2024-2025 Formula Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2024–25 Pfizer-BioNTech COVID-19 vaccine products.

Distributed in:

Ages: 6 months through 4 years
- **Multi-dose vial**
  yellow cap and yellow label

Ages: 5 through 11 years
- **Single-dose vial**
  blue cap and blue label

Ages: 12 years and older
- **Manufacturer-filled syringe**

Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Comirnaty | FDA
- Pfizer COVID-19 FACT SHEET
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Ages	6 months through 4 years	5 through 11 years	12 Years and Older
Supplied in:	3-dose multi-dose vial (MDV) with diluent	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)*
Cap and/or label color:	Yellow cap and yellow label	Blue cap and blue label	Not Applicable
Storage temperature before puncture or use after puncture	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. 8°C and 25°C (46°F and 77°F) for up to 12 hours prior to the first puncture. **Do NOT store in a standard freezer.** Once vials are thawed, they should not be refrozen. **Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.** **NOTE:** The beyond-use date (10 weeks) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date.		Between 2°C and 8°C (36°F and 46°F) until the expiration date. **Do NOT FREEZE.** **Note:** The total time out of refrigeration (at temperatures between 8°C and 25°C [46°F and 77°F]) must not exceed 12 hours. **Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.**
Thawing frozen vaccine	If not previously thawed at 2°C to 8°C (36°F and 46°F), allow MDV or SDV to thaw at room temperature up to 25°C (77°F) for 30 minutes. Cartons of MDV with yellow caps and labels and cartons of SDV with blue caps and labels may take up to **2 hours** to thaw at 2°C to 8°C (36°F and 46°F) temperature. Once vials are thawed, they should not be refrozen.		Not Applicable
Storage temperature for punctured vials or activated manufactured-filled syringe	After dilution, MDV should be held between 2°C to 25°C (35° to 77°F). **Note:** MDV should be discarded 12 hours after dilution.		After removing the tip cap and attaching an appropriate needle, the glass prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours or discarded. **DO NOT FREEZE.**

* Single-dose vials for people 12 years and older are not available in the U.S. but may be available in other countries.

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Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- COVID-19 Vaccines | FDA
- Package Insert and FDA Approved Patient Labeling - COMIRNATY
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Preparation

- Check that vial or syringe states 2024-25 Formula.
- If the vaccine is frozen, thaw before use.
- Check the vial or syringe label to ensure the expiration date or beyond-use date/time (if applicable) has not passed.
- Product for ages 6 months through 4 years: Mix with diluent.
  - Mix vial with 1.1 mL of diluent provided by the manufacturer. If using the MDV for the first time, record the date and time the vial was punctured. After dilution, MDV contain 3 doses of 0.3 mL each. If the amount of vaccine in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. **Do not pool excess vaccine from multiple vials.**
  - **NOTE:** The beyond-use time of 12 hours after dilution replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date.
  - **Do NOT use vaccine after the expiration date or beyond-use time.**
- Products for ages 5 years and older: **Do NOT dilute.**
- **For MDV:** Gently invert the vaccine vial 10 times to mix. **Do NOT shake.**
- **For SDV:** Prior to withdrawing the dose, mix by inverting the vial gently 10 times. **Do Not Shake**
- **Discard vial and any excess volume.**
- Refer to package insert or EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
6 months through 4 years of age	0.3 mL/3 *µg*	IM injection	22–25 gauge, 1 inch*	**6 months–2 years of age:** Vastus lateralis muscle in the anterolateral thigh†
				2 through 4 years: Deltoid muscle in the upper arm‡
5 through 11 years of age	0.3 mL/10 *µg*L	IM injection	22–25 gauge, 1 inch*	Deltoid muscle in the upper arm‡
12 years of age and older	0.3 mL/30 *µg*	IM injection	22–25 gauge, 1–1.5 inch*§	Deltoid muscle in the upper arm‡

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched for children and adolescents ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

† The deltoid muscle in the upper arm may be used if the muscle mass is adequate for children ages 1–2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

§ See Vaccine Administration: Needle Gauge and Length chart for more details.

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Scheduling Doses

The number of recommended 2024–25 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Current moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- **30 minutes** for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- **15 minutes:** All other persons

Reporting of Vaccine Adverse Events

For licensed Pfizer-BioNTech COVID-19 vaccines (for people ages 12 years and older), healthcare providers are **strongly encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

For Pfizer-BioNTech COVID-19 vaccines given under an Emergency Use Authorization (for persons 11 years of age and younger)Vaccination providers are **required** to report to VAERS:

- Vaccine administration errors whether or not associated with an adverse event(AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for other clinically significant adverse events, even if it is uncertain whether the vaccine caused the event.

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, anyone can register in About V-safe | Vaccine Safety Systems | CDC after their COVID-19 vaccination to receive health check-ins via text messages or email.