Vaccine Formulation/Presentation Guide

For further details about the Pfizer-BioNTech COVID-19 Vaccine, please see appropriate Fact Sheet or contact US Medical Information at PfizerMedicalInformation.com or 1-800-438-1985.

Children ages 5 through 11 years old should only be vaccinated with the Ages 5 through 11 years ("Age 5y to <12y" on vial label) DILUTE BEFORE USE Orange Cap presentation. **No other vaccine presentation should be used for children 5 through 11 years old because of the potential for vaccine administration errors, including dosing errors.** For children who will turn 12 between their first and second dose, consult the EUA Fact Sheets for Vaccination Providers.

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older (purple cap and gray cap) can be used interchangeably without presenting any safety or effectiveness concerns, but **should not be used** for individuals **5 through 11 years of age**, because of the potential for vaccine administration errors, including dosing errors.

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older[1,2]	12 years and older[3]	5 through 11 years[4] ("Age 5y to <12y" on vial label)
Vial Cap Color	Purple 	Gray 	Orange 
Dose	**30 mcg**	**30 mcg**	**10 mcg**
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial*	1.8 mL	**NO DILUTION**	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)
Storage Conditions			
Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]	9 months†	9 months‡	9 months‡
Freezer [-25°C to -15°C (-13°F to 5°F)]	2 weeks	**DO NOT STORE**	**DO NOT STORE**
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month	10 weeks	10 weeks
Room Temperature [8°C to 25°C (46°F to 77°F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2°C to 25°C (35°F to 77°F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Bacteriostatic saline or other diluents must NOT be used.

†Regardless of storage condition, vaccine should not be used past the 9-month expiry. For vials with expiry dates through March 2022: 6 months printed on the vial plus an additional 3 months. For vials with expiry dates after March 2022: vials will already reflect the 9-month shelf life.

‡Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

Emergency uses of the vaccine have not been approved or licensed by FDA but have been authorized to prevent COVID-19 in ages 5+.

Please see Important Safety Information and Indication & Authorized Use on pages 2 and 3.
Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.

Emergency Use Authorization

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Important Safety Information and Indication & Authorized Use

Important Safety Information

Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine.

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

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

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

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.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

Primary Series Adverse Events:
In clinical studies (30 mcg modRNA) of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies (30 mcg modRNA) of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study (30 mcg modRNA) of adolescents 12 through 15 years of age, adverse reactions following the administration of the primary series included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of any primary series dose included pain at the injection site (84.3%), fatigue (51.7%), headache (38.2%), injection site redness (26.4%), injection site swelling (20.4%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%).

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

Important Safety Information and Indication & Authorized Use continued on next page.

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Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.

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

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older (purple cap and gray cap), when prepared according to their respective instructions for use, can be used interchangeably. COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older (purple cap and gray cap) **should not be used** for individuals **5 through 11 years of age**, because of the potential for vaccine administration errors, including dosing errors.

Indication

COMIRNATY® is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Authorized Use

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 5 years of age and older to provide:

- a 10 mcg modRNA 2-dose primary series to individuals 5 through 11 years of age
- a 30 mcg modRNA 2-dose primary series to individuals 12 years of age and older
- a 10 mcg modRNA third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination

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

- a 30 mcg modRNA 2-dose primary series to individuals 12 through 15 years of age
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination

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Fact Sheets and Prescribing Information for individuals 12 years of age and older

Full Prescribing Information (16 years of age and older) DILUTE BEFORE USE, Purple Cap
Full Prescribing Information (16 years of age and older) DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
Recipients and Caregivers Fact Sheet (12 years of age and older)

Fact Sheets for individuals 5 through 11 years of age

EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
Recipients and Caregivers Fact Sheet (5 through 11 years of age)

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

References: **1**. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; December 16, 2021. **2**. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(12 years of age and older), DILUTE BEFORE USE, Purple Cap. Pfizer and BioNTech; January 31, 2022. **3**. Pfizer and BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(12 years of age and older), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; January 31, 2022. **4**. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(5 through 11 years of age), DILUTE BEFORE USE, Orange Cap. Pfizer and BioNTech; January 3, 2022.

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Marketing Authorization Holder

Manufactured by
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The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.