Janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

The Janssen COVID-19 Vaccine

How It's Designed

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 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.

The Janssen COVID-19 Vaccine: How It's Designed

Mechanism of Action

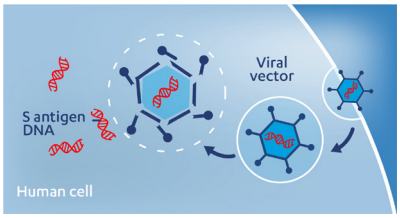
The Janssen COVID-19 Vaccine is composed of a recombinant, replication-incompetent human adenovirus type 26 vector that, after entering human cells, expresses the SARS-CoV-2 spike (S) antigen without virus propagation. An immune response elicited to the S antigen protects against COVID-19.

Replication-Incompetent Viral Vector Technology[1,2]

The viral vector used in the Janssen COVID-19 Vaccine is based on a naturally occurring, low-prevalence human adenovirus. Adenoviruses are known to cause common cold–like symptoms. The deletion of a specific gene renders the adenovirus unable to replicate within humans, transforming it into a delivery vehicle for the genetic material encoding the spike protein of SARS-CoV-2. In this form, the vaccine cannot cause COVID-19 or adenoviral disease.

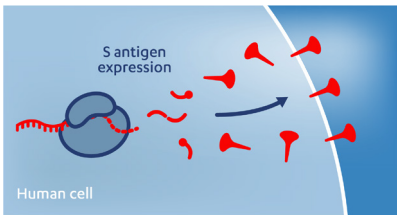
Delivery of S Antigen DNA

The viral vector shuttles the gene encoding the S antigen into a human cell.



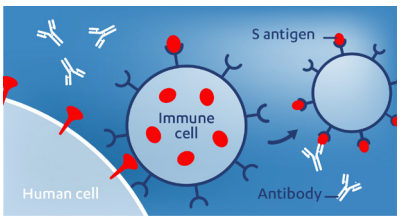
S Antigen Production

Once inside a cell, the cell's machinery uses this gene to produce the S antigen and display it on the cell's surface.



Immune Response to S Antigen

The displayed S antigen triggers an immune response that will help prepare the body to respond to future exposure to SARS-CoV-2.



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 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.

  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.

- **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.

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IMPORTANT SAFETY INFORMATION (CONT.)

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.

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.

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IMPORTANT SAFETY INFORMATION (CONT.)

USE IN SPECIFIC POPULATIONS (CONT.)

- **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. Custers J, Kim D, Leyssen M, et al. Vaccines based on replication incompetent Ad26 viral vectors: standardized template with key considerations for a risk/benefit assessment. *Vaccine*. 2021;39:3081-3101. **2.** Understanding viral vector COVID-19 vaccines. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/covid-19/hcp/viral-vector-vaccine-basics.html. Updated October 18, 2021. Accessed October 21, 2021.

For medical inquiries or product-related questions:

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