Expiry Information for All Three Vaccine Presentations

Document Updated as of April 26, 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 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.

Regardless of storage condition, **orange cap** and **gray cap** vaccine vials should not be used after 12 months from the **date of manufacture** printed on the vial and cartons. The **purple cap** vaccine vials with an **expiry date** of October 2021-November 2022 (printed on the label) may remain in use beyond the printed date until the updated expiry date shown below; as long as approved storage conditions have been maintained.[1-3]

Expiry information for Ages 5 through 11 DILUTE BEFORE USE Orange Cap presentation* and Ages 12 years and older DO NOT DILUTE Gray Cap presentation*

Printed Manufacturing Date	12-Month Expiry Date
06/2021	31-May-2022
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
03/2022	28-Feb-2023

Expiry information for Ages 12 years and older DILUTE BEFORE USE Purple Cap presentation†

Printed Expiry Date	Updated Expiry Date
10/2021	30-Apr-2022
11/2021	31-May-2022
12/2021	30-Jun-2022
01/2022	31-Jul-2022
02/2022	31-Aug-2022
03/2022	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

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

†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 July 2022 through November 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.

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.

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

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

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

Important Safety Information

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%)

Indication & Authorized Use

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.

Interchangeability

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.

Authorized Use

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

- a 2-dose 30 mcg modRNA primary series to individuals 12 through 15 years of age
- 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; and

Authorized Use continued on next page.

Please see additional Important Safety Information and Indication & Authorized Use on pages 1 and 3.
Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information and the respective EUA Fact Sheets.

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

Authorized Use

- 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 in individuals 5 years of age and older to provide:

- 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 who have been determined to have 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 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; and
- 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 1 and 2.
Before administration of the vaccine, please click or visit cvdvaccine-us.com to see

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)**

References: 1. 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; April 13, 2022. **2.** 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; April 13, 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), DILUTE BEFORE USE, Purple Cap. Pfizer and BioNTech; April 26, 2022.

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Marketing Authorization Holder

Manufactured by
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New York, NY 10017

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