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.

### 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](#)

<table>
<thead>
<tr>
<th>Vial cap color</th>
<th>BIVALENT Maroon Cap</th>
<th>BIVALENT Orange Cap</th>
<th>BIVALENT Gray Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ages</td>
<td>6 months through 4 years</td>
<td>5 through 11 years</td>
<td>12 years and older</td>
</tr>
<tr>
<td>Supplied in:</td>
<td>MDV: 10 doses per vial Requires diluent</td>
<td>MDV: 10 doses per vial Requires diluent</td>
<td>MDV: 6 doses per vial SDV: 1 dose No diluent</td>
</tr>
</tbody>
</table>

**Storage Temperature: Before Puncture**

- **Maroon Cap (Ages 6 months through 4 years)**
  - 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.

- **Orange Cap (Ages 5 through 11 years)**
  - 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.

- **Gray Cap (Ages 12 years and older)**
  - 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.

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*Vaccine expires 18 months after the manufacture date on the vial. Use Pfizer-BioNTech expiration date tool at [lotexpiry.cvdvaccine.com](http://lotexpiry.cvdvaccine.com)*
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Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:
- Pfizer-BioNTech COVID-19 Vaccines | FDA
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Preparation Bivalent Vaccine

<table>
<thead>
<tr>
<th>Vial cap color</th>
<th>Bivalent Maroon Cap</th>
<th>Bivalent Orange Cap</th>
<th>Bivalent Gray Cap</th>
<th>Bivalent Gray Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ages</td>
<td>6 months through 4 years</td>
<td>5 through 11 years</td>
<td>12 years and older</td>
<td></td>
</tr>
<tr>
<td>Vial type</td>
<td>Multidose vial (MDV)</td>
<td>Multidose vial (MDV)</td>
<td>Multidose vial (MDV)</td>
<td>Single-dose vial (SDV)</td>
</tr>
<tr>
<td>Diluent*</td>
<td>2.2 mL per vial</td>
<td>1.3 mL per vial</td>
<td>No diluent</td>
<td>No diluent</td>
</tr>
<tr>
<td>Beyond-use date/time</td>
<td>After mixing with diluent, use within 12 hours.</td>
<td>After 1st puncture, use within 12 hours.</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Do NOT use a punctured multidose vial after 12 hours</td>
<td>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.</td>
<td>Vial contains 1 dose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

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

* 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.
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 and pericarditis (for mRNA vaccines)
- 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.