The Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY® (COVID-19 Vaccine, mRNA)

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.

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.

Emergency Use Authorization
Emergency uses of the vaccine 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 6 months of age and older. 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.

Because of the potential for vaccine administration errors, including dosing errors, COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 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.

Instructions for Each Presentation/Formulation

- For 12 years of age and older, DILUTE BEFORE USE (Purple Cap) formulation: pages 2-5
- For 12 years of age and older, DO NOT DILUTE (Gray Cap) formulation: pages 6-8
- For 5 through 11 years of age, DILUTE BEFORE USE (Orange Cap) formulation: pages 9-11
- For 6 months through 4 years of age, DILUTE BEFORE USE (Maroon Cap) formulation: pages 12-14

Selected Safety Information

Do not administer to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Vial Verification

- Verify that the vial of vaccine has a purple plastic cap. Some vials also may have a purple label border on the vial label.

Thawing Prior to Dilution

- Thaw vial(s) of vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month.
  - Allowing vial(s) to sit at room temperature (up to 25°C [77°F]) for 30 minutes.

- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

- Before dilution invert vaccine vial gently 10 times.
- Do not shake.

- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

Dilution

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.

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.

Please see additional Dilution steps on the next page.

Please see Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Withdrawal of Individual 0.3 mL Doses

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the vaccine, preferentially using a low dead-volume syringe and/or needle
- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Administer immediately

Selected Safety Information

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 the vaccine.

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 additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17. Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Primary Series

The vaccine is administered intramuscularly as a primary series of 2 doses (0.3 mL each) 3 weeks apart in individuals 12 years of age and older.

A third primary series dose of the vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age with certain kinds of immunocompromise.*

* 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.

Selected Safety Information

Myocarditis and Pericarditis

Myocarditis and pericarditis have been reported following administration of the vaccine.

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males. 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 the vaccine.

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Vaccination Schedule¹ (cont’d)

Booster Doses

First Booster Dose
A first booster dose (0.3 mL) of the vaccine is authorized for emergency use and may be administered at least 5 months after completing a primary series of the vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals 12 years of age and older. A first booster dose of the vaccine may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Second Booster Dose
A second booster dose of the vaccine (0.3 mL) may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
A second booster dose of the vaccine (0.3 mL) may be administered at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine to individuals 12 years of age and older with certain kinds of immunocompromise. *

* 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.

Selected Safety Information

Limitation of Effectiveness
The vaccine may not protect all vaccine recipients.

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 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 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%).

Continued on page 7.

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.
Before administration of the vaccine, please click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Fact Sheets for individuals 6 months through 4 years of age
EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
Recipients and Caregivers Fact Sheet (6 months through 4 years of age)
Fact Sheets for individuals 5 through 11 years of age
EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
Recipients and Caregivers Fact Sheet (5 through 11 years of age)
Fact Sheets and Prescribing Information for individuals 12 years of age and older
Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
Recipients and Caregivers Fact Sheet (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, COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer–BioNTech COVID-19 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.

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.

**Vial Verification**

- Verify that the vial of vaccine has a *gray plastic cap* and a label with a *gray border*

**Thawing Prior to Use**

- Thaw vial(s) of vaccine (Do Not Dilute, for 12 years of age and older) before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 6 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes
- Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use

- Before use, mix by inverting vaccine vial gently 10 times
- **Do not shake**
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles
- **Do not use if liquid is discolored or if particles are observed after mixing**

**Preparation of Individual 0.3 mL Doses**

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw **0.3 mL** of the vaccine, preferentially using a low dead-volume syringe and/or needle
- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Administer immediately

Please see additional Preparation steps on next page.

Please see Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Preparation of Individual 0.3 mL Doses (cont’d)

- Record the date and time of first vial puncture on the vial label
- Store between 2°C to 25°C (35°F to 77°F)
- Discard any unused vaccine 12 hours after first puncture

Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection:

- Verify the final dosing volume of 0.3 mL
- Confirm there are no particulates and that no discoloration is observed
- Do not administer if vaccine is discolored or contains particulate matter

Administer the vaccine intramuscularly.

Vials of vaccine with gray caps and labels with gray borders contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Do not pool excess vaccine from multiple vials

Vaccination Schedule

Primary Series

The vaccine is administered intramuscularly as a primary series of 2 doses (0.3 mL each) 3 weeks apart in individuals 12 years of age and older.

A third primary series dose of the vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age with certain kinds of immunocompromise.*

*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.

Please see additional Vaccination Schedule information on next page.

Selected Safety Information

Primary Series Adverse Events (cont’d):

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of any primary series dose 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 adolescents 12 through 15 years of age, the most commonly reported adverse reactions (≥8%) 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 (8.8%).

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Vaccination Schedule² (cont’d)

**Booster Doses**

**First Booster Dose**

A first booster dose (0.3 mL) of the vaccine is authorized for emergency use and may be administered at least 5 months after completing a primary series of the vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals 12 years of age and older.

A first booster dose of the vaccine may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

**Second Booster Dose**

A second booster dose of the vaccine (0.3 mL) may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.

A second booster dose of the vaccine (0.3 mL) may be administered at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine to individuals 12 years of age and older with certain kinds of immunocompromise.*

*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.

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**Selected Safety Information**

**Primary Series Adverse Events (cont’d):**

In clinical studies (30 mcg modRNA) of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) 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%) 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%).

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Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.

Fact Sheets for individuals 6 months through 4 years of age

- EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
- Recipients and Caregivers Fact Sheet (6 months through 4 years of age)

Fact Sheets for individuals 5 through 11 years of age

- EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- Recipients and Caregivers Fact Sheet (5 through 11 years of age)

Fact Sheets and Prescribing Information for individuals 12 years of age and older

- Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
- Recipients and Caregivers Fact Sheet (12 years of age and older)
Because of the potential for vaccine administration errors, including dosing errors, the Pfizer-BioNTech COVID-19 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.

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.

**Vial Verification**

- Verify that the vial of vaccine has an **orange plastic cap** and a label with an **orange border** and states “Age 5y to < 12y”

**Thawing Prior to Dilution**

- Thaw vial(s) of vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes
  - Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use

- Before dilution, mix by inverting vaccine vial gently 10 times
  - **Do not shake**

- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles
  - **Do not use if liquid is discolored or if other particles are observed**

**Dilution**

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent
- Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle)
- Cleanse the vaccine vial stopper with a single-use antiseptic swab
- Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial
- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe

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.

Please see additional Dilution steps on the next page.

Please see Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Withdrawal of Individual 0.2 mL Doses

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the vaccine, preferentially using a low dead-volume syringe and/or needle
- Each dose must contain 0.2 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume
- Administer immediately

Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection:

- Verify the final dosing volume of 0.2 mL
- Confirm there are no particulates and that no discoloration is observed
- Do not administer if vaccine is discolored or contains particulate matter

Administer the vaccine intramuscularly.

Please see additional Administration Information on the next page.

Selected Safety Information

**Booster Dose Adverse Events:**

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of a single booster dose 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%).

Continued on next page.

Please see Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
**Administration Information** (cont’d)

After dilution, vials of vaccine with orange caps and labels with orange borders contain 10 doses of 0.2 mL of vaccine. 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. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content
- Do not pool excess vaccine from multiple vials

**Vaccination Schedule**

**Primary Series**
The vaccine is administered intramuscularly as a primary series of 2 doses (0.2 mL each) 3 weeks apart in individuals 5 through 11 years of age.

A third primary series dose of the vaccine supplied in multiple dose vials with orange caps and labels with orange borders (0.2 mL) at least 28 days following the second dose is authorized for administration to individuals 5 through 11 years of age with certain kinds of immunocompromise.*

*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.

**Booster Dose**
A single vaccine booster dose (0.2 mL) may be administered at least 5 months after completing a primary series of the vaccine to individuals 5 through 11 years of age.

**Selected Safety Information**

**Booster Dose Adverse Events (cont’d):**

In a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a first booster dose 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%).

**Post Authorization Experience**
Severe allergic reactions, including anaphylaxis, have been reported following administration of the vaccine.

Myocarditis and pericarditis have been reported following administration of the vaccine.

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.
Before administration of the vaccine, please click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.

Fact Sheets for individuals 6 months through 4 years of age
- EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
- Recipients and Caregivers Fact Sheet (6 months through 4 years of age)

Fact Sheets for individuals 5 through 11 years of age
- EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- Recipients and Caregivers Fact Sheet (5 through 11 years of age)

Fact Sheets and Prescribing Information for individuals 12 years of age and older
- Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
- Recipients and Caregivers Fact Sheet (12 years of age and older)
HOW TO PREPARE AND DOSE
DILUTE BEFORE USE (MAROON CAP) - 6 MONTHS THROUGH 4 YEARS OF AGE

Because of the potential for vaccine administration errors, including dosing errors, the 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.

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.

The vial labels may state “Age 2y to < 5y” or “Age 6m to < 5y” and carton labels may state “For age 2 years to < 5 years” or “For age 6 months to < 5 years.” Vials with either printed age range can be used for individuals 6 months through 4 years of age.

### Vial Verification

- Verify that the vial of vaccine has a maroon plastic cap and a label with a maroon border

### Thawing Prior to Dilution

- Thaw vial(s) of vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 2 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes
- Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use

- Before dilution, mix by inverting vaccine vial gently 10 times
- Do not shake
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles
- Do not use if liquid is discolored or if other particles are observed

### Dilution

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent
- Using aseptic technique, withdraw 2.2 mL of diluent into a transfer syringe (21-gauge or narrower needle)
- Cleanse the vaccine vial stopper with a single-use antiseptic swab
- Add 2.2 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial

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.

*Please see additional Dilution steps on the next page.*

Please see Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Dilution\(^4\) (cont’d)

- Equalize vial pressure before removing the needle from the vial by withdrawing 2.2 mL air into the empty diluent syringe
- Gently invert the vial containing the vaccine 10 times to mix
  - Do not shake
  - Inspect the vaccine in the vial
  - The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter
- Record the date and time of dilution on the vial label
  - Store between 2°C to 25°C (35°F to 77°F)
  - Discard any unused vaccine 12 hours after dilution

Withdrawal of Individual 0.2 mL Doses\(^4\)

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the vaccine, preferentially using a low dead-volume syringe and/or needle
- Each dose must contain 0.2 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume
- Administer immediately

Selected Safety Information

Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine.

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 the vaccine.

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 additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.
Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection:

- Verify the final dosing volume of 0.2 mL
- Confirm there are no particulates and that no discoloration is observed
- Do not administer if vaccine is discolored or contains particulate matter

Administer the vaccine intramuscularly.

After dilution, vials of vaccine with maroon caps and labels with maroon borders contain 10 doses of 0.2 mL of vaccine. 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. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content
- Do not pool excess vaccine from multiple vials

Vaccination Schedule

Primary Series

The vaccine is administered intramuscularly as a primary series of 3 doses (0.2 mL each) in individuals 6 months through 4 years of age. The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose.

Individuals who will turn from 4 years to 5 years of age between any doses in the primary series may receive:

- a 2-dose primary series with the vaccine authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA, supplied in multiple dose vials with orange caps and labels with orange borders)
  OR
- a 3-dose primary series initiated with the vaccine authorized for use in individuals 6 months through 4 years of age (each 0.2 mL dose containing 3 mcg modRNA, supplied in multiple dose vials with maroon caps). Each of Doses 2 and 3 may be with:
  - Vaccine authorized for use in individuals 6 months through 4 years of age (supplied in multiple dose vials with maroon caps), or
  - Vaccine authorized for use in individuals 5 years through 11 years of age (supplied in multiple dose vials with orange caps and labels with orange borders)

Booster Dose

A booster dose is not authorized for children 6 months through 4 years of age.

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 through 17.

Before administration of the vaccine, please click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.

Fact Sheets for individuals 6 months through 4 years of age
- EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
- Recipients and Caregivers Fact Sheet (6 months through 4 years of age)

Fact Sheets for individuals 5 through 11 years of age
- EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- Recipients and Caregivers Fact Sheet (5 through 11 years of age)

Fact Sheets and Prescribing Information for individuals 12 years of age and older
- Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
- Recipients and Caregivers Fact Sheet (12 years of age and older)
Important Safety Information and Indication & Authorized Use

Important Safety Information

Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine.

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 the vaccine.

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 vaccine.

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males. 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 the vaccine.

Limitation of Effectiveness

The vaccine may not protect all vaccine recipients.

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 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 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) in children 5 through 11 years of age, adverse reactions following administration of any primary series dose 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 adolescents 12 through 15 years of age, the most commonly reported adverse reactions (≥8%) 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%) 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%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.8%), 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%).

Continued on next page.

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 16 and 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Booster Dose Adverse Events:

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of a single booster dose 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 a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a first booster dose 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%).

Post Authorization Experience

Severe allergic reactions, including anaphylaxis, have been reported following administration of the vaccine. Myocarditis and pericarditis have been reported following administration of the vaccine.

Indication & Authorized Use

Indication

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.

Interchangeability

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, COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 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.

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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is authorized for emergency use to provide:

• a third 30 mcg modRNA primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise
• a first 30 mcg modRNA booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
• a first 30 mcg modRNA booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination
• a second 30 mcg modRNA booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
• a second 30 mcg modRNA booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 to provide:

• a 3-dose 3 mcg modRNA primary series to individuals 6 months through 4 years of age
• a 2-dose 10 mcg modRNA primary series to individuals 5 through 11 years of age
• a 2-dose 30 mcg modRNA primary series to individuals 12 years of age and older
• a third 10 mcg modRNA primary series dose to individuals 5 through 11 years of age with certain kinds of immunocompromise

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 and 17.

Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.
Important Safety Information and Indication & Authorized Use (cont’d)

- a third 30 mcg modRNA primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise
- a single 10 mcg modRNA booster dose to individuals 5 through 11 years of age who have completed a primary series with Pfizer–BioNTech COVID-19 Vaccine
- a first 30 mcg modRNA booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer–BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
- a first 30 mcg modRNA booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination
- a second 30 mcg modRNA booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second 30 mcg modRNA booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 15 and 16.

Before administration of the vaccine, please click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and respective EUA Fact Sheets.

Fact Sheets for individuals 6 months through 4 years of age
- EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
- Recipients and Caregivers Fact Sheet (6 months through 4 years of age)

Fact Sheets for individuals 5 through 11 years of age
- EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- Recipients and Caregivers Fact Sheet (5 through 11 years of age)

Fact Sheets and Prescribing Information for individuals 12 years of age and older
- Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
- Recipients and Caregivers Fact Sheet (12 years of age and older)
Find additional resources about the vaccine at www.cvdvaccine-us.com


The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.