

# 6 Months Through 4 Years of Age Pfizer-BioNTech COVID-19 Vaccine

## Vaccine Preparation and Administration Summary



### General Information

Vaccine: Pfizer-BioNTech: 6 months through 4 years of age (maroon cap and maroon bordered label) **Use the correct formulation based on the age of the recipient**

Diluent: 2.2 mL of 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 10 doses per vial

Dosage: 0.2 mL

**Prepare the vaccine using a NEW vial of diluent EVERY TIME. Discard the diluent vial and remaining diluent after mixing the vaccine.**

### Age Indications

6 months through 4 years of age

### Vaccination Schedule

- For an up-to-date vaccination schedule for for Pfizer-BioNTech COVID-19 Vaccine for infants and young children see [www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf](http://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf)

### 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 storage unit. **Check the vial label to ensure it is the correct formulation based on the age of the recipient. The vial for children 6 months through 4 years of age has a maroon cap and maroon border on the label.** Allow vaccine to come to room temperature. Vials can be held at room temperature at room temperature for up to 12 hours before mixing.



Before mixing, check the:

- Age indications on the label
- Expiration date of the vaccine and diluent
- Any beyond-use dates/times



**NEVER** use expired vaccine or diluent. **NEVER** use vaccine after the beyond-use date or times.

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.



### Administration

Intramuscular injection:

- 6 months through 2 years: Vastus lateralis muscle in the anterolateral thigh.\*
- 2 through 4 years: Deltoid muscle in the upper arm.†
- COVID-19 vaccines may be coadministered with other vaccines, including simultaneous administration.

### Thawing Frozen Vaccine

- Vaccine stored at ultra-cold temperatures must be thawed before use.
- Thaw vaccine in the refrigerator or at room temperature:
  - Unpunctured vials may be stored in the refrigerator for up to 10 weeks.
  - Unpunctured vials maybe stored between 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to mixing (including thaw time).
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
- Do NOT** refreeze thawed vaccine.
- Use CDC's beyond-use date labels to track storage time at refrigerated temperatures.

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 2.2 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.



Inject 2.2 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.



Using the mixing syringe, remove 2.2 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.



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) for up to 12 hours. **Discard any unused vaccine after 12 hours.** Do not return to ultra-cold freezer storage.



\* For children 1 through 2 years of age, the deltoid muscle in the upper arm may be used if the muscle mass is adequate.

† The vastus lateralis muscle in the anterolateral thigh may also be used.

‡ 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 vaccine formulation based on the age of the recipient and equipment, including the correct needle size.



- **Check the age indications on the label.** The vial for children 6 months through 4 years of age has a maroon cap and a maroon bordered label. Do **NOT** vaccinate that has an orange/gray/purple cap or label to children younger than 5 years.
- Use a new, sterile needle and syringe for each injection. Use 1 mL low-dead volume syringes to withdraw the vaccine. 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.

Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.2 mL of mixed vaccine into the syringe.



0.2 mL

- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.2 mL.
- If the amount of vaccine remaining in the vial cannot provide a full 0.2 mL dose, discard the vial and contents.
- **Do NOT** combine vaccine from multiple vials to obtain a dose.

### Contraindications and Precautions

#### Contraindications:

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to 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)

#### Precaution:

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

- Immediate allergic reaction<sup>¶</sup> to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or

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



**Check the age indications on the vial label, again, to ensure it is the correct formulation based on the age of the recipient.**

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 injection (IM). For children:

- 6 months through 2 years: vastus lateralis muscle in the anterolateral thigh
- 3 through 5 years: Deltoid muscle in the upper arm.



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

subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]

- This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- History of MIS-C or MIS-A
- 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](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).

<sup>§</sup> 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.

<sup>¶</sup> 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.



### 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](http://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](http://www.vaers.hhs.gov).

For additional information, see the vaccine manufacturer's product information at [www.cvdvaccine.com](http://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>