

Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary



» General Information

Vaccine: COVID-19 vaccine (Pfizer)
 Diluent: 0.9% sodium chloride (normal saline, preservative-free)
 Multidose vial: Up to 6 doses per vial
 Dosage: 0.3 mL
Vaccine MUST be mixed with diluent before administration.

» Age Indications

16 years of age and older

» Schedule

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

» Administer

Intramuscular (IM) injection in the deltoid muscle



» Thawing Frozen Vaccine

- Vaccine may be thawed in the refrigerator or at room temperature. Do **NOT** refreeze thawed vaccine.
- **Refrigerator:** Between 2°C and 8°C (36°F and 46°F)
 - 25 to 195 vials may take 2 to 3 hours to thaw in the refrigerator.
 - Fewer number of vials will take less time.
- **Room temperature:** Up to 25°C (77°F) between 30 minutes and 2 hours
 - Vials at room temperature must be mixed within 2 hours or returned to the refrigerator.

» 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. After 2 hours, return unmixed vials to the refrigerator.	
Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent. The expiration date for the diluent and the vaccine is located on the vial.	
With the vaccine at room temperature, gently invert vial 10 times. Do not shake the vial. If the vial is shaken, discard the vaccine. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.	
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. Do NOT use bacteriostatic normal saline or other diluents to mix the vaccine.	
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, discard the vaccine.	
Note the date and time the vaccine was mixed on the vial.	
Keep mixed vaccine at room temperature (2°C to 25°C [36°F to 77°F]) and administer within 6 hours. Discard any unused vaccine after 6 hours. Do not return to refrigerator or 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

<p>Assess recipient status:</p> <ul style="list-style-type: none"> • Screen for contraindications and precautions. • Review vaccination history. 	
<p>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).</p>	
<p>Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.</p>	
<p>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. Ensure the prepared syringe is not cold to the touch.</p>	
<p>Remove any air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle* to withdraw and administer the vaccine, unless contaminated or damaged.</p>	
<p>Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.</p>	
<p>Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.</p>	
<p>Observe recipients after vaccination for an immediate adverse reaction:</p> <ul style="list-style-type: none"> • 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause • 15 minutes: All other persons. 	

*Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary 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)	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 since dose 1	No dose today	Give dose 2 at least 21 days after dose 1
2 doses (Pfizer) at least 21 days apart†			Series complete; no additional doses needed

*COVID-19 vaccine (Pfizer) should not be administered at the same time as other vaccines. Separate COVID-19 vaccine (Pfizer) from other vaccines by 14 days before or after the administration of COVID-19 vaccine (Pfizer).

†Vaccine doses administered at/after day 17 are considered valid. The 4-day grace period should not routinely be used to schedule doses.

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» Contraindications and Precautions

Contraindications:

- Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine
- Immediate allergic reaction* of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG]). See Table 1 of vaccine components on page 3.
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

Precautions:

- History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
- Moderate to severe acute illness

» 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 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, 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.

» Management of Anaphylaxis

Healthcare professionals should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and should be competent in treating these events at the time of vaccine administration. Equipment and medications should be available, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse.

For more information, please see Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites at <https://www.cdc.gov/vaccines/covid-19/info-byproduct/pfizer/anaphylaxis-management.html>.

» 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 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.

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» **Table 1: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines**

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination with both the Pfizer-BioNTech and Moderna vaccines. The following is a list of ingredients for the Pfizer-BioNTech and Moderna COVID-19 vaccines, as reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	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
Lipids	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(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
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

*Neither vaccine contains 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 whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed database (<https://dailymed.nlm.nih.gov/dailymed/index.cfm>) may also be used as a resource. Medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533–1540. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf>