

Janssen COVID-19 Vaccine (Johnson & Johnson)

Vaccine Preparation and Administration Summary



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

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.jnj.

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.

Schedule for Janssen COVID-19 Vaccine Doses

mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen vaccine is not approved for use as an additional dose for moderately or severely immunocompromised persons.

For an up-to-date vaccination schedule for primary and booster doses of Janssen COVID-19 Vaccine see <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf>

Prepare and Administer the Vaccine

Assess recipient status:

- Screen for contraindications and precautions.
- Review vaccination history.*
- Review medical considerations.†



Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.



Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.



Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.‡



Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.



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.

Withdraw 0.5 mL of vaccine into the syringe.§

- 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.



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.



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.



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.



* COVID-19 vaccines may be coadministered with other vaccines with regard to timing, including simultaneous administration.

† Considerations should include risks and symptoms of thrombosis with thrombocytopenia syndrome (TTS) after receipt of a Janssen vaccine.

‡ 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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Prepare and Administer the Vaccine (continued)

Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.



Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients (if tolerated).



Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.



Observe recipients after vaccination for an immediate adverse reaction:



- **30 minutes:** Persons with a history of:
 - » A contraindication to another type of COVID-19 vaccine product
 - » Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine
 - » Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
 - » Anaphylaxis due to any cause
- **15 minutes:** All other persons

Contraindications and Precautions

Contraindications:

History of a:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine (see <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C> for a list of vaccine components)
- Thrombosis with thrombocytopenia syndrome (TTS) following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors)
 - Persons with a history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic heparin-induced thrombocytopenia (HIT) should not receive Janssen COVID-19 vaccine. Administer an mRNA COVID-19 vaccine.

Precautions:

Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.

- Immediate allergic reaction* to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])

* 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.

- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Allergy-related contradiction to one type of COVID-19 vaccines (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)[†]
- History of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- History of Guillian-Barré syndrome
 - Persons who develop GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine should not receive another dose of Janssen. Administer an mRNA vaccine.
- Moderate to severe acute illness, with or without fever

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

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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>