




# Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine

## At-A-Glance



Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2023–24 Pfizer-BioNTech COVID-19 Vaccine products.

### Distributed in:

 <b>Ages: 6 months through 4 years</b> <b>Multiple-dose vial:</b> yellow cap and yellow label	 <b>Ages: 5 through 11 years</b> <b>Single dose vial:</b> blue cap and blue label	 <b>Ages: 12 years and older</b> <b>Single-dose vial:</b> gray cap and gray label <b>Manufacturer-filled syringe</b>
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### Storage and Handling

Find additional guidance on storing vaccine properly at:

- [CDC Vaccine Storage and Handling Toolkit](#)
- [Pfizer-BioNTech COVID-19 Vaccine | FDA](#)
- [Comirnaty | FDA](#)
- [Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com](#)

Ages	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
<b>Supplied in:</b>	3-dose multiple-dose vial (MDV)	Single-dose vial (SDV)	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)
<b>Cap and/or label color:</b>	Yellow cap and yellow label	Blue cap and blue label	Gray cap and gray label	N/A
<b>Storage temperature before puncture</b>	<p><b>Between:</b></p> <ul style="list-style-type: none"> <li>▪ -90°C and -60°C (-130°F and -76°F) until the expiration date</li> <li>▪ 2°C and 8°C (36°F and 46°F) for up to 10 weeks</li> <li>▪ 8°C and 25°C (46°F and 77°F) for up to 12 hours prior to the first puncture or use.</li> </ul> <p><b>Do not store between -25°C and -15°C (-13°F and 5°F).</b></p> <p><b>NOTE:</b> The beyond-use date (10 weeks) replaces the manufacturer's expiration date but <b>NEVER</b> extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.</p>			
<b>Thawing frozen vaccine</b>	<p><b>Between:</b></p> <ul style="list-style-type: none"> <li>▪ 2°C and 8°C (36°F and 46°F) for up to 2 hours</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>▪ Up to 25°C (77°F) for 30 minutes</li> </ul>			<p><b>Between:</b></p> <ul style="list-style-type: none"> <li>▪ 2°C and 8°C (36°F and 46°F) for 2 hours (preferred method)</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>▪ Up to 25°C (77°F) for 60 minutes</li> </ul> <p><b>Note:</b> Individual syringes thawed at room temperature that are not used immediately must be used within 4 hours or discarded.</p>

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

### Preparation

- If the vaccine is frozen, thaw before use.
- Check the vial label to ensure the expiration date has not passed.
  - Use Pfizer-BioNTech expiration date tool at [lotexpiry.cvdvaccine.com](#)
- Product for ages 6 months through 4 years: mix with diluent.
  - Mix vial with 1.1 mL diluent. If using the MDV for the first time, record the date and time the vial was punctured.  
**NOTE:** The beyond-use time of 12 hours 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 through 11 years and 12 years and older: **Do NOT dilute.**
- **Do NOT shake.** If using an SDV, gently invert prior to withdrawing vaccine.
- 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.
- If using a MDV, Do NOT "pool vaccine" from more than 1 vial to obtain a dose. If a full dose cannot be withdrawn, discard the MDV and any remaining vaccine.
- If using a SDV, withdraw 1 dose. After withdrawing the dose, discard the vial and any residual vaccine. Do NOT save used SDVs.
- Administer intramuscularly.

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

\* 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 2023–24 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
- 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

### Documentation

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- **Vaccination record for recipient:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

### Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

- Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:
  - Vaccine administration errors, whether or not associated with an adverse event
  - Serious adverse events, irrespective of attribution to vaccination
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
  - Cases of myocarditis
  - Cases of pericarditis
  - Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, 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.