COVID-19 vaccines from BioNTech and Pfizer Dose and Schedule Guidance

Individuals 12 Years of Age and Older

Explore More >

Individuals 6 Months Through 11 Years of Age

Explore More >

COMIRNATY®

(COVID-19 Vaccine, mRNA)

Individuals 12 Years of Age and Older

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 4.
Please click for COMIRNATY Full Prescribing Information and Patient Information.

Dose and schedule for individuals 12 years of age and older
Confirm vial and syringe labeling states "2023-2024 Formula"

COMIRNATY is administered as a single 0.3 mL dose*

Single Dose Vial

DO NOT DILUTE

NDC 0069-2362-10

NDC 0069-2362-01

GRAY cap and label with GRAY border

or

Single Dose Glass Prefilled Syringe

DO NOT FREEZE

If glass prefilled syringes have been frozen, discard.

NDC 0069-2377-10

NDC 0069-2377-01

or

Single Dose Plastic Prefilled Syringe

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

NDC 0069-2392-10

NDC 0069-2392-01

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.

*Each 0.3 mL dose is formulated to contain 30 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

Individuals who are immunocompromised, or 65 years of age and older

The CDC has published considerations related to COVID-19 vaccination for individuals who are moderately to severely immunocompromised, or for those who are 65 years of age and older (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html).

CDC=Centers for Disease Control and Prevention.

Selected Safety Information (cont'd)

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 additional Important Safety Information on page 4.
Please click for COMIRNATY Full Prescribing Information and Patient Information.

Important Safety Information and Indication

COMIRNATY®
(COVID-19 Vaccine, mRNA)

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 and Patient Information.

Reference: 1. COMIRNATY® (COVID-19 Vaccine, mRNA). Full Prescribing Information. BioNTech Manufacturing GmbH and Pfizer Inc.; October 17, 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 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.

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 additional Important Safety Information on page 8.
Please click for Pfizer-BioNTech COVID-19 Vaccine Vaccination Provider and Recipient and Caregiver EUA Fact Sheets.

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

Individuals 6 Months Through 4 Years of Age

Pfizer-BioNTech COVID-19 Vaccination Status:

Multiple Dose Vial

NDC 59267-4315-2
NDC 59267-4315-1

(Contains 3 doses)
YELLOW cap and label with YELLOW border
DILUTE PRIOR TO USE

Number of Previous Doses of Pfizer-BioNTech COVID-19 Vaccines[a]	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Dose and Schedule[b]
0 previous doses[c]	**3 doses,**[d] **0.3 mL each** Dose 1: Week 0 Dose 2: Week 3 Dose 3: ≥8 weeks after Dose 2
1 previous dose	**2 doses,**[d] **0.3 mL each** Dose 1: 3 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine[a] Dose 2: ≥8 weeks after Dose 1
2-4 previous doses	**Single dose, 0.3 mL** ≥8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine[a]

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).

[a]Previous doses of Pfizer-BioNTech COVID-19 vaccines refers to doses with Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.

[b]For individuals with certain kinds of immunocompromise previously vaccinated with Pfizer-BioNTech COVID-19 vaccines, see page 7 for further dosing information.

[c]Not previously vaccinated with any COVID-19 vaccine.

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

Individuals 5 Through 11 Years of Age

Irrespective of COVID-19 Vaccination Status:

Single Dose Vial

NDC 59267-4331-2
NDC 59267-4331-1

BLUE cap and label with BLUE border
DO NOT DILUTE

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Dose and Schedule[a]

Single Dose, 0.3 mL

If previously vaccinated, ≥2 months after receipt of the last dose of any COVID-19 vaccine[b]

Each 0.3 mL dose is formulated to contain 10 mcg of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

[a]For individuals with certain kinds of immunocompromise, see page 7 for further dosing information.

[b]COVID-19 vaccine refers to the monovalent COVID-19 vaccines that encode the spike protein of the original SARS-CoV-2 and the bivalent COVID-19 vaccines encoding the spike protein of original SARS-CoV-2 and of the Omicron variant lineages BA.4 and BA.5 that are no longer authorized for use in the United States.

Individuals 6 Months Through 11 Years of Age With Certain Kinds of Immunocompromise

See next page for details.

Selected Safety Information (cont'd)

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).

Please see additional Important Safety Information on page 8.
Please click for Pfizer-BioNTech COVID-19 Vaccine Vaccination Provider and Recipient and Caregiver EUA Fact Sheets.

Individuals 6 Months Through 11 Years of Age with Certain Kinds of Immunocompromise

Individuals 6 months through 11 years of age with certain kinds of immunocompromise[3] should complete at least a 3-dose series with an age-appropriate dose and dosing schedule[4,5] of a COVID-19 vaccine. At least 1 dose should be with a COVID-19 vaccine (2023-2024 Formula).

- If previously not vaccinated, complete the 3-dose series with age-appropriate doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula).
- If previously vaccinated with 1 or 2 dose(s) of Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and/or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, complete the remaining dose(s) in the 3-dose series with age-appropriate doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula).
- If previously vaccinated with 3 or more doses, administer a single age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) at least 2 months following the last previous dose.[6,7]

An age-appropriate additional dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) may be administered at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula).[8,9] Age-appropriate additional doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.

[3]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.

[4]Dosing schedule for individuals 6 months through 4 years of age for Pfizer-BioNTech COVID-19 vaccines: Dose 1: Week 0; Dose 2: Week 3; Dose 3: ≥8 Weeks after Dose 2. For individuals turning from 4 to 5 years of age during the vaccination series, complete the series with doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) supplied in vials with yellow caps and labels with yellow borders.

[5]Dosing schedule for individuals 5 through 11 years of age for Pfizer-BioNTech COVID-19 vaccines: Dose 1: Week 0; Dose 2: Week 3; Dose 3: ≥4 weeks after Dose 2. Individuals turning from 11 to 12 years of age during the vaccination series may complete the series with doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) supplied in vials with blue caps and labels with blue borders.

[6]For immunocompromised individuals 6 months through 4 years of age, the last previous dose refers to the last dose of Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or Pfizer-BioNTech COVID-19 Vaccine, Bivalent, which are no longer authorized for use in the U.S.

[7]For immunocompromised individuals 5 through 11 years of age, the last previous dose refers to the last dose of a COVID-19 vaccine (Original monovalent) or bivalent COVID-19 vaccine, which are no longer authorized for use in the U.S.

[8]For immunocompromised individuals 6 months through 4 years of age, the last dose of a COVID-19 vaccine (2023-2024 Formula) refers to a dose with Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula).

[9]For immunocompromised individuals 5 through 11 years of age, the last dose of a COVID-19 vaccine (2023-2024 Formula) refers to a dose with Moderna COVID-19 Vaccine (2023-2024 Formula) or Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula).

Selected Safety Information

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.

Please see additional Important Safety Information on page 8.

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.