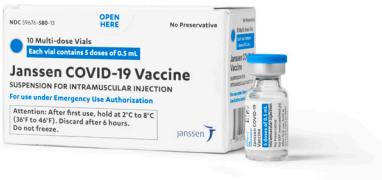
The Janssen COVID-19 Vaccine



Storage, Dosage and Administration Guide

How It's Supplied

The Janssen COVID-19 Vaccine is supplied in a carton of 10 multi-dose vials. A maximum of 5 doses of 0.5 mL can be withdrawn from the multi-dose vial. The vial stoppers are not made with natural rubber latex.

Storage and Handling

Storage Prior to First Puncture of the Vaccine Vial

- Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 36°F to 46°F (2°C to 8°C) and protect from light
- Unpunctured vials of the vaccine may be stored between 47°F to 77°F (9°C to 25°C) for up to 12 hours
- Do not store frozen

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 36°F to 46°F (2°C to 8°C). If vaccine is still frozen upon receipt, thaw at 36°F to 46°F (2°C to 8°C). If needed immediately, thaw at room temperature (maximally 77°F/25°C). Do not re-freeze once thawed.

- At room temperature, a carton of 10 vials will take ~4 hours to thaw
- At room temperature, an individual vial will take ~1 hour to thaw

Storage After First Puncture of the Vaccine Vial

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

Dosing and Schedule

Primary Vaccination

The primary vaccination regimen for the Janssen COVID-19 Vaccine is a single-dose (0.5 mL) administered to individuals 18 years of age and older.

Booster Dose

A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after primary vaccination with the Janssen COVID-19 Vaccine, to individuals 18 years of age and older.

A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS

- **Management of Acute Allergic Reactions:** 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).

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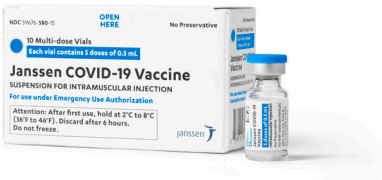

Storage, Dosage and Administration Guide

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 5 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 36°F to 46°F (2°C to 8°C) for up to 6 hours or at room temperature (maximally 77°F/25°C) 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
  - Verify the final dosing volume of 0.5 mL
  - Do not administer if vaccine is discolored or contains particulate matter
- **Administer the Janssen COVID-19 Vaccine intramuscularly**
- There is no information on the co-administration of the Janssen COVID-19 Vaccine with other vaccines

Coding and Reimbursement[1,2]

Vaccine CPT® code*: 91303	Carton NDC: 59676-580-15	CVX: 212
Primary Vaccination Administration CPT® code†: 0031A	Vial NDC: 59676-580-05	MVX: JSN
Booster Dose Administration CPT® code†: 0034A		

CPT®=Current Procedural Terminology; CVX=Code for Vaccine Administered; MVX=Manufacturers of Vaccines; NDC=National Drug Code.
CPT® is a registered trademark of the American Medical Association, 2021.
*Janssen COVID-19 Vaccine purchased by the US government is provided to immunizers at no cost.
†This CPT® code reports the actual work of administering the vaccine, in addition to all necessary counseling provided to patients or caregivers and updating the electronic record.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

- **Thrombosis with Thrombocytopenia Syndrome (TTS):** Reports to the Vaccine Adverse Events Reporting System (VAERS), a passive surveillance system, provide evidence for an increased risk of thrombosis with thrombocytopenia syndrome (TTS) with onset of symptoms approximately one to two weeks after administration of the Janssen COVID-19 Vaccine. An analysis of VAERS reports of TTS following the receipt of the Janssen COVID-19 Vaccine used the following case definition:
  - a thrombosis in an unusual location for a thrombus (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery or vein) and new-onset thrombocytopenia (i.e., platelet count <150,000/µL) occurring any time after vaccination;
    or;
  - new-onset thrombocytopenia (i.e., platelet count <150,000/µL), thrombosis in an extremity vein or pulmonary artery in the absence of thrombosis at an unusual location, and a positive anti-PF4 antibody ELISA test or functional Heparin-Induced Thrombocytopenia (HIT) platelet test occurring any time after vaccination.

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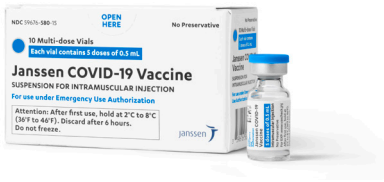

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Cases of TTS following administration of the Janssen COVID-19 Vaccine have been reported in males and females, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30-49 years; overall, approximately 15% of TTS cases have been fatal.

The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. Specific risk factors for TTS following administration of the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Currently available evidence supports a causal relationship between TTS and the Janssen COVID-19 Vaccine.

Healthcare professionals should be alert to the signs and symptoms of TTS in individuals who receive the Janssen COVID-19 Vaccine. In individuals with suspected TTS following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended.

The American Society of Hematology has published considerations relevant to the diagnosis and treatment of TTS following administration of the Janssen COVID-19 Vaccine (https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia).

Recipients of Janssen COVID-19 Vaccine should be instructed to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination.

- **Immune Thrombocytopenia (ITP):** Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of immune thrombocytopenia (ITP) during the 42 days following vaccination. Individuals with a history of ITP should discuss with their healthcare provider the risk of ITP and the potential need for platelet monitoring following vaccination with the Janssen COVID-19 Vaccine.
- **Guillain-Barré Syndrome:** Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.
- **Syncope:** Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Limitations of Vaccine Effectiveness:** The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials

In study COV3001, the most common local solicited adverse reaction (≥10%) reported was injection site pain (48.6%). The most common systemic adverse reactions (≥10%) were headache (38.9%), fatigue (38.2%), myalgia (33.2%), and nausea (14.2%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Janssen COVID-19 Vaccine.

Adverse Reactions Identified during Post Authorization Use

Anaphylaxis and other severe allergic reactions, thrombosis with thrombocytopenia, Guillain-Barré syndrome, and capillary leak syndrome have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination outside of clinical trials.

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

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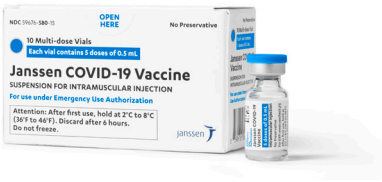

IMPORTANT SAFETY INFORMATION (CONT.)

ADVERSE REACTIONS (CONT.)

Reporting Adverse Events and Vaccine Administration Error

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.

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 below. Reports should include the words "Janssen COVID-19 Vaccine EUA" in the description section of the report as the first line.

- 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

Report adverse events to Janssen Biotech, Inc. by calling 1-800-565-4008 or provide a copy of the VAERS form by faxing 1-215-293-9955.

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Available data on Janssen COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- **Lactation:** Data are not available to assess the effects of Janssen COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
- **Pediatric Use:** Emergency Use Authorization of the Janssen COVID-19 Vaccine does not include use in individuals younger than 18 years of age.
- **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. No overall differences in safety or efficacy were observed between individuals 65 years of age and older and younger individuals.

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References: 1. Find your COVID-19 vaccine CPT codes. American Medical Association. Accessed November 2, 2021. https://www.ama-assn.org/find-covid-19-vaccine-codes **2.** COVID-19 vaccine related codes. Centers for Disease Control and Prevention. Updated October 29, 2021. Accessed November 2, 2021. https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html

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For medical inquiries or product-related questions:

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