

Janssen COVID-19 Vaccine (Johnson & Johnson)

Vaccine Preparation and Administration Summary



» Clinical Materials Update

On April 13, 2021, **CDC and FDA recommended a pause in the use of Janssen COVID-19 Vaccine (Johnson & Johnson)** out of an abundance of caution while they review data involving a small number of reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia in individuals after receiving Janssen COVID-19 Vaccine (<https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine>). The Advisory Committee on Immunization Practices (ACIP, <https://www.cdc.gov/vaccines/acip/index.html>) met on April 14. After hearing additional data on these reports, ACIP agreed that more information is needed before policy recommendations can be made regarding continued use of the Janssen COVID-19 vaccine. CDC will collect more information and convene another ACIP meeting on April 23 to review any additional scientific evidence.

At this time, the recommended pause supersedes any other recommendations for use of Janssen COVID-19 Vaccine.

Recommendations for clinicians related to the detection, evaluation, proper management, and reporting of cases of CVST with thrombocytopenia after receipt of Janssen COVID-19 Vaccine are outlined in Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>. These can also be found in CDC's Health Alert (<https://emergency.cdc.gov/han/2021/han00442.asp>) , issued April 13.

If you are a COVID-19 vaccination provider with Janssen COVID-19 Vaccine:

1. Mark any Janssen COVID-19 Vaccine in your inventory "Do not use. Awaiting guidance."
2. Continue to store the vaccine in the refrigerator between 2°C and 8°C (36°F and 46°F).
3. Continue to monitor and document storage unit temperatures and follow recommended vaccine storage practices.

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» General Information

Vaccine: Janssen COVID-19 Vaccine
(Johnson & Johnson)

Multidose vial: 5 doses per vial

Dosage: 0.5 mL

Do NOT mix with a diluent. Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

» Age Indications

18 years of age and older

» Schedule

1 dose

Do not use the Janssen COVID-19 Vaccine as part of any other COVID-19 vaccine series.

» Administration

Intramuscular (IM) injection in the deltoid muscle



» Expiration Date

The expiration date is NOT printed on the vaccine vial or carton.

To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.njnj.

Write date on carton. As the expiration date approaches, check the expiration date again. Do not discard vaccine until ensuring the expiration date has passed. Use CDC's expiration date tracking tool to document expiration date changes.

» Prepare and Administer the Vaccine

<p>Assess recipient status:</p> <ul style="list-style-type: none"> ■ Screen for contraindications and precautions. ■ Review vaccination history. ■ Review medical considerations. 		<p>Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.</p>	
<p>Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*</p>		<p>Withdraw 0.5 mL of vaccine into the syringe.†</p> <ul style="list-style-type: none"> ■ Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.5 mL. ■ If the amount of vaccine remaining in the vial cannot provide a full 0.5 mL dose, discard the vial and contents. ■ Do not combine vaccine from multiple vials to obtain a dose. 	
<p>Unpunctured vials: Check the expiration date. Never use expired vaccine. Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.</p>		<p>Note the date and time the vial was first punctured. Keep the vaccine between 2°C and 8°C (36°F and 46°F) for up to 6 hours or at room temperature (up to 25°C or 77°F) for up to 2 hours. Discard if not used within this time.</p>	
<p>With the vial upright, gently swirl the vaccine for 10 seconds. Do NOT shake. If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.</p>		<p>Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.</p>	
<p>Examine the vaccine. It should be a colorless to slightly yellow, clear to very opalescent suspension. Do not use if liquid contains particulate matter or if it is discolored.</p>		<p>Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients (if tolerated).</p>	
<p>Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.</p>		<p>Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.</p>	
<p>Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.</p>		<p>Observe recipients after vaccination for an immediate adverse reaction:</p> <ul style="list-style-type: none"> ■ 30 minutes: Persons with a: <ul style="list-style-type: none"> » History of an immediate allergic reaction of any severity to a vaccine or injectable therapy » Contraindication to mRNA COVID-19 vaccines who receive Janssen COVID-19 Vaccine » History of anaphylaxis due to any cause ■ 15 minutes: All other persons 	

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

†It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or contaminated.

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» Contraindications and Precautions

Contraindications:

- Severe allergic reaction (e.g., anaphylaxis) to a component of Janssen COVID-19 Vaccine
- Immediate allergic reaction* of any severity or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of ingredients in COVID-19 vaccines)

Note: Persons who have a contraindication to Janssen COVID-19 Vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).[†]

Precautions:

- History of an immediate allergic reaction* to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
 - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polysorbate or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- People with a contraindication to either mRNA COVID-19 vaccine have a precaution to Janssen COVID-19 Vaccine.[†]
- Moderate or severe acute illness

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

» Management of Anaphylaxis

Be prepared to manage medical emergencies.

- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

For more information, please see Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>.

» Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration. They should aim to report administration data to the relevant system for the jurisdiction (i.e., immunization information system) as soon as practicable and no later than 72 hours after administration.

Document each patient's vaccine administration information in the:

■ Medical record:

- Vaccine and the date it was administered
- Manufacturer and lot number
- Vaccination site and route
- Name and title of the person administering the vaccine

■ Personal vaccination record card (shot card):

- Date of vaccination
- Product name/manufacturer
- Lot number
- Name/location of the administering clinic or healthcare professional
- Give to the vaccine recipient.

■ Immunization information system (IIS) or "registry": Report the vaccination to the appropriate state/local IIS.

» Report Adverse Events

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety reporting requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the Emergency Use Authorization

AEs should be reported even if the cause is uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration. Submit reports to www.vaers.hhs.gov.

For additional information, see the vaccine manufacturer's product information at <https://www.janssencovid19vaccine.com/hcp.html>.

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

[†]Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

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» Table 1: Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the [Pfizer-BioNTech](#), [Moderna](#), and [Janssen](#) COVID-19 vaccines reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

*None of the vaccines contain eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients in vaccines and medications can be found in the package insert. [CDC's vaccine excipient summary](#) and the National Institutes of Health [DailyMed database](#) can also be used as resources.