Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary

General Information

Vaccine: Pfizer-BioNTech COVID-19 Vaccine

Diluent: 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 6 doses per vial

Dosage: 0.3 mL

Vaccine MUST be mixed with diluent before administration.

Age Indications

12 years of age and older

Schedule

2-dose series separated by 21 days
A series started with Pfizer-BioNTech COVID-19 Vaccine should be completed with this product.

Administration

Intramuscular (IM) injection in the deltoid muscle

Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
  - **Refrigerator:** Between 2°C and 8°C (36°F and 46°F) Unpunctured vials may be stored in the refrigerator for up to 1 month (31 days).
  - **Room temperature (for immediate use):** Up to 25°C (77°F) Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
- **Do NOT** refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from ultra-cold temperature or freezer storage.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

Prepare the Vaccine

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

Remove vaccine from the freezer or refrigerator. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing.

Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent. The expiration dates for the diluent and the vaccine are located on the respective vials.

With the vaccine at room temperature, gently invert vial 10 times. **Do not shake the vial.** If the vial is shaken, contact the manufacturer. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.

10x

Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, **withdraw 1.8 mL** of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent every time. **Do NOT** use bacteriostatic normal saline or other diluents to mix the vaccine.

1.8 ml

Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.

Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.

Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. **Do not shake.** If the vial is shaken, contact the manufacturer.

10x

Note the date and time the vaccine was mixed on the vial.

Keep mixed vaccine between 2°C and 25°C (36°F to 77°F), minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Administer within 6 hours. **Discard any unused vaccine after 6 hours.** Do not return to freezer storage.

*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.

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Administer the Vaccine

Assess recipient status:
- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.

Choose the correct equipment, including the correct needle size.
- Use a new, sterile needle and syringe for each injection. Use low dead-volume syringes/needles to extract 6 doses from a single vial. If sufficient low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes per vial (e.g., 4 low dead-volume syringes and 2 non-low dead-volume syringes).

Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe.
- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.3 mL.
- If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and contents.
- **Do NOT** combine vaccine from multiple vials to obtain a dose.

Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle* to withdraw and administer the vaccine. Ensure the prepared syringe is not cold to the touch.

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 older than 2 years of age (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 an immediate allergic reaction of any severity to a vaccine or injectable therapy
  - Contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech vaccine
  - History of anaphylaxis due to any cause
- **15 minutes:** All other persons

*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.

Scheduling Doses

Vaccination History†‡	And	Then	Next Dose Due
0 doses	→	Give dose 1 today	Give dose 2 at least 21 days after dose 1§
1 dose (Pfizer COVID-19 Vaccine)	It has been at least 21 days since dose 1	Give dose 2 today	Series complete; no additional doses needed
	It has not been at least 21 days from dose 1	No dose today	Give dose 2 at least 21 days after dose 1§
2 doses (Pfizer COVID-19 Vaccine) at least 21 days apart§	→	→	Series complete; no additional doses needed
2 doses (1 product unknown) at least 28 days apart ‡	→	→	Series complete; no additional doses needed

†COVID-19 vaccines and other vaccines may be administered at the same visit, as well as within 14 days of each other. When deciding whether to administer COVID-19 vaccines and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

‡Every effort should be made to determine which vaccine product was received as the first dose. In exceptional situations in which the vaccine product given for the first dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at least 28 days after the first dose.

§**Administer the second dose as close to the recommended interval (21 days) as possible.** If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Doses inadvertently administered less than 21 days apart do not need to be repeated.

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Contraindications and Precautions

Contraindications:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
- Immediate allergic reaction* of any severity to a previous dose or known (see Table 1 for a list of ingredients in COVID-19 vaccine products)

Note: Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).†

Precautions:

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of an immediate allergic reaction* to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote).†
- Moderate to 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 www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html.

Document the Vaccination

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

Document each recipient'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, and 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.

Reporting 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 EUA

Adverse events 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 www.cvdvaccine.com.

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A

*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.

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)azanediyl)bis(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.