

COVID-19 vaccines from BioNTech and Pfizer

Formulation/Presentation Guide

Individuals 12 Years
of Age and Older

[Explore More >](#)

Individuals 6 Months
Through 11 Years of Age

[Explore More >](#)

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.

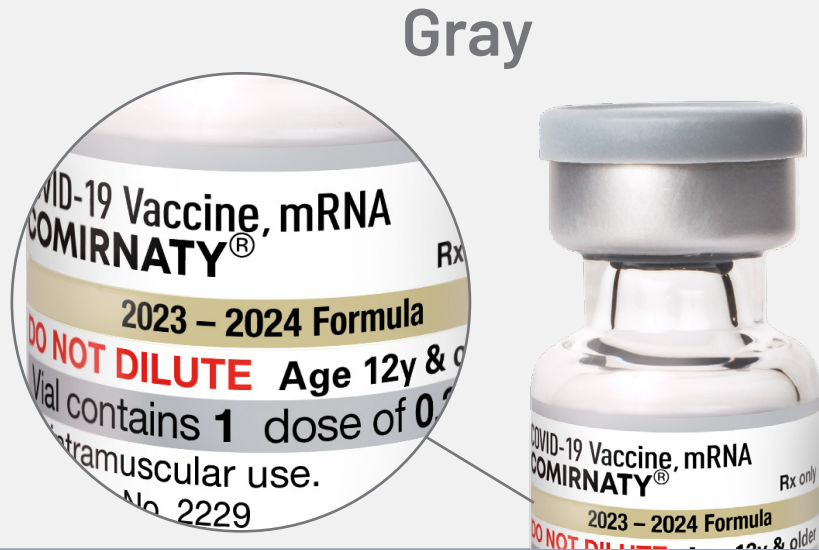
Management of Acute Allergic Reactions

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.



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

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

Name	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula Single Dose Vial DO NOT DILUTE
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)
Age Group	12 years and older
Cap Color & Label <i>Cap colors and labels with matching borders</i> 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

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 confirm vial labeling states "2023-2024 Formula."

See next page for information about prefilled syringes

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.


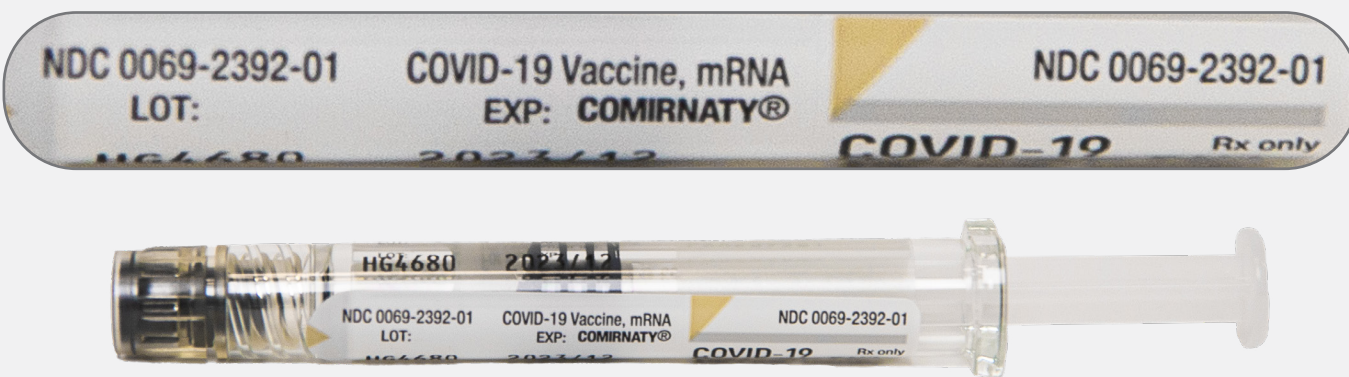
The Centers for Disease Control and Prevention (CDC) has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

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 7.
Please click for COMIRNATY Full Prescribing Information and Patient Information.

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

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

Name	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula GLASS SINGLE DOSE PREFILLED SYRINGE ^a	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula PLASTIC SINGLE DOSE PREFILLED SYRINGE ^a
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
Verify syringe label states "2023-2024 Formula"		
NDC Codes	Glass Single Dose Prefilled Syringe: 0069-2377-01 Carton of 10 Single Dose Prefilled Syringes: 0069-2377-10	Plastic Single Dose Prefilled Syringe: 0069-2392-01 Carton of 10 Single Dose Prefilled Syringes: 0069-2392-10

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.

Confirm syringe labeling states "2023-2024 Formula."

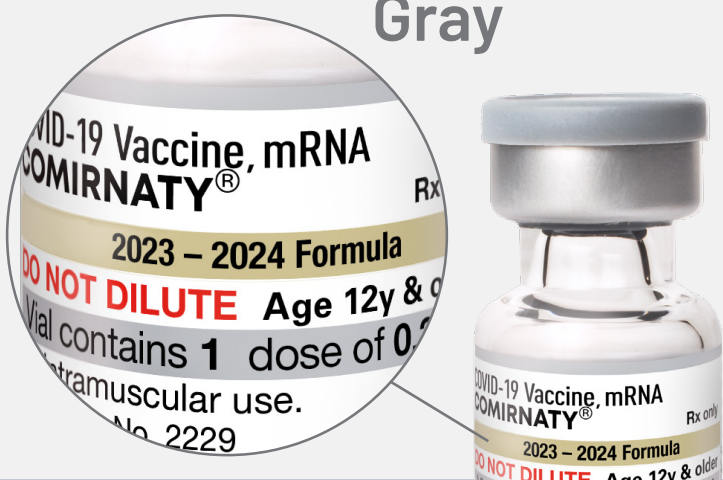
See additional pages for information about vials

^aPrefilled syringes for individuals 12 years of age and older are available in limited quantities.

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 7.
Please click for COMIRNATY Full Prescribing Information and Patient Information.

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

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

See next page for information about prefilled syringes


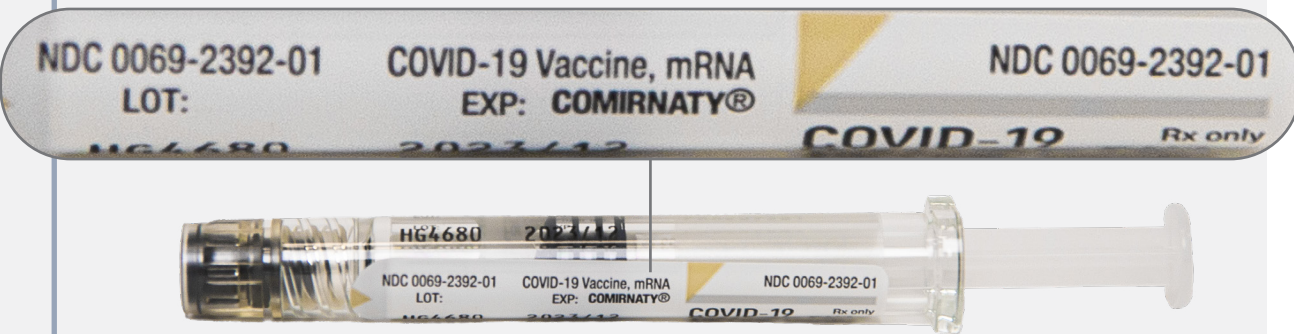
^aLow dead-volume syringes and/or needles are not required for single dose vial (SDV).

^bIf 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 and cartons.

^cThe 10-week refrigerated expiry date should be recorded on the carton at the time of transfer to 2 °C to 8 °C (35 °F to 46 °F). Check to ensure that cartons of COMIRNATY single dose vials received at 2 °C to 8 °C (35 °F to 46 °F) have been previously updated to reflect the 10-week refrigerated expiry date.

For eligible individuals 12 years of age and older

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

Name	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula GLASS SINGLE DOSE PREFILLED SYRINGE ^a	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula PLASTIC SINGLE DOSE PREFILLED SYRINGE ^a
Age Group	12 years and older	12 years and older
Verify syringe label states "2023-2024 Formula"		
Confirm NDC		
Dose	30 mcg	30 mcg
Dose Volume	0.3 mL	0.3 mL
Dilution	N/A	N/A
Doses per Syringe	Glass Single Dose Prefilled Syringe ^a	Plastic Single Dose Prefilled Syringe ^b
Storage Conditions ^c		Storage Conditions ^c
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	DO NOT STORE	Check the expiration date printed on the prefilled syringes and cartons ^b
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)]	Refrigerator-stable for up to 6 months from date of manufacture to the expiration date printed on the carton and on the syringe labels	Check to ensure that cartons of COMIRNATY plastic prefilled syringes received at 2 °C to 8 °C (35 °F to 46 °F) have been previously updated to reflect the 10-week refrigerated expiry date
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	Must not exceed 12 hours ^d	Must be used within 4 hours of thawing ^d

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.

Confirm syringe labeling states "2023-2024 Formula."

PLASTIC PREFILLED SYRINGES
Once thawed, they should not be refrozen. Refer to product labeling for detailed thawing instructions and information related to product handling.

GLASS PREFILLED SYRINGES
DO NOT FREEZE. If glass prefilled syringes have been frozen, discard.

See previous page for information about vials

^aPrefilled syringes for individuals 12 years of age and older are available in limited quantities.
^bIf 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 prefilled syringes and cartons.
^cRegardless of presentation, during storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
^dAfter 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.

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 ($\geq 10\%$) 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 and Patient Information.



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

Individuals 6 Months Through 11 Years of Age

Emergency Use Authorization

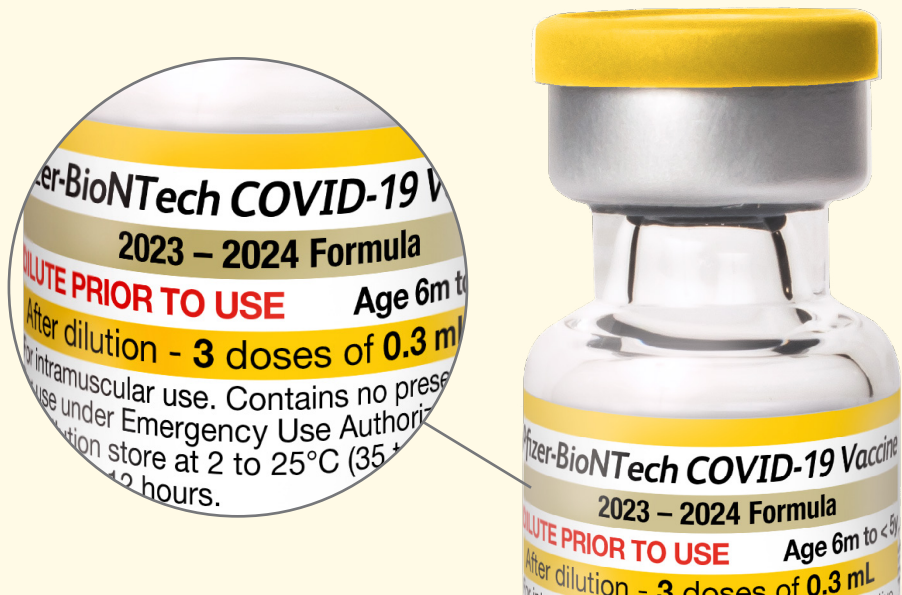
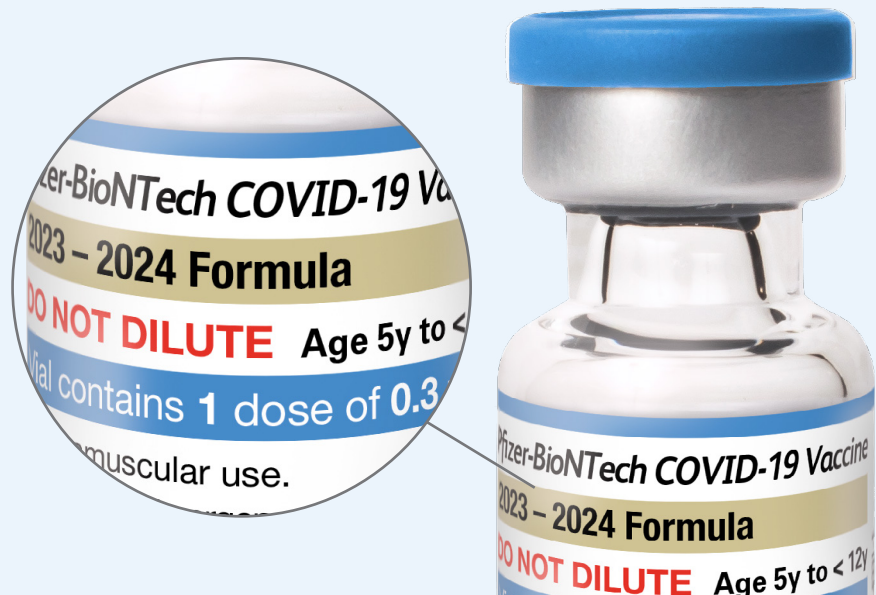
Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 6 months through 11 years of age. The emergency use of this product is only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

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

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

Name	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Multiple Dose Vial DILUTE BEFORE USE	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Single Dose Vial 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 <i>Cap colors and labels with matching borders</i> 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

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 confirm vial labeling states "2023-2024 Formula."

^aFor 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.

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.

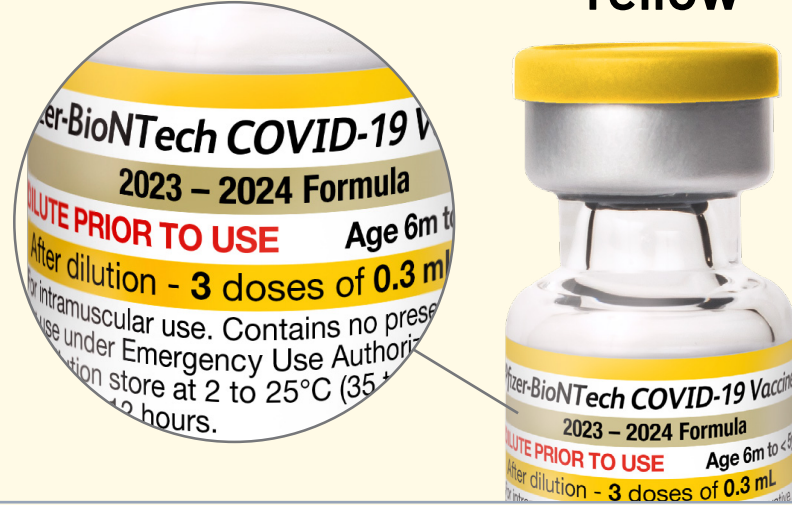
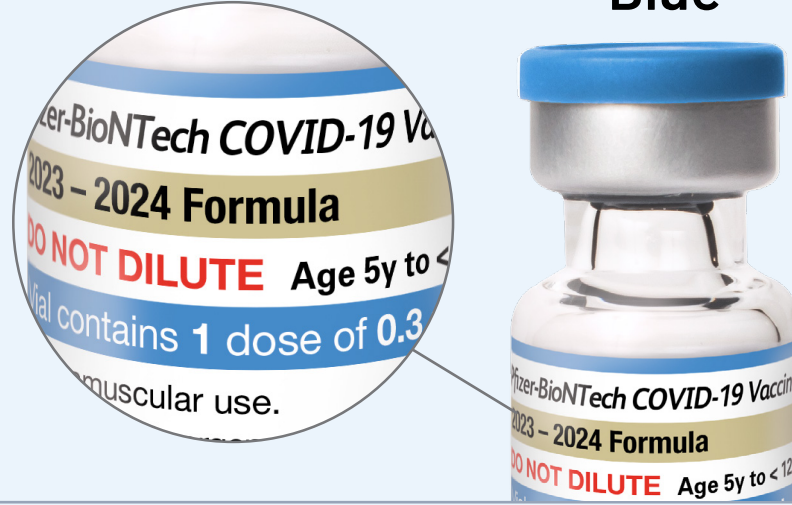
Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

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 11.

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

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

	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Multiple Dose Vial DILUTE BEFORE USE	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Single Dose Vial DO NOT DILUTE
Age Group	6 months through 4 years ^a	5 through 11 years ^a
Cap Color & Label <i>Cap colors and labels with matching borders</i>		
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

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 confirm 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.

^aFor 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.

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

^cLow dead-volume syringes and/or needles are not required for single dose vial (SDV) or multiple dose vial (MDV).

^dIf 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.

^eIf 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>.

^fOnce vials are thawed, they should not be refrozen.

^gAfter 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 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.



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.

PP-CVV-USA-3932
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