





# Vaccine Formulation/Presentation Guide

For further details about the Pfizer-BioNTech COVID-19 Vaccine, please see appropriate Fact Sheet or contact US Medical Information at [PfizerMedicalInformation.com](https://www.pfizer.com/medinfo) or 1-800-438-1985.

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.

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use	Dilute Before Use
<b>Age Group</b>	12 years and older <sup>1,2</sup>	12 years and older <sup>3</sup>	5 through 11 years <sup>4</sup> ("Age 5y to <12y" on vial label)	6 months through 4 years <sup>5</sup> (See additional information in boxed maroon text below table)
<b>Vial Cap Color</b>	Purple 	Gray 	Orange 	Maroon 
<b>Dose</b>	30 mcg	30 mcg	10 mcg	3 mcg
<b>Dose Volume</b>	0.3 mL	0.3 mL	0.2 mL	0.2 mL
<b>Amount of Diluent Needed per Vial*</b>	1.8 mL	NO DILUTION	1.3 mL	2.2 mL
<b>Doses per Vial</b>	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)

\*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.  
[Information about Storage Conditions on next page.](#)

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.

Please see Important Safety Information and Indication & Authorized Use on pages 3 through 5.

Before administration of the vaccine, please [scroll down](#) and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.

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## Storage Conditions

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use	Dilute Before Use
Vial Cap Color	Purple 	Gray 	Orange 	Maroon 
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	12 months*	12 months†	12 months†	12 months†
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	2 weeks	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>
Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]	1 month	10 weeks	10 weeks	10 weeks
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours‡

\*Regardless of storage condition, purple cap vaccine should not be used past the 12-month expiry. For vials with expiry dates of October 2021 through March 2022, the printed date on the label/carton reflects 6-month expiry. For vials with expiry dates of June 2022 through December 2022, the printed date on the label/carton reflects 9-month expiry. The vaccine should not be used past the 12-month (updated) expiry date as noted in the [Fact Sheet](#).

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

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

Emergency uses of the vaccine have not been approved or licensed by FDA but have been authorized to prevent COVID-19 in individuals 6 months through 15 years of age.

Please see Important Safety Information and Indication & Authorized Use on pages 3 through 5.

Before administration of the vaccine, please [scroll down](#) and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.

## 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.

## 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>).

*Indication & Authorized Use continued on next page.*

**Please see additional Important Safety Information and Indication & Authorized Use on pages 4 and 5.**

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

## 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® 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.

#### **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.

*Indication & Authorized Use continued on next page.*

**Please see additional Important Safety Information and Indication & Authorized Use on pages 3 and 5.**

**Before administration of the vaccine, please scroll down and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.**

### **Authorized Use**

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

- a 2-dose 30 mcg modRNA primary series to individuals 12 through 15 years of age
- 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
- 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

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

- 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 and Indication & Authorized Use on pages 3 and 4.

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

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 \(5 through 11 years of age\)](#)

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 \(6 months through 4 years of age\)](#)



Manufactured for  
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Marketing Authorization Holder

Manufactured by  
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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.

Find additional resources about the vaccine at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)



**References:** **1.** COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; December 16, 2021. **2.** 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 and BioNTech; June 17, 2022. **3.** Pfizer and 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 and BioNTech; June 17, 2022. **4.** 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 and BioNTech; June 17, 2022. **5.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap. Pfizer and BioNTech; June 17, 2022.