Vaccine Formulation/Presentation Guide

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

Emergency Use Authorization

Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older for the Pfizer-BioNTech COVID-19 Vaccine and 5 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. The emergency uses are 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.

Interchangeability (Primary Series for Individuals 12 Years of Age and Older)

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

Because of the potential for vaccine administration errors, including dosing errors, vaccine presentations should only be used for the ages specified on the vial labels, cartons, or the respective age-based Fact Sheet. The information in the Fact Sheets supersedes the information printed on the vial labels and cartons.
Low dead-volume syringes and/or needles can be used to extract 6 doses from a single multiple dose vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.

* Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

### Distinguishing Between Gray Cap Vials: Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

- **Name**
  - Pfizer-BioNTech COVID-19 Vaccine
  - COMIRNATY® (COVID-19 Vaccine, mRNA)
  - Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

<table>
<thead>
<tr>
<th>Variant Composition</th>
<th>PRIMARY SERIES ONLY</th>
<th>BOOSTER DOSE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monovalent: 30 mcg modRNA-Original</td>
<td>Primary Series AU: as a 2-dose primary series to individuals 12 years of age and older; and a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise</td>
<td>Primary Series AU: as a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise</td>
</tr>
<tr>
<td>Bivalent: 15 mcg modRNA-Original and 15 mcg modRNA-Omicron BA.4/BA.5</td>
<td>Primary Series Indication: as a 2-dose primary series to individuals 12 years of age and older</td>
<td>AU: for 12 years of age and older as a single booster dose administered at least 2 months after: completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine</td>
</tr>
</tbody>
</table>

- **Cap Color & Label**
  - Gray caps and labels with gray borders

- **Selected Safety Information**
  - Do not administer Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of these vaccines.

- **Management of Acute Allergic Reactions**
  - Appropriate medical treatment used 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, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

- **Monitoring Vaccine Recipients**
  - Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Please see full Important Safety Information and Indication & Authorized Use on pages 6 through 8. Before administration, please scroll down and click or visit cvd vaccine-us.com to review the full Prescribing Information (COMIRNATY (COVID-19 Vaccine, mRNA) Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
**Vaccine Formulation/Presentation Guide**

For eligible individuals **12 years of age and older**

- **Age Group**: 12 years and older
- **Vial Cap Color**: Gray
- **Dose**: 30 mcg
- **Dose Volume**: 0.3 mL
- **Amount of Diluent Needed per Vial**: No dilution
- **Doses per Vial**: 6 doses per vial

**Storage Conditions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>PRIMARY SERIES ONLY</th>
<th>BOOSTER DOSE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra-Low-Temperature (ULT) Freezer</td>
<td>[−90 °C to −60 °C (−130 °F to −76 °F)]</td>
<td>12 months†</td>
</tr>
<tr>
<td>Freezer [−25 °C to −15 °C (−13 °F to 5 °F)]</td>
<td>DO NOT STORE</td>
<td></td>
</tr>
<tr>
<td>Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]</td>
<td></td>
<td>10 Weeks</td>
</tr>
<tr>
<td>Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]</td>
<td>12 hours prior to first puncture (including any thaw time)</td>
<td></td>
</tr>
<tr>
<td>After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]</td>
<td>Discard after 12 hours</td>
<td></td>
</tr>
</tbody>
</table>

Low dead-volume syringes and/or needles can be used to extract 6 doses from a single multiple dose vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.

*For vaccination of individuals advancing into the next age group (11 years of age turning 12 years of age) between any primary series dose, refer to the respective age-based Fact Sheet for Healthcare Providers for instructions for administration.

† Regardless of storage condition, gray cap vaccine should not be used after 12 months from the date of manufacture printed on the vial and carton.

**The original monovalent Pfizer–BioNTech COVID-19 Vaccine presentations are no longer authorized for booster doses.**

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Please see following pages for dosage and storage information for individuals 5 through 11 years of age and 6 months through 4 years of age.
Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial.

Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

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

### Distinguishing Between Orange Cap Vials:

<table>
<thead>
<tr>
<th>Name</th>
<th>Pfizer-BioNTech COVID-19 Vaccine</th>
<th>Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variant Composition</td>
<td>Monovalent: 10 mcg modRNA-Original</td>
<td>Bivalent: 5 mcg modRNA-Original and 5 mcg modRNA-Omicron BA.4/BA.5</td>
</tr>
<tr>
<td>Authorized Use (AU)</td>
<td>Primary Series AU: as a 2-dose primary series to individuals 5 through 11 years of age; and a third primary series dose to individuals 5 through 11 years of age with certain kinds of immunocompromise*</td>
<td>AU: for 5 through 11 years of age as a single booster dose administered at least 2 months after: • completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine</td>
</tr>
</tbody>
</table>

Selected Safety Information
Myocarditis and Pericarditis
Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
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 receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and 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).

Please see full Important Safety Information and Indication & Authorized Use on pages 6 through 8.

Before administration, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (COMIRNATY (COVID-19 Vaccine, mRNA) Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
For eligible individuals 6 months through 4 years of age and 5 through 11 years of age

For vaccination of individuals advancing into the next age group (4 years of age turning 5 years of age or 11 years of age turning 12 years of age) between any primary series dose, refer to the respective age-based Fact Sheet for Healthcare Providers for instructions for administration.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Vial Cap Color</th>
<th>Dose</th>
<th>Dose Volume</th>
<th>Amount of Diluent Needed per Vial*</th>
<th>Doses per Vial</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months through 4 years (See additional information in boxed maroon text to the right of table)</td>
<td>Maroon</td>
<td>3 mcg</td>
<td>0.2 mL</td>
<td>2.2 mL</td>
<td>10 doses per vial (after dilution)</td>
<td>Storage Conditions: 12 months†</td>
</tr>
<tr>
<td>5 through 11 years (&quot;Age 5y to &lt;12y&quot; on vial label)</td>
<td>Orange</td>
<td>10 mcg</td>
<td>0.2 mL</td>
<td>1.3 mL</td>
<td>10 doses per vial (after dilution)</td>
<td>Storage Conditions: 12 months†</td>
</tr>
<tr>
<td>5 through 11 years (&quot;Age 5y to &lt;12y&quot; on vial label) (See additional information in teal box to the right of table)</td>
<td>Orange</td>
<td>10 mcg</td>
<td>0.2 mL</td>
<td>1.3 mL</td>
<td>10 doses per vial (after dilution)</td>
<td>Storage Conditions: 12 months†</td>
</tr>
</tbody>
</table>

Storage Conditions:
- **Ultra-Low-Temperature (ULT) Freezer** [-90 °C to -60 °C (-130 °F to -76 °F)]: 12 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 dilution (including any thaw time)
- **After First Puncture** [2 °C to 25 °C (35 °F to 77 °F)]: Discard after 12 hours‡

* 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.

†Regardless of storage condition, maroon and orange cap vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons.

‡ Vials should be discarded 12 hours after dilution, even though some vial and carton labels may state that a vial should be discarded 6 hours after dilution. The information in the Fact Sheet supersedes the information printed on vial labels and cartons.

Please see full Important Safety Information and Indication & Authorized Use on pages 6 through 8. Before administration, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (COMIRNATY (COVID-19 Vaccine, mRNA) Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
Important Safety Information and Indication & Authorized Use

Important Safety Information
Do not administer Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY (COVID-19 Vaccine, mRNA), or Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of these vaccines.

Management of Acute Allergic Reactions
Appropriate medical treatment used 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, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis
Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

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 receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and 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, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Limitation of Effectiveness
Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Adverse Reactions

Primary Series Adverse Events
In a clinical study (3 mcg modRNA) of participants 6 through 23 months of age, adverse reactions following administration of any dose of Pfizer-BioNTech COVID-19 Vaccine included irritability (68.4%), decreased appetite (38.6%), tenderness at the injection site (26.4%), injection site redness (17.8%), fever (14.4%), injection site swelling (7.3%), and lymphadenopathy (0.2%).

In a clinical study (3 mcg modRNA) of participants 2 through 4 years of age, adverse reactions following administration of any dose of Pfizer-BioNTech COVID-19 Vaccine included pain at the injection site (47.0%), fatigue (44.8%), injection site redness (18.9%), fever (10.5%), headache (8.7%), injection site swelling (8.4%), chills (5.7%), muscle pain (5.0%), joint pain (2.4%), and lymphadenopathy (0.1%).

In a clinical study (10 mcg modRNA) of participants 5 through 11 years of age, adverse reactions following administration of any primary series dose of Pfizer-BioNTech COVID-19 Vaccine included pain at the injection site (84.3%), fatigue (51.7%), headache (38.2%), injection site redness (26.4%), injection site swelling (20.4%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%).

In clinical studies (30 mcg modRNA) of participants 12 through 15 years of age, the most commonly reported adverse reactions (≥8%) following any dose were pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), and injection site redness (8.6%).

In clinical studies (30 mcg modRNA) of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) following any dose were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).
In clinical studies (30 mcg modRNA) of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) following any dose were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

**Booster Dose Adverse Events**

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on:

- safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved, hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
- safety data from clinical trials which evaluated primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, and
- post marketing safety data with Pfizer-BioNTech COVID-19 Vaccine

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

The clinical study (30 mcg modRNA) that evaluated a booster dose of the bivalent vaccine (Original and Omicron BA.1) included participants greater than 55 years of age. Adverse reactions following administration of the bivalent vaccine (Original and Omicron BA.1) as a second booster dose included pain at the injection site (58.1%), fatigue (49.2%), headache (33.6%), muscle pain (22.3%), chills (13.0%), joint pain (11.3%), injection site redness (7.0%), injection site swelling (6.6%), fever (5.0%), lymphadenopathy (0.3%), nausea (0.3%), and malaise (0.3%).

In a clinical study (30 mcg modRNA) of participants 5 through 11 years of age, adverse reactions following administration of a single booster dose of Pfizer–BioNTech COVID-19 Vaccine were injection site pain (73.9%), fatigue (45.6%), headache (34.0%), muscle pain (18.3%), injection site swelling (16.4%), injection site redness (15.6%), chills (10.5%), fever (6.7%), joint pain (6.7%), diarrhea (4.9%), lymphadenopathy (2.5%), and vomiting (2.4%).

**Post Authorization Experience**

Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (eg, rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), and syncope have been reported following administration of the Pfizer–BioNTech COVID-19 Vaccine.

Myocarditis and pericarditis have been reported following administration of the Pfizer–BioNTech COVID-19 Vaccine.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of Pfizer–BioNTech COVID-19 Vaccine and post authorization use of the Pfizer–BioNTech COVID-19 Vaccine, Bivalent.
Important Safety Information and Indication & Authorized Use (cont’d)

Interchangeability (Primary Series for Individuals 12 Years of Age and Older)

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

Because of the potential for vaccine administration errors, including dosing errors, vaccine presentations should only be used for the ages specified on the vial labels, cartons, or the respective age-based Fact Sheet. The information in the Fact Sheets supersedes the information printed on the vial labels and cartons.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Authorized Use


EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
EUA Fact Sheet for Vaccination Providers (Primary Series 12 years of age and older), DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (Primary Series 12 years of age and older), DILUTE BEFORE USE, Purple Cap
COMIRNATY Full Prescribing Information (Primary Series 12 years of age and older), DO NOT DILUTE, Gray Cap
COMIRNATY Full Prescribing Information (Primary Series 12 years of age and older), DILUTE BEFORE USE, Purple Cap

Before administration of booster dose vaccination, please click to see EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (Booster Dose 5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (Booster Dose 12 years of age and older), DO NOT DILUTE, Gray Cap

Click here for Recipients and Caregivers Fact Sheets

Recipients and Caregivers Fact Sheet (6 months through 4 years of age)
Recipients and Caregivers Fact Sheet: (Primary Series and Bivalent Booster Dose 5 through 11 years of age)
Recipients and Caregivers Fact Sheet: (Primary Series and Bivalent Booster Dose 12 years of age and older)

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