# HOW TO PREPARE AND DOSE

**The Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)***

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*When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older can be used interchangeably without presenting any safety or effectiveness concerns, but **should not be used** for individuals **5 through 11 years of age**, because of the potential for vaccine administration errors, including dosing errors.

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 5 years 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.

## Instructions for Each Formulation

For 12 years of age and older, DILUTE BEFORE USE (Purple Cap) formulation: pages 2-4

For 12 years of age and older, DO NOT DILUTE (Gray Cap) formulation: pages 5-7

For 5 through 11 years of age, DILUTE BEFORE USE (Orange Cap) formulation: pages 8-10

## Selected Safety Information

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

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 and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

BIONTECH Pfizer

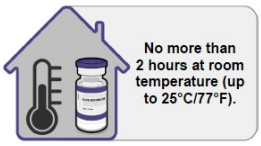
# HOW TO PREPARE AND DOSE
# DILUTE BEFORE USE (PURPLE CAP) – AGES 12 YEARS AND OLDER

## Vial Verification[1]

✓ Purple plastic cap and purple label border

- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a **purple cap**. Some vials also may have a **purple border** on the vial label

## Thawing Prior to Dilution[1]

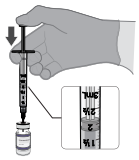



- Thaw vial(s) of vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and **thawed vials can be stored in the refrigerator for up to 1 month**
  - Allowing vial(s) to sit at room temperature [up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

Gently x 10

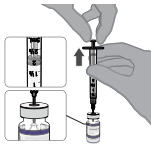
- Before dilution invert vaccine vial gently 10 times
- Do not shake
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles
- Do not use if liquid is discolored or if other particles are observed

## Dilution[1]



Add 1.8 mL of sterile 0.9% sodium chloride injection, USP.

- 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



Pull back plunger to 1.8 mL to remove air from vial.

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe

Gently x 10

- Gently invert the vial containing the vaccine 10 times to mix
- Do not shake
- Inspect the vaccine in the vial
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter

*Please see additional dilution step on the next page.*

**Please see Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

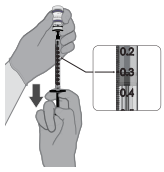
# HOW TO PREPARE AND DOSE
# DILUTE BEFORE USE (PURPLE CAP) – AGES 12 YEARS AND OLDER

## Dilution[1] (cont'd)

Record the date and time of dilution.
Use within 6 hours after dilution.

- Record the date and time of dilution on the vaccine vial label
- Store between 2°C to 25°C (35°F to 77°F)
- Discard any unused vaccine 6 hours after dilution

## Withdrawal of Individual 0.3 mL Doses[1]




Withdraw 0.3 mL dose of vaccine.

- 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

## Administration Information[1]

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an 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.

After dilution, vials of vaccine with purple caps contain six (6) doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six (6) doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract six (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

### Selected Safety Information

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

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.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

**Please see additional Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

# HOW TO PREPARE AND DOSE
# DILUTE BEFORE USE (PURPLE CAP) – AGES 12 YEARS AND OLDER

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

A single booster dose of the Pfizer-BioNTech COVID-19 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 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.

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older can be used interchangeably without presenting any safety or effectiveness concerns, but **should not be used for individuals 5 through 11 years of age**, because of the potential for vaccine administration errors, including dosing errors.

## Selected Safety Information

The vaccine may not protect all vaccine recipients.

Primary Series Adverse Events:
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%).

**Please see additional Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please click to see**

Fact Sheets and Prescribing Information for individuals 12 years of age and older
- Full Prescribing Information (16 years of age and older) DILUTE BEFORE USE, Purple Cap
- Full Prescribing Information (16 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
- 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)**

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)**

# HOW TO PREPARE AND DOSE
# DO NOT DILUTE (GRAY CAP) - AGES 12 YEARS AND OLDER

## Vial Verification[2]

✓ Gray plastic cap and gray label border

- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a **gray cap** and a label with a **gray border**

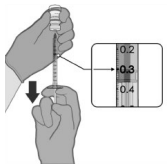
## Thawing Prior to Use[2]


- 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

Gently x 10

- 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[2]




Withdraw 0.3 mL dose of vaccine.

- 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

Record the date and time of first puncture. Use within 12 hours after first puncture.

- 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

**Please see Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

# HOW TO PREPARE AND DOSE
# DO NOT DILUTE (GRAY CAP) - AGES 12 YEARS AND OLDER

## Administration Information[2]

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 six (6) doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six (6) doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract six (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

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

*Please see additional dosing information on the next page.*

## Selected Safety Information

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%).

In a clinical study (30 mcg modRNA) of adolescents 12 through 15 years of age, adverse reactions following the administration of the primary series included 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%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

**Please see additional Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

# HOW TO PREPARE AND DOSE
# DO NOT DILUTE (GRAY CAP) - AGES 12 YEARS AND OLDER

A single booster dose of the Pfizer-BioNTech COVID-19 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 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.

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older can be used interchangeably without presenting any safety or effectiveness concerns, but **should not be used for individuals 5 through 11 years of age**, because of the potential for vaccine administration errors, including dosing errors.

## Selected Safety Information

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%).

Booster Dose Adverse Events:

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

**Please see additional Important Safety Information and Indication & Authorized Use on pages 11 and 12.**

**Before administration of the vaccine, please click to see**

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

- Full Prescribing Information (16 years of age and older) DILUTE BEFORE USE, Purple Cap
- Full Prescribing Information (16 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
- 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)**

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)**

# HOW TO PREPARE AND DOSE
# DILUTE BEFORE USE (ORANGE CAP) – 5 THROUGH 11 YEARS OF AGE

## Vial Verification[3]


Orange plastic cap and label with orange border

- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an **orange cap** and a label with an **orange border** and states "Age 5y to < 12y."

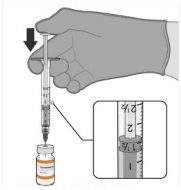
## Thawing Prior to Dilution[3]


- 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

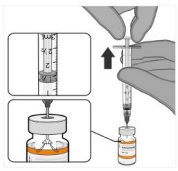

Gently x 10

- 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[3]


Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.

- 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


Pull back plunger to 1.3 mL to remove air from vial.

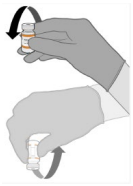
- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe

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

**Please see Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

# HOW TO PREPARE AND DOSE
# DILUTE BEFORE USE (ORANGE CAP) – 5 THROUGH 11 YEARS OF AGE

## Dilution[3] (cont'd)



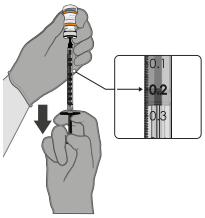
Gently x 10

- 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

Use within 12 hours after dilution.

- 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 dilution

## Withdrawal of Individual 0.2 mL Doses[3]




Withdraw 0.2 mL dose of vaccine.

- 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

**Please see Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

# HOW TO PREPARE AND DOSE
# DILUTE BEFORE USE (ORANGE CAP) - 5 THROUGH 11 YEARS OF AGE

## Administration Information[3]

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 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

**Primary Series**

The Pfizer-BioNTech COVID-19 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 (0.2 mL) at least 28 days following the second dose is authorized for administration to individuals 5 through 11 years of age 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 booster dose is not authorized for children 5 through 11 years of age.

## Selected Safety Information

In a clinical study (30 mcg modRNA) of adolescents 12 through 15 years of age, adverse reactions following the administration of the primary series included 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%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

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%).

**Please see additional Important Safety Information and Indication & Authorized Use on pages 11 and 12.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

**References: 1.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DILUTE BEFORE USE, Purple Cap. Pfizer-BioNTech; January 3, 2022. **2.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DO NOT DILUTE, Gray Cap. Pfizer-BioNTech; January 3, 2022. **3.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap. Pfizer-BioNTech; January 3, 2022.

# 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.

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).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

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.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

Primary Series Adverse Events:
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%).

In a clinical study (30 mcg modRNA) of adolescents 12 through 15 years of age, adverse reactions following the administration of the primary series included 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%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

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%).

Booster Dose Adverse Events:
In a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a 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%).

## Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

*Indication & Authorized Use information continued on next page.*

**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

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

### Indication

COMIRNATY® 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 16 years of age and older.

### Authorized Use

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 5 years of age and older to provide:

- a 10 mcg modRNA 2-dose primary series to individuals 5 through 11 years of age
- a 30 mcg modRNA 2-dose primary series to individuals 12 years of age and older
- a 10 mcg modRNA third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single 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 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized 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

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

- a 30 mcg modRNA 2-dose primary series to individuals 12 through 15 years of age
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single 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 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized 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

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 5 years 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 Important Safety Information on page 11.**

**Before administration of the vaccine, please click to see**

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

- Full Prescribing Information (16 years of age and older) DILUTE BEFORE USE, Purple Cap
- Full Prescribing Information (16 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
- 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)**

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)**

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

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.