Vaccine Formulation/ Presentation Guide

For further details please scroll down and click to see the Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Emergency Use Authorization Fact Sheets or contact US Medical Information at PfizerMedicalInformation.com or 1-800-438-1985.

Emergency Use Authorization

Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older for the Pfizer-BioNTech COVID-19 Vaccine and 5 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheets at www.cvdvaccine-us.com.

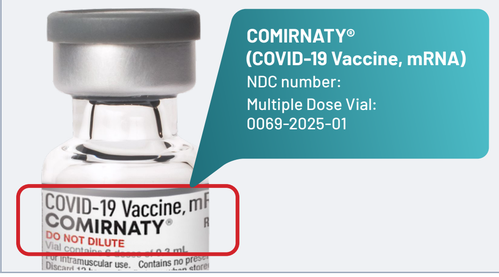
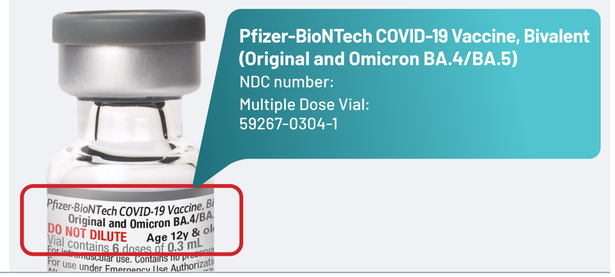
Interchangeability (Primary Series for Individuals 12 Years of Age and Older)

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, vaccine presentations should only be used for the ages specified on the vial labels, cartons, or the respective age-based Fact Sheet. The information in the Fact Sheets supersedes the information printed on the vial labels and cartons.

Distinguishing Between Gray Cap Vials: Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)[1-3]

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

	PRIMARY SERIES ONLY		BOOSTER DOSE ONLY
Name	**Pfizer-BioNTech COVID-19 Vaccine** DO NOT DILUTE	**COMIRNATY® (COVID-19 Vaccine, mRNA)** DO NOT DILUTE	**Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)** DO NOT DILUTE
Variant Composition	**Monovalent: 30 mcg modRNA-Original** ["Monovalent" refers to vaccine that encodes the spike protein of only the Original SARS-CoV-2]		**Bivalent: 15 mcg modRNA-Original and 15 mcg modRNA-Omicron BA.4/BA.5**
Authorized Use (AU) or Indication	**Primary Series AU:** as a 2-dose primary series to individuals 12 years of age and older; and a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise*	**Primary Series AU:** as a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise* **Primary Series Indication:** as a 2-dose primary series to individuals 12 years of age and older	**AU:** for 12 years of age and older as a single booster dose administered at least 2 months after: • completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine
Cap Color & Label *Gray caps and labels with gray borders*			

Low dead-volume syringes and/or needles can be used to extract 6 doses from a single multiple dose vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.

*Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent gray cap vials have the same storage, handling, preparation, dose volume, and administration instructions as Pfizer-BioNTech COVID-19 Vaccine gray cap vials and COMIRNATY gray cap vials, all of which MUST NOT BE DILUTED.

Selected Safety Information

Do not administer Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of these vaccines.

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

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

Please see full Important Safety Information and Indication & Authorized Use on pages 6 through 8.
Before administration, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (COMIRNATY (COVID-19 Vaccine, mRNA) Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.

Vaccine Formulation/Presentation Guide

For eligible individuals 12 years of age and older

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

	PRIMARY SERIES ONLY PFIZER-BIONTECH COVID-19 VACCINE OR COMIRNATY (COVID-19 VACCINE, mRNA), DO NOT DILUTE[1]	BOOSTER DOSE ONLY PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT, DO NOT DILUTE[3]
Age Group	12 years and older*	12 years and older (See additional information in teal box to the right of table)
Vial Cap Color	Gray 	Gray 
Dose	30 mcg	30 mcg
Dose Volume	0.3 mL	0.3 mL
Amount of Diluent Needed per Vial	NO DILUTION	NO DILUTION
Doses per Vial	6 doses per vial	Multiple dose vial: 6 doses per vial
Storage Conditions		
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	12 months†	
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	DO NOT STORE	
Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]	10 Weeks	
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	12 hours prior to first puncture (including any thaw time)	
After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]	Discard after 12 hours	

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

Low dead-volume syringes and/or needles can be used to extract 6 doses from a single multiple dose vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.

*For vaccination of individuals advancing into the next age group (11 years of age turning 12 years of age) between any primary series dose, refer to the respective age-based Fact Sheet for Healthcare Providers for instructions for administration.

†Regardless of storage condition, **gray** cap vaccine should not be used after 12 months from the date of manufacture printed on the vial and carton.

Identify the name on the vial label. Bivalent vial will specify: Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (Gray Cap).

Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a purple cap distributed in the U.S. will have reached the 12-month expiry on or before September 30, 2022.[4]

Expired product should not be used. Please follow COVID-19 vaccine procedures for documentation and disposal.

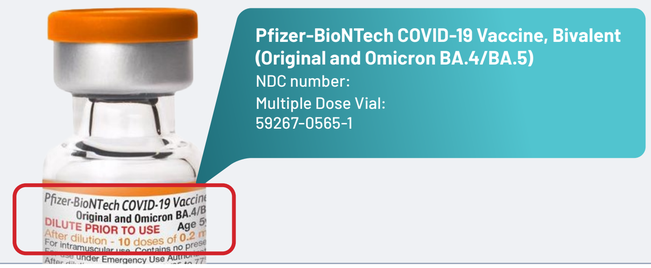
Expiry information can be found at: https://lotexpiry.cvdvaccine.com/

Please see following pages for dosage and storage information for individuals 5 through 11 years of age and 6 months through 4 years of age.

Please see full Important Safety Information and Indication & Authorized Use on pages 6 through 8.
Before administration, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (COMIRNATY (COVID-19 Vaccine, mRNA) Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.

Distinguishing Between Orange Cap Vials: Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)[5,6]

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

	PRIMARY SERIES ONLY	BOOSTER DOSE ONLY
Name	**Pfizer-BioNTech COVID-19 Vaccine** DILUTE BEFORE USE	**Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)** DILUTE BEFORE USE
Variant Composition	**Monovalent: 10 mcg modRNA-Original** ["Monovalent" refers to vaccine that encodes the spike protein of only the Original SARS-CoV-2]	**Bivalent: 5 mcg modRNA-Original and 5 mcg modRNA-Omicron BA.4/BA.5**
Authorized Use (AU)	**Primary Series AU:** as a 2-dose primary series to individuals 5 through 11 years of age; and a third primary series dose to individuals 5 through 11 years of age with certain kinds of immunocompromise*	**AU:** for 5 through 11 years of age as a single booster dose administered at least 2 months after: • completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine
Cap Color & Label *Orange caps and labels with orange borders*		

Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial.

*Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

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

Selected Safety Information

Myocarditis and Pericarditis

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

Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

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

Please see full Important Safety Information and Indication & Authorized Use on pages 6 through 8.
Before administration, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (COMIRNATY (COVID-19 Vaccine, mRNA) Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.

Vaccine Formulation/Presentation Guide

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

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.

	PRIMARY SERIES ONLY PFIZER-BIONTECH COVID-19 VACCINE, DILUTE BEFORE USE[7]	PRIMARY SERIES ONLY PFIZER-BIONTECH COVID-19 VACCINE, DILUTE BEFORE USE[5]	BOOSTER DOSE ONLY PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT, DILUTE BEFORE USE[6]
Age Group	6 months through 4 years (See additional information in boxed maroon text to the right of table)	5 through 11 years ("Age 5y to <12y" on vial label)	5 through 11 years ("Age 5y to <12y" on vial label) (See additional information in teal box to the right of table)
Vial Cap Color	Maroon 	Orange 	Orange 
Dose	3 mcg	10 mcg	10 mcg
Dose Volume	0.2 mL	0.2 mL	0.2 mL
Amount of Diluent Needed per Vial*	2.2 mL	1.3 mL	1.3 mL
Doses per Vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)	10 doses per vial (after dilution)
	Storage Conditions	**Storage Conditions**	
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	12 months†	12 months†	
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	DO NOT STORE	DO NOT STORE	
Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]	10 weeks	10 weeks	
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	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 12 hours‡	Discard after 12 hours	

Identify the name on the vial label. Bivalent vial will specify: Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (Orange Cap).

*ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

†Regardless of storage condition, **maroon** and **orange** cap vaccines should not be used after 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.

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 (Maroon Cap).

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.

Important Safety Information and Indication & Authorized Use

Important Safety Information

Do not administer Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY (COVID-19 Vaccine, mRNA), or Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of these vaccines.

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

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

Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Adverse Reactions

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 of Pfizer-BioNTech COVID-19 Vaccine 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 of Pfizer-BioNTech COVID-19 Vaccine 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) of participants **5 through 11 years of age**, adverse reactions following administration of any primary series dose of Pfizer-BioNTech COVID-19 Vaccine 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 participants **12 through 15 years of age**, the most commonly reported adverse reactions (≥8%) following any dose 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%) following any dose 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%).

Continued on next page.

Primary Series Adverse Events (cont'd)

In clinical studies (30 mcg modRNA) of participants **56 years of age and older**, the most commonly reported adverse reactions (≥10%) following any dose 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%).

Booster Dose Adverse Events

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on:

- safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved, hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
- safety data from clinical trials which evaluated primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, and
- post marketing safety data with Pfizer-BioNTech COVID-19 Vaccine

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

The clinical study (30 mcg modRNA) that evaluated a booster dose of the bivalent vaccine (Original and Omicron BA.1) included participants **greater than 55 years of age**. Adverse reactions following administration of the bivalent vaccine (Original and Omicron BA.1) as a second booster dose included pain at the injection site (58.1%), fatigue (49.2%), headache (33.6%), muscle pain (22.3%), chills (13.0%), joint pain (11.3%), injection site redness (7.0%), injection site swelling (6.6%), fever (5.0%), lymphadenopathy (0.3%), nausea (0.3%), and malaise (0.3%).

In a clinical study (30 mcg modRNA) of participants **18 through 55 years of age**, adverse reactions following administration of a first booster dose of Pfizer-BioNTech COVID-19 Vaccine were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%).

In a clinical study (10 mcg modRNA) of participants **5 through 11 years of age**, adverse reactions following administration of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine were injection site pain (73.9%), fatigue (45.6%), headache (34.0%), muscle pain (18.3%), injection site swelling (16.4%), injection site redness (15.6%), chills (10.5%), fever (6.7%), joint pain (6.7%), diarrhea (4.9%), lymphadenopathy (2.5%), and vomiting (2.4%).

Post Authorization Experience

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

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

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of Pfizer-BioNTech COVID-19 Vaccine and post authorization use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

INDICATION AND AUTHORIZED USES

COMIRNATY® (COVID-19 Vaccine, mRNA)

Indication & Authorized Use

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

Pfizer-BioNTech COVID-19 Vaccine

Authorized Use

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

Continued on next page.

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

Interchangeability (Primary Series for Individuals 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, 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.

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

Authorized Use

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.

Please see additional Important Safety Information and Indication & Authorized Use on pages 6 and 7.

Before administration of primary series dose vaccination, please click to see

- EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
- EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- EUA Fact Sheet for Vaccination Providers (Primary Series 12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (Primary Series 12 years of age and older), DILUTE BEFORE USE, Purple Cap
- COMIRNATY Full Prescribing Information (Primary Series 12 years of age and older), DO NOT DILUTE, Gray Cap
- COMIRNATY Full Prescribing Information (Primary Series 12 years of age and older), DILUTE BEFORE USE, Purple Cap

Before administration of booster dose vaccination, please click to see

- EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (Booster Dose 5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (Booster Dose 12 years of age and older), DO NOT DILUTE, Gray Cap

Click here for Recipients and Caregivers Fact Sheets

- Recipients and Caregivers Fact Sheet (6 months through 4 years of age)
- Recipients and Caregivers Fact Sheet: (Primary Series and Bivalent Booster Dose 5 through 11 years of age)
- Recipients and Caregivers Fact Sheet: (Primary Series and Bivalent Booster Dose 12 years of age and older)

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), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; August 31, 2022. **2.** COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; July 8, 2022. **3.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), Bivalent (Original and Omicron BA.4/BA.5) (Booster Dose for 12 years of age and older), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; October 12, 2022. **4.** 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; August 31, 2022. **5.** 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; October 12, 2022. **6.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), Bivalent (Original and Omicron BA.4/BA.5) (Booster Dose for 5 through 11 years of age), DILUTE BEFORE USE, Orange Cap. Pfizer and BioNTech; October 12, 2022. **7.** 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; August 31, 2022.

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

Manufactured by
Pfizer Inc.
New York, NY 10017

COVID-19 vaccines from BioNTech and Pfizer, which are based on BioNTech proprietary mRNA technology, were developed by both BioNTech and Pfizer.

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

PP-CVV-USA-1565