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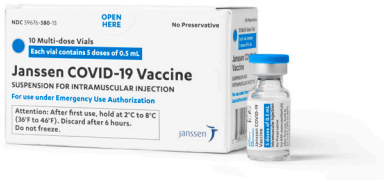
The Janssen COVID-19 Vaccine



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.

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 A maximum of 5 doses of 0.5 mL can be withdrawn from the multi-dose vial.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- After the first dose has been withdrawn, hold the vial between 36°F and 46°F (2°C to 8°C) for up to 6 hours or at room temperature (maximally 77°F/25°C) for up to 2 hours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

Expiration Tracking

Janssen is conducting ongoing stability assessment studies for the Janssen COVID-19 Vaccine. Expiry dates may be updated as these studies are completed. Therefore, no expiry date appears on the carton or vial.

Three Different Methods to Check Expiration:

1. **Scan the QR code on the back of the carton using a mobile device camera**
2. **On the web:** www.vaxcheck.jnj
3. **By phone:** 1-800-565-4008 (US Toll Free) or 1-908-455-9922 (US Toll)

*Current as of July 12, 2021.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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.

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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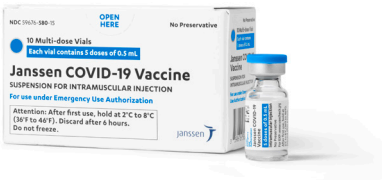

Storage, Dosage and Administration Guide

Dose Preparation

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension that does not contain a preservative
- Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exist, 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
- Record the date and time of first use on the Janssen COVID-19 Vaccine vial label

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

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. For more information, visit: www.cdc.gov/vsafe

Coding and Reimbursement

Vaccine CPT® code†: 91303	Carton NDC: 59676-580-15	CVX: 212
Administration CPT® code‡: 0031A	Vial NDC: 59676-580-05	MVX: JSN

CPT®=Current Procedural Terminology; CVX=Code for Vaccine Administered; FD&C Act=Federal Food, Drug, and Cosmetic Act; MVX=Manufacturers of Vaccines; NDC=National Drug Code; QR=quick response.

†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

- **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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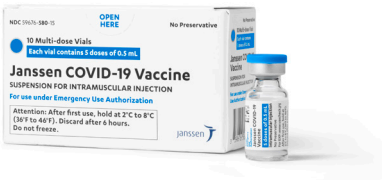

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

- **Thrombosis with Thrombocytopenia:** Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination. The reporting rate of thrombosis with thrombocytopenia following the administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. Specific risk factors for thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.

  Healthcare professionals should be alert to the signs and symptoms of thrombosis with thrombocytopenia in individuals who receive the Janssen COVID-19 Vaccine. In individuals with suspected thrombosis with thrombocytopenia 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 thrombosis with thrombocytopenia 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.

- **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

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.

Adverse Reactions Identified during Post Authorization Use

Severe allergic reactions (including anaphylaxis), 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.

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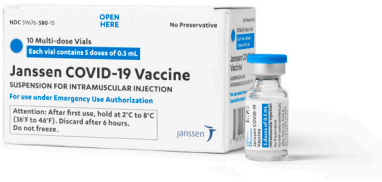

IMPORTANT SAFETY INFORMATION (CONT.)

ADVERSE REACTIONS (CONT.)

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

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.

PREGNANCY AND LACTATION

- **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.

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.

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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For medical inquiries or product-related questions:

US Toll Free: 1-800-565-4008
US Toll: 1-908-455-9922
janssenmd.com