Vaccine Formulation/Presentation Guide

For further details please scroll down and click to see the COMIRNATY® (COVID-19 Vaccine, mRNA) full Prescribing Information, and respective Pfizer-BioNTech COVID-19 Vaccine and 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 Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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 as appropriate. 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 of COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine (Primary Series for Individuals 12 Years of Age and Older)
When prepared according to their respective instructions for use, the FDA-approved COMIRNATY 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.

Age-Specific Vaccine Presentation Information
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.
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)*

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

### PRIMARY SERIES ONLY

<table>
<thead>
<tr>
<th>Name</th>
<th>Variant Composition</th>
<th>Authorized Use (AU) or Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech COVID-19 Vaccine</td>
<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>
</tr>
<tr>
<td>DO NOT DILUTE</td>
<td></td>
<td>Primary Series Indication: as a 2-dose primary series to individuals 12 years of age and older</td>
</tr>
</tbody>
</table>
| COMIRNATY® (COVID-19 Vaccine, mRNA)       |                              | AU: for 12 years of age and older as a single booster dose administered at least 2 months after either:  
| DO NOT DILUTE                             |                              | • completion of primary vaccination with any authorized or approved COVID-19 vaccine, or  
|                                           |                              | • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine |

### BOOSTER DOSE ONLY

<table>
<thead>
<tr>
<th>Name</th>
<th>Variant Composition</th>
<th>Authorized Use (AU) or Indication</th>
</tr>
</thead>
</table>
| Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) | Bivalent: 15 mcg modRNA-Original and 15 mcg modRNA-Omicron BA.4/BA.5 | AU: for 12 years of age and older as a single booster dose administered at least 2 months after either:  
| DO NOT DILUTE                             |                              | • completion of primary vaccination with any authorized or approved COVID-19 vaccine, or  
|                                           |                              | • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine |

**Selected 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 the 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).

Please see following page for dosage and storage information for individuals 12 years of age and older (gray cap).

Please see full Important Safety Information and Indication & Authorized Use on pages 7 through 9.

Before administration, please scroll down and click or visit cvdvaccine-us.com to review the COMIRNATY® (COVID-19 Vaccine, mRNA) full Prescribing Information 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**

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

<table>
<thead>
<tr>
<th>PRIMARY SERIES ONLY</th>
<th>BOOSTER DOSE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group</strong></td>
<td><strong>12 years and older</strong>&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>Vial Cap Color</td>
<td>Gray</td>
</tr>
<tr>
<td>Dose</td>
<td>30 mcg</td>
</tr>
<tr>
<td>Dose Volume</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>Amount of Diluent Needed per Vial</td>
<td>NO DILUTION</td>
</tr>
<tr>
<td>Doses per Vial</td>
<td>Multiple dose vial: 6 doses per vial</td>
</tr>
</tbody>
</table>

**Storage Conditions**

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra-Low-Temperature (ULT) Freezer (-90 °C to -60 °C (-130 °F to -76 °F))</td>
<td>18 months&lt;sup&gt;†&lt;/sup&gt;</td>
</tr>
<tr>
<td>Freezer (-25 °C to -15 °C (-13 °F to 5 °F))</td>
<td><strong>DO NOT STORE</strong></td>
</tr>
<tr>
<td>Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]</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>
</tr>
<tr>
<td>After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

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**Identify the name on the vial label. Bivalent vial will specify:**

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

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

Low dead-volume syringes and/or needles can be used to extract 6 doses from one multiple dose vial.

If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.

<sup>*</sup>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.

<sup>†</sup>Regardless of storage condition, gray cap vaccine should not be used after 18 months from the date of manufacture printed on the vial and carton.

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Pfizer-BioNTech COVID-19 Vaccine is no longer supplied in vials with a purple cap in the US. For information related to Pfizer-BioNTech COVID-19 Vaccine, Dilute Before Use, purple cap, please review the EUA Fact Sheet and the full Prescribing Information or visit cvdvaccine-us.com.

Expiry information can be found at:

https://lotexpiry.cvdvaccine.com/

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Please see following page for distinguishing information between orange cap vials for individuals 5 through 11 years of age.

Please see full Important Safety Information and Indication & Authorized Use on pages 7 through 9.

Before administration, please scroll down and click or visit cvdvaccine-us.com to review the COMIRNATY® (COVID-19 Vaccine, mRNA) full Prescribing Information and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
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

<table>
<thead>
<tr>
<th>Name</th>
<th>Pfizer-BioNTech COVID-19 Vaccine DILUTE BEFORE USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variant Composition</td>
<td>Monovalent: 10 mcg modRNA-Original</td>
</tr>
<tr>
<td><em>Monovalent</em> refers to vaccine that encodes the spike protein of only the Original SARS-CoV-2</td>
<td></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>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) DILUTE BEFORE USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variant Composition</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>AU: for 5 through 11 years of age as a single booster dose administered at least 2 months after either: • completion of primary vaccination with any authorized or approved 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
Orange caps and labels with orange borders

Selected Safety Information
Myocarditis and Pericarditis
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 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 following page for distinguishing information between maroon cap vials for individuals 6 months through 4 years of age.

Please see full Important Safety Information and Indication & Authorized Use on pages 7 through 9. Before administration, please scroll down and click or visit cvdvaccine-us.com to review the COMIRNATY® (COVID-19 Vaccine, mRNA) full Prescribing Information and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
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.

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

**Pfizer-BioNTech COVID-19 Vaccine**

DILUTE BEFORE USE

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

DILUTE BEFORE USE

### Distinguishing Between Maroon Cap Vials:

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

<table>
<thead>
<tr>
<th>PRIMARY SERIES</th>
<th>DOSES 1 AND 2</th>
<th>DOSE 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
<td>Pfizer-BioNTech COVID-19 Vaccine</td>
<td>Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)</td>
</tr>
<tr>
<td><strong>Variant Composition</strong></td>
<td>Monovalent: 3 mcg modRNA-Original</td>
<td>Bivalent: 1.5 mcg modRNA-Original and 1.5 mcg modRNA-Omicron BA.4/BA.5</td>
</tr>
<tr>
<td><strong>Authorized Use (AU)</strong></td>
<td>Primary Series AU: As Dose 1 and Dose 2 in a 3-dose primary series in individuals 6 months through 4 years of age*</td>
<td>AU: As Dose 3 in a 3-dose primary series in individuals 6 months through 4 years of age*</td>
</tr>
</tbody>
</table>

Cap Color & Label
Orange caps and labels with orange borders

Pfizer-BioNTech COVID-19 Vaccine
NDC number: Multiple Dose Vial 59267-0078-01

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
NDC number: Multiple Dose Vial 59267-0609-1

Selected Safety Information

**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.

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

**Pfizer-BioNTech COVID-19 Vaccine, Bivalent maroon cap vials have the same storage, handling, preparation, dose volume, and administration instructions as Pfizer-BioNTech COVID-19 Vaccine maroon cap vials.**

Please see following page for dosage and storage information for individuals 6 months through 4 years of age (maroon cap) and 5 through 11 years of age (orange cap).

Please see full Important Safety Information and Indication & Authorized Use on pages 7 through 9.

Before administration, please scroll down and click or visit cvdvaccine-us.com to review the COMIRNATY® (COVID-19 Vaccine, mRNA) full Prescribing Information and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
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>PRIMARY SERIES</th>
<th>PRIMARY SERIES ONLY</th>
<th>BOOSTER DOSE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months through 4 years</td>
<td>PFIZER-BIONTECH COVID-19 VACCINE, AND PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT, DILUTE BEFORE USE™</td>
<td>PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT, DILUTE BEFORE USE™</td>
<td>PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT, DILUTE BEFORE USE™</td>
</tr>
<tr>
<td>Vial Cap Color</td>
<td>Maroon</td>
<td>Orange</td>
<td>Orange</td>
</tr>
<tr>
<td>Dose</td>
<td>3 mcg</td>
<td>10 mcg</td>
<td>10 mcg</td>
</tr>
<tr>
<td>Dose Volume</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>Amount of Diluent Needed per Vial*</td>
<td>2.2 mL</td>
<td>1.3 mL</td>
<td>1.3 mL</td>
</tr>
<tr>
<td>Doses per Vial</td>
<td>10 doses per vial (after dilution)</td>
<td>10 doses per vial (after dilution)</td>
<td>10 doses per vial (after dilution)</td>
</tr>
<tr>
<td>Storage Conditions</td>
<td>Storage Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultra-Low-Temperature (ULT) Freezer [−90 °C to −60 °C (−130 °F to −76 °F)]</td>
<td>18 months†</td>
<td>18 months†</td>
<td></td>
</tr>
<tr>
<td>Freezer [−25 °C to −15 °C (−13 °F to 5 °F)]</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
<td></td>
</tr>
<tr>
<td>Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]</td>
<td>10 weeks</td>
<td>10 weeks</td>
<td></td>
</tr>
<tr>
<td>Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]</td>
<td>12 hours prior to dilution (including any thaw time)</td>
<td>12 hours prior to dilution (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>Discard after 12 hours</td>
<td></td>
</tr>
</tbody>
</table>

*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 18 months from the date of manufacture printed on the vial and cartons. Expiry information can be found at: https://lotexpiry.cvdvaccine.com/.‡ 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.

For eligible individuals 6 months through 4 years of age and 5 through 11 years of age.

Please see full Important Safety Information and Indication & Authorized Use on pages 7 through 9.
Before administration, please scroll down and click or visit cvdvaccine-us.com to review the COMIRNATY® (COVID-19 Vaccine, mRNA) full Prescribing Information 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 the 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
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 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 Immune Competence
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.

Continued on next page.
In a clinical study (10 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%).

In clinical studies (30 mcg modRNA) of participants 5 through 11 years of age, the most commonly reported adverse reactions (≥8%) following any dose of Pfizer-BioNTech COVID-19 Vaccine 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 a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a first booster dose of Pfizer-BioNTech COVID-19 Vaccine were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%). Severe allergic reactions (including anaphylaxis), myocarditis and pericarditis have been reported following administration of Pfizer-BioNTech COVID-19 Vaccine.

In clinical studies (30 mcg modRNA) of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) following any dose of Pfizer-BioNTech COVID-19 Vaccine 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 a clinical study (30 mcg modRNA) of participants 12 through 15 years of age, adverse reactions following administration of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine were injection site pain (73.9%), 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%).

In clinical studies (30 mcg modRNA) of participants 12 through 15 years of age, the most commonly reported adverse reactions (≥8%) following any dose of Pfizer-BioNTech COVID-19 Vaccine were pain at the injection site (88.6%), 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 a clinical study (30 mcg modRNA) of participants 16 through 55 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%).

In clinical studies (30 mcg modRNA) of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥8%) following any dose of Pfizer-BioNTech COVID-19 Vaccine were pain at the injection site (88.6%), 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 a clinical study (30 mcg modRNA) of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) following any dose of Pfizer-BioNTech COVID-19 Vaccine 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%).

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

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

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 Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

INDICATION AND AUTHORIZED USE
COMIRNATY® (COVID-19 Vaccine, mRNA)

Indication & Authorized Use
COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. It is also authorized for emergency use to provide a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.


Authorized Use
Interchangeability of COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine (Primary Series for Individuals 12 Years of Age and Older)

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY 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.

Age-Specific Vaccine Presentation Information

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.

References: