Vaccine Formulation/Presentation Guide

For further details, please scroll down and click to see the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Emergency Use Authorization Fact Sheet or contact US Medical Information at PfizerMedicalInformation.com or 1-800-438-1985.

Emergency Use Authorization
Pfizer-BioNTech COVID-19 Vaccine, Bivalent has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals aged 6 months of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheets at www.cvdvaccine-us.com.
**Verify the vials (including labels) prior to preparation and administration to help avoid dosing errors**

### Name

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Variant Composition</td>
<td>Bivalent: 1.5 mcg modRNA-Original and 1.5 mcg modRNA-Omicron BA.4/BA.5</td>
<td>Bivalent: 5 mcg modRNA-Original and 5 mcg modRNA-Omicron BA.4/BA.5</td>
<td>Bivalent: 15 mcg modRNA-Original and 15 mcg modRNA-Omicron BA.4/BA.5</td>
</tr>
<tr>
<td>Age Group</td>
<td>6 months through 4 years*</td>
<td>5 through 11 years*</td>
<td>12 years and older</td>
</tr>
<tr>
<td>Cap Color &amp; Label</td>
<td>Cap colors and labels with matching borders</td>
<td>Cap colors and labels with matching borders</td>
<td>Cap colors and labels with matching borders</td>
</tr>
<tr>
<td>NDC Codes</td>
<td>Multiple Dose Vial: 59287-0609-1</td>
<td>Multiple Dose Vial: 59287-0565-1</td>
<td>Multiple Dose Vial: 59287-0304-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Single Dose Vial: 59287-1404-1</td>
</tr>
</tbody>
</table>

*Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in vials with maroon caps and labels with maroon borders.

### Selected Safety Information

Do not administer Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of Pfizer-BioNTech COVID-19 Vaccine, Pfizer-BioNTech COVID-19 Vaccine, Bivalent, or COMIRNATY® (COVID-19 Vaccine, mRNA).

### Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.


Please see following page for dosage and storage information for individuals 6 months of age and older.

Please see Important Safety Information on page 4.

Please click or visit covidvaccine-us.com to see the Vaccination Provider and Recipient and Caregivers EUA Fact Sheets.
The original monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use in the United States.

### Vaccine Formulation/Presentation Guide

**For eligible individuals 6 months of age and older**

Verify the vials (including labels) prior to preparation and administration to help avoid dosing errors.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td>DILUTE BEFORE USE</td>
<td>5 through 11 years*</td>
<td>DO NOT DILUTE</td>
</tr>
<tr>
<td>Age Group</td>
<td>6 months through 4 years*</td>
<td>(<em>Age 5y to &lt;12y</em> on vial label)</td>
<td></td>
</tr>
<tr>
<td>Vial Cap Color</td>
<td>Maroon</td>
<td>Orange</td>
<td>Gray</td>
</tr>
<tr>
<td>Dose</td>
<td>3 mcg</td>
<td>10 mcg</td>
<td>30 mcg</td>
</tr>
<tr>
<td>Dose Volume</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>Amount of Diluent Needed per Vial</td>
<td>2.2 mL†</td>
<td>1.3 mL†</td>
<td>NO DILUTION</td>
</tr>
<tr>
<td>Doses per Vial</td>
<td>Multiple Dose Vial: 10 doses per vial (after dilution)</td>
<td>Multiple Dose Vial: 10 doses per vial (after dilution)</td>
<td>Multiple Dose Vial: 6 doses per vial</td>
</tr>
</tbody>
</table>

### Storage Conditions

- **Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]**: 18 months†
- **Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]**: DO NOT STORE
- **Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]**: 10 weeks
- **Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]**: 12 hours prior to first puncture (including any thaw time)³
- **After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]**: Discard after 12 hours§

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1. *Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in vials with maroon caps and labels with maroon borders.
2. **ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.**
3. **Do not refreeze thawed vials.**
4. **Regardless of storage condition, maroon cap, orange cap, and gray cap vaccines should not be used after 18 months from the date of manufacture printed on the vial and cartons. Expiry information can be found at:** [https://lotexpiry.cvdvaccine.com/](https://lotexpiry.cvdvaccine.com/).
5. **After dilution, the vial should be held between 2 °C to 25 °C (35 °F to 77 °F). Vials should be discarded 12 hours after dilution.**

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Please click or visit [cvdvaccine-us.com](http://cvdvaccine-us.com) to see the Vaccination Provider and Recipient and Caregivers EUA Fact Sheets.
Important Safety Information & Authorized Use

Important Safety Information

Do not administer Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of Pfizer-BioNTech COVID-19 Vaccine, Pfizer-BioNTech COVID-19 Vaccine, Bivalent, or COMIRNATY® (COVID-19 Vaccine, mRNA).

Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Monitor Pfizer-BioNTech COVID-19 Vaccine, Bivalent recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process. Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Limitation of Vaccine Effectiveness

Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Adverse Reactions

The safety of Pfizer-BioNTech COVID-19 Vaccine, Bivalent in individuals 6 months of age and older is based on the safety data accrued from the formulations described below because these vaccines are manufactured using the same process:

- safety data from clinical trials which evaluated primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine (monovalent formulation is no longer authorized for use in the United States),
- safety data from clinical trials which evaluated booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, Bivalent,
- safety data from a clinical study which evaluated a booster dose of bivalent vaccine (Original and Omicron BA.1), [not authorized or approved in the U.S., hereafter referred to as bivalent vaccine (Original and Omicron BA.1)] and
- postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine (monovalent formulation is no longer authorized for use in the United States) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Solicited adverse reactions include:

- 6 months through 23 months of age:
  Injection site redness, swelling, and tenderness; decreased appetite, drowsiness, fever, irritability.
- 2 years of age and older:
  Injection site pain, redness, and swelling; chills, diarrhea, fatigue, fever, headache, new or worsened muscle pain, vomiting.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors and all serious adverse events to the Vaccine Adverse Event Reporting System (VAERS) by submitting online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA” in the description section of the report. To the extent feasible, report adverse events to Pfizer 1-800-438-1985 or provide a copy of the VAERS form to Pfizer www.pfizersafetyreporting.com

AUTHORIZED USE


Please click for Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vaccination Provider and Recipient and Caregivers EUA Fact Sheets.

Find additional resources about the vaccines at www.cvdvaccine-us.com