

Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance



Guidance below summarizes basic storage, preparation, scheduling, and administration for ALL Pfizer-BioNTech COVID-19 Vaccine products.

Ages: 6 months through 4 years
(Maroon capped vial and bordered label)



BIVALENT

Ages: 5 through 11 years
(Orange capped vial and bordered label)



BIVALENT

Ages: 12 and older
(Gray capped vial and bordered label)










BIVALENT

Storage and Handling Basics

Find additional guidance on storing the vaccine properly at:

- [Vaccine Storage and Handling Toolkit-Updated with COVID-19 Vaccine Storage and Handling Information](#)
- [Pfizer-BioNTech COVID-19 Vaccines | FDA](#)
- [Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com](#)

Vial cap color	 BIVALENT Maroon Cap	 BIVALENT Orange Cap	 BIVALENT Gray Cap
Ages	6 months through 4 years	5 through 11 years	12 years and older
Supplied in:	MDV: 10 doses per vial Requires diluent	MDV: 10 doses per vial Requires diluent	MDV: 6 doses per vial SDV: 1 dose  No diluent
Storage Temperature: Before Puncture  Do NOT store vaccine in a standard freezer	Between: -90°C and -60°C (-130°F and -76°F) until the expiration date* 2°C and 8°C (36°F and 46°F) for up to 10 weeks NOTE: The beyond-use date (10 weeks) replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date or beyond-use date has passed.		
Thawing Frozen Vaccine  Do NOT refreeze thawed vaccine	Between: 2°C and 8°C (36°F and 46°F) OR Up to 25°C (77°F) Amount of time needed to thaw vaccine varies based on temperature and number of vials.		
Storage Temperature: After 1st Puncture  Do NOT use after 12 hours	Between: 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard vial and any unused vaccine after 12 hours.		

* Vaccine expires 18 months after the manufacture date on the vial. Use Pfizer-BioNTech expiration date tool at lotexpiry.cvdvaccine.com

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Preparation and Administration Basics








Find additional guidance on preparing and administering vaccine properly at:

■ [Vaccine Administration Resource Library | CDC](#)

■ [Pfizer-BioNTech COVID-19 Vaccines | FDA](#)




■ [Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com](#)

Preparation Bivalent Vaccine

Vial cap color	 Bivalent Maroon Cap	 Bivalent Orange Cap	 Bivalent Gray Cap	 Bivalent Gray Cap
Ages	6 months through 4 years	5 through 11 years	12 years and older	
Vial type	Multidose vial (MDV)	Multidose vial (MDV)	Multidose vial (MDV)	Single-dose vial (SDV)
Diluent*	2.2 mL per vial	1.3 mL per vial	 No diluent	 No diluent
Beyond-use date/time	After mixing with diluent, use within 12 hours.		After 1st puncture, use within 12 hours.	N/A
 Do NOT use a punctured multidose vial after 12 hours	If using a multidose vial for the 1st time, record the date and time the vial was punctured. NOTE: The beyond-use time (12 hours) replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date or beyond-use time has passed.			Vial contains 1 dose

Administration

- COVID-19 vaccine may be administered at the same clinical visit as other routinely recommended vaccines.
- **Do NOT** "pool vaccine" from more than 1 vial to obtain a dose. If a full dose cannot be withdrawn, discard the multidose vial and any remaining vaccine.
- Withdraw 1 dose from a single-dose vial. After withdrawing the dose, discard the vial and any residual vaccine. Do NOT save used single-dose vials.
- Gently swirl vaccine to mix. **Do NOT** shake.

Recipient's Age	Vial Cap/Label Color	Administer	Route	Needle gauge and length	Site
6 months through 4 years	 Bivalent Maroon cap and maroon bordered label	3 µg/0.2 mL	IM injection	22–25 gauge, 1"	6 months – 2 years of age: Vastus lateralis muscle in the anterolateral thigh*
					3 years and older: Deltoid muscle in the upper arm†
5 through 11 years	 Bivalent Orange cap and orange bordered label	10 µg/0.2 mL	IM injection	22–25 gauge, 1"	Deltoid muscle in the upper arm†
12 years of age and older	 Bivalent Gray cap and gray bordered label Single-dose Vials and Multidose Vials	30 µg/0.3 mL	IM injection	22–25 gauge, 1 – 1½"	Deltoid muscle in the upper arm†

*The deltoid muscle in the upper arm may be used if the muscle mass is adequate.

† Vastus lateralis muscle in the anterolateral thigh may be used.

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Scheduling Doses

- The number of bivalent doses varies by age, vaccine, previous COVID-19 vaccines received, and the presence of moderate or severe immune compromise. Review [CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#) for detailed clinical guidance when scheduling doses, and the [Interim COVID-19 Immunization Schedule](#).
 - Children who turn from 4 to 5 years of age: Use vaccine from the maroon-capped vial (0.3mL/3 mcg) for all doses.
- Consider observing persons after vaccination to monitor for allergic reactions and syncope:
 - **30 minutes for persons with:**
 - » An allergy-related contraindication to a different type of COVID-19 vaccine
 - » A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
 - » A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies
 - **15 minutes:** All other persons

Document the vaccination

For each vaccine recipient, record

- Both in their medical record and on their vaccination card: vaccination date and vaccine administered (product name, manufacturer, lot number)
- In their medical record: vaccination site and route, vaccinator's name and title.
- On their vaccination card: name/location of clinic or health care professional, note bivalent dose if possible.

Report the vaccination to the appropriate [state/local immunization information system \(IIS\)](#)

Contraindications and precautions

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered. Use [CDC's Prevaccination Checklist for COVID-19 Vaccination](#) to determine whether the vaccine may be administered.

Contraindications

History of:

- 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 COVID-19 vaccine

Precautions

History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy, including intramuscular, intravenous, or subcutaneous vaccines or therapies, but excluding subcutaneous immunotherapy for allergies (i.e., "allergy shots").
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

Report adverse reactions and administration errors

Healthcare professionals are required to report to the [Vaccine Adverse Event Reporting System \(VAERS\)](#) including:

- 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 and children
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety requirements per the [Food and Drug Administration's](#) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to [VAERS](#) clinically important adverse events even if unsure whether the vaccine caused the adverse event.