

Expiry Information for the Pfizer-BioNTech COVID-19 Vaccine Presentations

Document Updated as of July 8, 2022.

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 6 months 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. Please see EUA Fact Sheets at www.cvdvaccine-us.com.

Vaccine vial labels may state either the printed manufacturing date or the printed expiry date.¹⁻⁴

As long as approved storage conditions have been maintained, the **maroon**, **orange**, **gray**, and **purple** cap vaccine vials should not be used after 12 months from the **date of manufacture**. For vials labeled with a printed **expiry date**, vaccine vials may be used beyond the printed expiry date as per the table below. Please see the below tables for additional details.¹⁻⁴

 Pfizer-BioNTech COVID-19 Vaccine Ages 6 months through 4 years of age, DILUTE BEFORE USE, Maroon Cap presentation^{1*}	
Printed Manufacturing Date	12-Month Expiry Date
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023
04/2022	31-Mar-2023
05/2022	30-Apr-2023
06/2022	31-May-2023

 Pfizer-BioNTech COVID-19 Vaccine Ages 5 through 11 years of age, DILUTE BEFORE USE, Orange Cap presentation^{2*}	
Printed Manufacturing Date	12-Month Expiry Date
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

*Regardless of storage condition, **maroon**, **orange**, and **gray** cap vaccines should not be used after 12 months from the date of manufacture.

See next page for continued additional presentation information.

Please see full Important Safety Information and Indication & Authorized Use on pages 2 through 5. Before administration of the vaccine, please **scroll down** and click or visit cvdvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.

Expiry Information for the Pfizer-BioNTech COVID-19 Vaccine Presentations (cont'd)

 Pfizer-BioNTech COVID-19 Vaccine 12 years of age and older, DO NOT DILUTE, Gray Cap presentation^{3*}	
Printed Manufacturing Date	12-Month Expiry Date
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

 COMIRNATY® (COVID-19 Vaccine, mRNA)-labeled vials 12 years of age and older, DO NOT DILUTE, Gray Cap presentation^{3*}	
Printed Expiry Date	Updated Expiry Date
09/2022	31-Dec-2022
10/2022	31-Jan-2023
Additional expiry dates will be provided at a later date	

 Pfizer-BioNTech COVID-19 Vaccine 12 years of age and older, DILUTE BEFORE USE, Purple Cap presentation^{4†}	
Printed Expiry Date	Updated Expiry Date
12/2021	30-Jun-2022
01/2022	31-Jul-2022
02/2022	31-Aug-2022
03/2022	30-Sept-2022
06/2022	30-Sept-2022
07/2022	31-Oct-2022
08/2022	30-Nov-2022
09/2022	31-Dec-2022
10/2022	31-Jan-2023
11/2022	28-Feb-2023
12/2022	31-Mar-2023

The vaccine ingredients and formulation contained in all **DO NOT DILUTE (Gray Cap)** vaccine vials are the same. When prepared according to instructions for use, these can be used interchangeably for vaccinating people ages 12 and older.

*Regardless of storage condition, **maroon**, **orange**, and **gray** cap vaccines should not be used after 12 months from the date of manufacture.

†Regardless of storage condition, **purple** cap vaccine should not be used past the 12-month expiry. For vials with expiry dates of October 2021 through March 2022, the printed date on the label/carton reflects 6-month expiry. For vials with expiry dates of June 2022 through December 2022, the printed date on the label/carton reflects 9-month expiry. The vaccine should not be used past the 12-month (updated) expiry date in the table above.

Contact Pfizer Medical Information for more information. Refer to the EUA Fact Sheets for the most recent expiry information.

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.

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 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>).

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Please see additional Important Safety Information and Indication & Authorized Use on pages 3 through 5. Before administration of the vaccine, please **scroll down** and click or visit covidvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.

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

Myocarditis and Pericarditis

Myocarditis and pericarditis have been reported following administration of the vaccine.

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among adolescent males and adult 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

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 the vaccine.

Limitation of Effectiveness

The vaccine may not protect all vaccine recipients.

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 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 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) 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%).

In clinical studies (30 mcg modRNA) of adolescents 12 through 15 years of age, the most commonly reported adverse reactions ($\geq 8\%$) 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 ($\geq 10\%$) 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 ($\geq 10\%$) 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%).

Booster Dose Adverse Events:

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of a single booster dose 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%).

In a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a first 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%).

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Please see additional Important Safety Information and Indication & Authorized Use on pages 2, 4, and 5.

Before administration of the vaccine, please [scroll down](#) and click or visit covidvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.

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

Post Authorization Experience

Severe allergic reactions, including anaphylaxis, have been reported following administration of the vaccine.

Myocarditis and pericarditis have been reported following administration of the vaccine.

Indication & Authorized Use

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.

Interchangeability

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, COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 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.

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.

Authorized Use

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

- a third 30 mcg modRNA primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise
- a first 30 mcg modRNA 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 first 30 mcg modRNA 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
- a second 30 mcg modRNA booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second 30 mcg modRNA booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 to provide:

- a 3-dose 3 mcg modRNA primary series to individuals 6 months through 4 years of age
- a 2-dose 10 mcg modRNA primary series to individuals 5 through 11 years of age
- a 2-dose 30 mcg modRNA primary series to individuals 12 years of age and older
- a third 10 mcg modRNA primary series dose to individuals 5 through 11 years of age with certain kinds of immunocompromise
- a third 30 mcg modRNA primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise
- a single 10 mcg modRNA booster dose to individuals 5 through 11 years of age who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine
- a first 30 mcg modRNA 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)

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Please see additional Important Safety Information and Indication & Authorized Use on pages 2, 3, and 5.

Before administration of the vaccine, please scroll down and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.

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

- a first 30 mcg modRNA 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
- a second 30 mcg modRNA booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second 30 mcg modRNA booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

Please see additional Important Safety Information and Indication & Authorized Use on pages 2 through 4.

Before administration of the vaccine, please click or visit covidvaccine-us.com to review the full Prescribing Information (Purple Cap or Gray Cap) and the respective EUA Fact Sheets.

Fact Sheets for individuals 6 months through 4 years of age

[EUA Fact Sheet for Vaccination Providers \(6 months through 4 years of age\), DILUTE BEFORE USE, Maroon Cap](#)

[Recipients and Caregivers Fact Sheet \(6 months through 4 years of age\)](#)

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 \(5 through 11 years of age\)](#)

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

[Full Prescribing Information \(12 years of age and older\), DO NOT DILUTE, Gray Cap](#)

[Full Prescribing Information \(12 years of age and older\), DILUTE BEFORE USE, Purple Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DO NOT DILUTE, Gray Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DILUTE BEFORE USE, Purple Cap](#)

[Recipients and Caregivers Fact Sheet \(12 years of age and older\)](#)

References: **1.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap. Pfizer and BioNTech; June 17, 2022. **2.** 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; June 17, 2022. **3.** 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; July 8, 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; July 8, 2022.

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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.