Orange Cap and Gray Cap Presentations - Expiry Information
Document Updated as of November 19, 2021.

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.

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

Regardless of storage condition, orange cap and gray cap vaccine vials should not be used after 6 months from the date of manufacture printed on the vial and cartons.1,2

<table>
<thead>
<tr>
<th>Date of Manufacture on Vial and Carton</th>
<th>6-month EXPIRY Date3</th>
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<tr>
<td>08/2021</td>
<td>Jan 31, 2022</td>
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<td>05/2022</td>
<td>Oct 31, 2022</td>
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</tbody>
</table>

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.

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.

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Before administration of the vaccine, please click to see

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

Full Prescribing Information (16 years of age and older)
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)
Important Safety Information and Indication & Authorized Use (cont’d)

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have 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

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the 2 EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

COMIRNATY® (COVID-19 Vaccine, mRNA) and the 2 formulations of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older 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.

Continued on next page

Before administration of the vaccine, please click to see

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

Full Prescribing Information (16 years of age and older)
EU A Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EU A 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

EU A 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)
Important Safety Information and Indication & Authorized Use (cont’d)

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 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 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized 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 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized 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

Before administration of the vaccine, please click to see

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

- Full Prescribing Information (16 years of age and older)
- 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)