COVID-19 vaccines from BioNTech and Pfizer Formulation/Presentation Guide

Individuals 12 Years of Age and Older

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Individuals 6 Months Through 11 Years of Age

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COMIRNATY®
(COVID-19 Vaccine, mRNA)

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.

Selected Safety Information

Do not administer COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

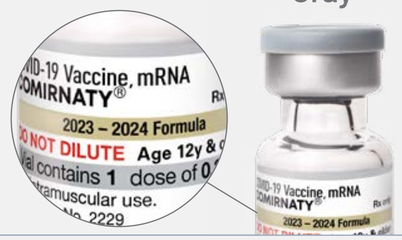
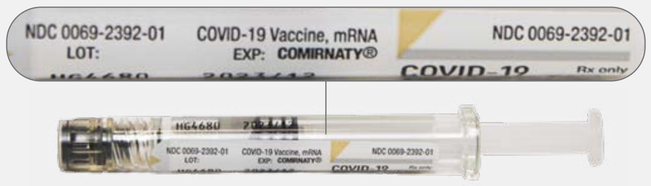
Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COMIRNATY.

Please see additional Important Safety Information on page 5.
Please click for COMIRNATY Full Prescribing Information.

Identifying vials and prefilled syringes of COMIRNATY® (COVID-19 Vaccine, mRNA)

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

Name	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula DO NOT DILUTE	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula PREFILLED SYRINGE
Composition	**Each 0.3 mL dose is formulated to contain 30 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).**	**Each 0.3 mL dose is formulated to contain 30 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).**
Age Group	12 years and older	12 years and older
Cap Color & Label *Cap colors and labels with matching borders* ***Verify vial label states "2023-2024 Formula"***	Gray 	
NDC Codes	**Single Dose Vial:** 0069-2362-01 **Carton of 10 single dose vials:** 0069-2362-10	**Single Dose Prefilled Syringe[a]:** 0069-2392-01 **Carton of 10 single dose prefilled syringes:** 0069-2392-10

[a]Pfizer anticipates availability of a limited quantity of a prefilled syringe presentation for individuals 12 years of age and older.

Important Reminder

Previous COVID-19 vaccines, including original monovalent COVID-19 vaccines and bivalent (original and Omicron BA.4/BA.5) mRNA COVID-19 vaccines, are no longer authorized for use in the United States.

FDA and CDC guidance is to check inventory and dispose of previous COVID-19 vaccines according to state and local regulations.

Identify the vial cap color for respective presentation and ensure vial/syringe labeling states "2023-2024 Formula."

Selected Safety Information

Myocarditis and Pericarditis

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For COMIRNATY, 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 Centers for Disease Control and Prevention (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 12 years of age and older.

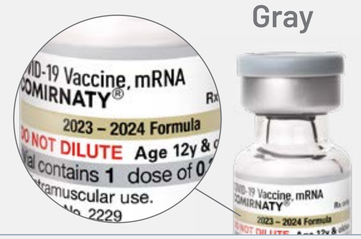
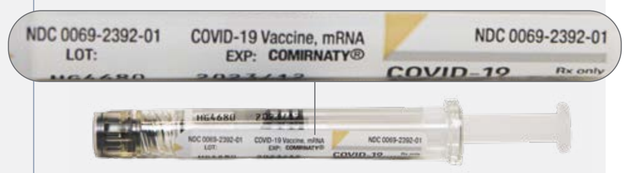
Please see additional Important Safety Information on page 5.
Please click for COMIRNATY Full Prescribing Information.

Vaccine Formulation/Presentation Guide

For eligible individuals **12 years of age and older**

COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula

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

Name	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula DO NOT DILUTE	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula PREFILLED SYRINGE
Age Group	12 years and older	12 years and older
Cap Color & Label *Cap colors and labels with matching borders*	Gray 	
Dose	**30 mcg**	**30 mcg**
Dose Volume	0.3 mL	0.3 mL
Dilution	**DO NOT DILUTE**	**N/A**
Doses per Vial/Syringe	**Single Dose Vial[a]**	**Single Dose Prefilled Syringe[b]**
Storage Conditions		
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	18 months[c]	9 months[c]
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)]	Up to 10 weeks	Up to 10 weeks
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	A total of 12 hours	Refer to product labeling[d]
After Puncture [2 °C to 25 °C (35 °F to 77 °F)]	N/A	N/A

Important Reminder

Previous COVID-19 vaccines, including original monovalent COVID-19 vaccines and bivalent (original and Omicron BA.4/BA.5) mRNA COVID-19 vaccines, are no longer authorized for use in the United States.

FDA and CDC guidance is to check inventory and dispose of previous COVID-19 vaccines according to state and local regulations.

Identify the vial cap color for respective presentation and ensure vial/syringe labeling states "2023-2024 Formula."

Do not refreeze thawed vials or prefilled syringes.

Refer to product labeling for detailed thawing instructions and information related to product handling.

[a]Low dead-volume syringes and/or needles are not required for single dose vial (SDV).

[b]Pfizer anticipates availability of a limited quantity of a prefilled syringe presentation for individuals 12 years of age and older.

[c]If cartons are received refrigerated at 2 °C to 8 °C (35 °F to 46 °F), they should be stored in a refrigerator at 2 °C to 8 °C (35 °F to 46 °F). Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vials, prefilled syringes, and cartons.

[d]After removing the tip cap and attaching an appropriate needle, the prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours.

Please see additional Important Safety Information on page 5.
Please click for COMIRNATY Full Prescribing Information.

COMIRNATY® (COVID-19 Vaccine, mRNA)

Important Safety Information & Indication

Important Safety Information

Do not administer COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 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 COMIRNATY.

Myocarditis and Pericarditis

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For COMIRNATY, 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 Centers for Disease Control and Prevention (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, including COMIRNATY. 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 COMIRNATY.

Limitation of Vaccine Effectiveness

COMIRNATY may not protect all vaccine recipients.

Adverse Reactions

The most commonly reported adverse reactions (≥10%) after a dose of COMIRNATY were pain at the injection site (up to 90.5%), fatigue (up to 77.5%), headache (up to 75.5%), chills (up to 49.2%), muscle pain (up to 45.5%), joint pain (up to 27.5%), fever (up to 24.3%), injection site swelling (up to 11.8%), and injection site redness (up to 10.4%).

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or https://www.pfizersafetyreporting.com or VAERS at 1-800-822-7967 or http://vaers.hhs.gov

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.

Please click for COMIRNATY Full Prescribing Information.

Reference: 1. COMIRNATY® (COVID-19 Vaccine, mRNA). Full Prescribing Information. Pfizer and BioNTech; September 11, 2023.

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

Individuals 6 Months Through 11 Years of Age

Emergency Use Authorization

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals aged 6 months through 11 years of age. The emergency use of this product is 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

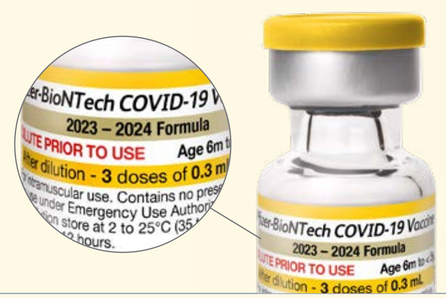
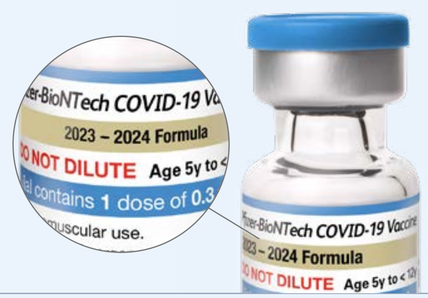
Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

Please see additional Important Safety Information on page 9.

Please click for Pfizer-BioNTech COVID-19 Vaccine Vaccination Provider and Recipient and Caregiver EUA Fact Sheets.

Identifying vials of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

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

Name	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) DILUTE BEFORE USE	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) DO NOT DILUTE
Variant Composition	**After dilution, each 0.3 mL dose is formulated to contain 3 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).**	**Each 0.3 mL dose is formulated to contain 10 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).**
Age Group	6 months through 4 years[a]	5 through 11 years[a]
Cap Color & Label *Cap colors and labels with matching borders* ***Verify vial label states "2023-2024 Formula"***	Yellow 	Blue 
NDC Codes	**Multiple Dose Vial:** 59267-4315-1 **Carton of 10 multiple dose vials:** 59267-4315-2	**Single Dose Vial:** 59267-4331-1 **Carton of 10 single dose vials:** 59267-4331-2

[a]For individuals turning from 4 to 5 years of age during the vaccination series, administer all doses with Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) supplied in vials with yellow caps and labels with yellow borders.

Important Reminder

Previous COVID-19 vaccines, including original monovalent COVID-19 vaccines and bivalent (original and Omicron BA.4/BA.5) mRNA COVID-19 vaccines, are no longer authorized for use in the United States.

FDA and CDC guidance is to check inventory and dispose of previous COVID-19 vaccines according to state and local regulations.

Identify the vial cap color for respective presentation and ensure vial labeling states "2023-2024 Formula."

Selected Safety Information

Management of Acute Allergic Reactions

Appropriate medical treatment 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.

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

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

Please see additional Important Safety Information on page 9.

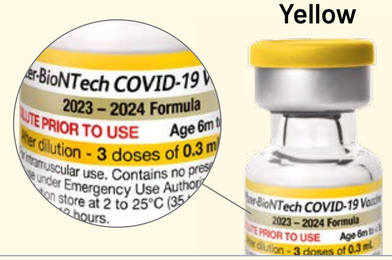
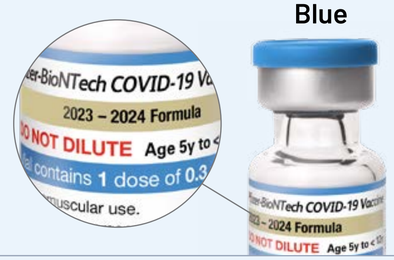
Please click for Pfizer-BioNTech COVID-19 Vaccine Vaccination Provider and Recipient and Caregiver EUA Fact Sheets.

Vaccine Formulation/Presentation Guide

For eligible individuals **6 months through 11 years of age**

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

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

	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) **DILUTE BEFORE USE**	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) **DO NOT DILUTE**
Age Group	**6 months through 4 years**[a]	**5 through 11 years**[a]
Cap Color & Label *Cap colors and labels with matching borders*	**Yellow** 	**Blue** 
Dose	**3 mcg**	**10 mcg**
Dose Volume	0.3 mL	0.3 mL
Dilution	1.1 mL[b]	**DO NOT DILUTE**
Doses per Vial	**Multiple Dose Vial**[c,d]: 3 doses per vial (after dilution)	**Single Dose Vial**[c]: 1 dose per vial
Storage Conditions		
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	12 months[e]	12 months[e]
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 first puncture[f,g]	12 hours prior to use[f]
After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]	Discard 12 hours after dilution.[e]	N/A

[a]For individuals turning from 4 to 5 years of age during the vaccination series, administer all doses with Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) supplied in vials with yellow caps and labels with yellow borders.

[b]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.

[c]Low dead-volume syringes and/or needles are not required for single dose vial (SDV) or multiple dose vial (MDV).

[d]If the amount of vaccine 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.

[e]If cartons are received refrigerated at 2 °C to 8 °C (35 °F to 46 °F), they should be stored in a refrigerator at 2 °C to 8 °C (35 °F to 46 °F). Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons. Expiry information can be found at https://lotexpiry.cvdvaccine.com.

[f]Once vials are thawed, they should not be refrozen.

[g]After dilution, multiple dose vials should be held between 2 °C to 25 °C (35 °F to 77 °F). Multiple dose vials should be discarded 12 hours after dilution.

Important Reminder

Previous COVID-19 vaccines, including the original monovalent COVID-19 vaccines and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (original and Omicron BA.4/BA.5) mRNA COVID-19 vaccines, are no longer authorized for use in the United States.

FDA and CDC guidance is to check inventory and dispose of previous COVID-19 vaccines according to state and local regulations.

Identify the vial cap color for respective presentation and ensure vial labeling states "2023-2024 Formula."

Do not refreeze thawed vials.

Refer to product labeling for detailed thawing instructions and information related to product handling.

Please see additional Important Safety Information on page 9.

Please click for Pfizer-BioNTech COVID-19 Vaccine Vaccination Provider and Recipient and Caregiver EUA Fact Sheets.

Important Safety Information and Authorized Use for Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

Important Safety Information

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

Management of Acute Allergic Reactions

Appropriate medical treatment 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.

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

Myocarditis and Pericarditis

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, 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. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to Pfizer-BioNTech COVID-19 Vaccine.

Limitation of Vaccine Effectiveness

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Solicited adverse reactions included:

- 6 months through 23 months of age: Injection site redness; swelling and tenderness; decreased appetite; drowsiness; fever; irritability.
- 2 through 11 years of age: Injection site pain; redness and swelling; chills; diarrhea; fatigue; fever; headache; new or worsened joint pain; new or worsened muscle pain; vomiting.

Vaccination providers must report all vaccine administration errors, all serious adverse events, cases of myocarditis, cases of pericarditis, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) to the Vaccine Adverse Event Reporting System (VAERS) by submitting online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) EUA" in the description section of the report. To the extent feasible, report adverse events to Pfizer 1-800-438-1985 or provide a copy of the VAERS form to Pfizer https://www.pfizersafetyreporting.com/

Authorized Use

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) 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 through 11 years of age.

Please click for Pfizer-BioNTech COVID-19 Vaccine Vaccination Provider and Recipient and Caregiver EUA Fact Sheets.

Reference: 1. Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (6 months of age and older); Pfizer and BioNTech; September 11, 2023.

Find additional resources about the vaccines 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 10001

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