CHECKLIST

for storage, handling, and preparation of the Pfizer-BioNTech COVID-19 Vaccine

AVAILABLE VACCINE PRESENTATIONS

Please see the Dosing and Preparation Guide and the Formulation/Presentation Guide for differences in storage, handling, and preparation requirements.

For individuals 12 years of age and older:

DO NOT USE *for individuals 6 months through 11 years of age*

DILUTE BEFORE USE
vials with purple caps

DO NOT DILUTE
vials with gray caps

For individuals 5 through 11 years of age:

DO NOT USE *for individuals 6 months through 4 years of age or individuals 12 years of age and older*

DILUTE BEFORE USE
vials with orange caps
("Age 5y to <12y" on vial label)

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 Pfizer-BioNTech COVID-19 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 Pfizer-BioNTech COVID-19 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:*
  - *Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (supplied in multiple dose vials with maroon caps), or*
  - *Pfizer-BioNTech COVID-19 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)*

For individuals 6 months through 4 years of age:

DO NOT USE *for 5 years of age and older*

DILUTE BEFORE USE
vials with maroon caps
(Vial labels may state "Age 2y to <5y" or "Age 6m to <5y." Vials with either printed age range can be used for individuals 6 months through 4 years of age)

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.

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.

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 full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
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 the respective EUA Fact Sheets.

BIONTECH Pfizer

MULTIPLE DOSE VIAL FOR INDIVIDUALS 12 YEARS OF AGE AND OLDER - DILUTE BEFORE USE (PURPLE CAP)

Vaccines may be received in medium or single-use thermal shipping containers. The single-use thermal shipping container cannot be used as temporary storage.

Storage and Handling of the Vaccine and Thermal Shipping Container

Reminder: This presentation for **individuals 12 years of age and older** comes in a multiple dose vial that contains **6 doses** after dilution.

Resource materials available on www.cvdvaccine-us.com:

- ☐ EUA Fact Sheet for Vaccination Providers (12 years and older), DILUTE BEFORE USE, Purple Cap
- ☐ Full Prescribing Information (16 years of age and older), DILUTE BEFORE USE, Purple Cap
- ☐ EUA Fact Sheet for Recipients and Caregivers (12 years and older)
- ☐ Dosing and Preparation Guide
- ☐ Dry Ice Replenishment Sheet
- ☐ Returning Real-Time Temperature Monitor and Thermal Shipping Container Instructions
- ☐ Shipping and Handling Guidelines
- ☐ Formulation/Presentation Guide

Materials checklist for storage and handling:

- ☐ Safety goggles or safety glasses with side shields
- ☐ Waterproof insulated gloves
- ☐ Box cutter or tool to open box
- ☐ Hand truck or dolly to move the thermal shipping container, which can weigh up to ~36 kg (~80 lb)
- ☐ Ultra-low-temperature freezer, freezer, or refrigerator

For information on alternate, temporary storage options and transfer times between environments, visit www.cvdvaccine-us.com.

If using the medium thermal shipping container as temporary storage, you will also need:

- ☐ Dry ice supply (ice pellets 10-16 mm, for re-icing)
- ☐ Dry ice scoop
- ☐ Temperature-monitoring device
- ☐ Packing tape or equivalent
- ☐ A method for tracking dry ice replenishment dates to ensure protocol is being followed

Before receiving the thermal shipping container, you must have:

- ☐ A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- ☐ An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- ☐ Proper security so only authorized personnel can access the thermal shipping container contents
- ☐ Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
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 the respective EUA Fact Sheets.

MULTIPLE DOSE VIAL FOR INDIVIDUALS 12 YEARS OF AGE AND OLDER - DILUTE BEFORE USE (PURPLE CAP)

Thawing, Dilution, and Preparation

Reminder: This presentation for **individuals 12 years of age and older** comes in a multiple dose vial that contains **6 doses** after dilution.

Materials checklist for vaccine preparation:
(Dilute Before Use, 12 years of age and older)

- ☐ **If removing from ultra-low-temperature storage:** Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
  - ☐ Secondary container, such as a small tray, to transport vials removed from original vial carton
- ☐ 3-mL or 5-mL syringe (for dilution)
- ☐ 21-gauge or narrower needle (for dilution)
- ☐ Low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- ☐ Vials of sterile 0.9% Sodium Chloride Injection, USP (for one-time use). ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent
- ☐ Antiseptic swabs
- ☐ Sharps container for disposal

For detailed step by step instructions for preparation and administration, please refer to the EUA Fact Sheet for Vaccination Providers which is available at www.cvdvaccine-us.com.

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
Before administration of the vaccine, please visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the 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
- Full Prescribing Information (12 years of age and older), DILUTE BEFORE USE, Purple 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)**

MULTIPLE DOSE VIAL FOR INDIVIDUALS 12 YEARS OF AGE AND OLDER - DO NOT DILUTE (GRAY CAP)

Vaccines may be received in medium or single-use thermal shipping containers. The single-use thermal shipping container cannot be used as temporary storage.

Storage and Handling of the Vaccine and Thermal Shipping Container

Reminder: DO NOT DILUTE. This presentation for individuals 12 years of age and older comes in a multiple dose vial that contains **6 doses**.

Resource materials available on www.cvdvaccine-us.com:

- ☐ EUA Fact Sheet for Vaccination Providers (12 years and older), DO NOT DILUTE, Gray Cap
- ☐ Full Prescribing Information (16 years of age and older), DO NOT DILUTE, Gray Cap
- ☐ EUA Fact Sheet for Recipients and Caregivers (12 years and older)
- ☐ Dosing and Preparation Guide
- ☐ Dry Ice Replenishment Sheet
- ☐ Returning Real-Time Temperature Monitor and Thermal Shipping Container Instructions
- ☐ Shipping and Handling Guidelines
- ☐ Formulation/Presentation Guide

Materials checklist for storage and handling:

- ☐ Safety goggles or safety glasses with side shields
- ☐ Waterproof insulated gloves
- ☐ Box cutter or tool to open box
- ☐ Hand truck or dolly to move the thermal shipping container, which can weigh up to ~36 kg (~80 lb)
- ☐ Ultra-low-temperature freezer* or refrigerator

***DO NOT STORE IN STANDARD FREEZER.**

For information on alternate, temporary storage options and transfer times between environments, visit www.cvdvaccine-us.com.

If using the medium thermal shipping container as temporary storage, you will also need:

- ☐ Dry ice supply (ice pellets 10-16 mm, for re-icing)
- ☐ Dry ice scoop
- ☐ Temperature-monitoring device
- ☐ Packing tape or equivalent
- ☐ A method for tracking dry ice replenishment dates to ensure protocol is being followed

Before receiving the thermal shipping container, you must have:

- ☐ A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- ☐ An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- ☐ Proper security so only authorized personnel can access the thermal shipping container contents
- ☐ Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
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 the respective EUA Fact Sheets.

MULTIPLE DOSE VIAL FOR INDIVIDUALS 12 YEARS OF AGE AND OLDER - DO NOT DILUTE (GRAY CAP)

Thawing and Preparation

Reminder: DO NOT DILUTE. This presentation for individuals 12 years of age and older comes in a multiple dose vial that contains **6 doses**.

Materials checklist for vaccine preparation:

(Do Not Dilute, 12 years of age and older)

- ☐ **If removing from ultra-low-temperature storage:** Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
  - ☐ Secondary container, such as a small tray, to transport vials removed from original vial carton
- ☐ Low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- ☐ Antiseptic swabs
- ☐ Sharps container for disposal

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
Before administration of the vaccine, please visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the 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
- Full Prescribing Information (12 years of age and older), DILUTE BEFORE USE, Purple 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)**

MULTIPLE DOSE VIAL FOR INDIVIDUALS 5 THROUGH 11 YEARS OF AGE – DILUTE BEFORE USE (ORANGE CAP)

Storage and Handling of the Vaccine and Thermal Shipping Container

Reminder: The presentation for **individuals 5 through 11 years of age** comes in a multiple dose vial that contains **10 doses** after dilution.

Resource materials available on www.cvdvaccine-us.com:

- ☐ EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- ☐ EUA Fact Sheet for Recipients and Caregivers (5 through 11 years of age)
- ☐ Dosing and Preparation Guide
- ☐ Returning Real-Time Temperature Monitor Instructions
- ☐ Shipping and Handling Guidelines - Single-Use Thermal Shipping Container
- ☐ Formulation/Presentation Guide
- ☐ Dry Ice Safety Data Sheet

Materials checklist for storage and handling:

- ☐ Safety goggles or safety glasses with side shields
- ☐ Waterproof insulated gloves
- ☐ Box cutter or tool to open box
- ☐ Hand truck or dolly to move the thermal shipping container. Use caution when lifting the thermal shipping container, as it may be heavy
- ☐ Ultra-low-temperature freezer* or refrigerator

***DO NOT STORE IN STANDARD FREEZER.**

For information on alternate, temporary storage options and transfer times between environments, visit www.cvdvaccine-us.com.

Before receiving the thermal shipping container, you must have:

- ☐ A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- ☐ An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- ☐ Proper security so only authorized personnel can access the thermal shipping container contents
- ☐ Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
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 the respective EUA Fact Sheets.

MULTIPLE DOSE VIAL FOR INDIVIDUALS 5 THROUGH 11 YEARS OF AGE - DILUTE BEFORE USE (ORANGE CAP)

Thawing, Dilution, and Preparation

Reminder: The presentation for **individuals 5 through 11 years of age** comes in a multiple dose vial that contains **10 doses** after dilution.

Materials checklist for vaccine preparation:
(Dilute Before Use, 5 through 11 years of age)

- ☐ **If removing from ultra-low-temperature storage:** Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
  - ☐ Secondary container, such as a small tray, to transport vials removed from original vial carton
- ☐ 3-mL or 5-mL syringe (for dilution)
- ☐ 21-gauge or narrower needle (for dilution)
- ☐ 1 mL low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- ☐ Vials of sterile 0.9% Sodium Chloride Injection, USP (for one-time use). ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.3 mL of diluent
- ☐ Antiseptic swabs
- ☐ Sharps container for disposal

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
Before administration of the vaccine, please visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the 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
- Full Prescribing Information (12 years of age and older), DILUTE BEFORE USE, Purple 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)**

MULTIPLE DOSE VIAL FOR INDIVIDUALS 6 MONTHS THROUGH 4 YEARS OF AGE - DILUTE BEFORE USE (MAROON CAP)

Storage and Handling of the Vaccine and Thermal Shipping Container

Reminder: The presentation for **individuals 6 months through 4 years of age** comes in a multiple dose vial that contains **10 doses** after dilution.

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.

Resource materials available on www.cvdvaccine-us.com:

- ☐ EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
- ☐ EUA Fact Sheet for Recipients and Caregivers (6 months through 4 years of age)
- ☐ Dosing and Preparation Guide
- ☐ Returning Real-Time Temperature Monitor Instructions
- ☐ Shipping and Handling Guidelines - Single-Use Thermal Shipping Container
- ☐ Formulation/Presentation Guide
- ☐ Dry Ice Safety Data Sheet

Materials checklist for storage and handling:

- ☐ Safety goggles or safety glasses with side shields
- ☐ Waterproof insulated gloves
- ☐ Box cutter or tool to open box
- ☐ Hand truck or dolly to move the thermal shipping container. Use caution when lifting the thermal shipping container, as it may be heavy
- ☐ Ultra-low-temperature freezer* or refrigerator

***DO NOT STORE IN STANDARD FREEZER.**

For information on alternate, temporary storage options and transfer times between environments, visit www.cvdvaccine-us.com.

Before receiving the thermal shipping container, you must have:

- ☐ A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- ☐ An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- ☐ Proper security so only authorized personnel can access the thermal shipping container contents
- ☐ Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
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 the respective EUA Fact Sheets.

MULTIPLE DOSE VIAL FOR INDIVIDUALS 6 MONTHS THROUGH 4 YEARS OF AGE - DILUTE BEFORE USE (MAROON CAP)

Thawing, Dilution, and Preparation

Reminder: The presentation for **individuals 6 months through 4 years of age** comes in a multiple dose vial that contains **10 doses** after dilution.

Materials checklist for vaccine preparation:
(Dilute Before Use, 6 months through 4 years of age)

- ☐ **If removing from ultra-low-temperature storage:** Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
  - ☐ Secondary container, such as a small tray, to transport vials removed from original vial carton
- ☐ 3-mL or 5-mL syringe (for dilution)
- ☐ 21-gauge or narrower needle (for dilution)
- ☐ 1 mL low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- ☐ Vials of sterile 0.9% Sodium Chloride Injection, USP (for one-time use). ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 2.2 mL of diluent
- ☐ Antiseptic swabs
- ☐ Sharps container for disposal

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.

Please see full Important Safety Information and Indication & Authorized Use on pages 10 through 12.
Before administration of the vaccine, please visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the 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
- Full Prescribing Information (12 years of age and older), DILUTE BEFORE USE, Purple 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 (45.9%), 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%).

Continued on next page.

Please see full Important Safety Information and Indication & Authorized Use on pages 11 and 12.
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 the respective EUA Fact Sheets.

Important Safety Information and Indication & Authorized Use (cont'd)

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

Continued on next page.

Important Safety Information and Indication & Authorized Use (cont'd)

- 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
- 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

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.

Please see full Important Safety Information and Indication & Authorized Use on pages 10 and 11.
Before administration of the vaccine, please visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the 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

Full Prescribing Information (12 years of age and older), DILUTE BEFORE USE, Purple 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)

Current as of July 20, 2022. For the most up-to-date version, visit www.cvdvaccine-us.com.

BIONTECH Pfizer

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 10017

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

PP-CVV-USA-1103