

# COVID-19 VACCINATION RESOURCES

## for healthcare professionals

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.

The following online resources include important information on the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age, as well as additional information on COVID-19 vaccination in general.

### Pfizer-BioNTech COVID-19 Vaccine resources from [cvdvaccine-us.com](https://www.cvdvaccine-us.com)

<a href="#"><u>How to Prepare and Dose Guide</u></a>	Guide to storing, handling, and preparing the vaccine as well as instructions on administering, safely disposing the vaccine, and returning the thermal shipping container
<a href="#"><u>Vaccine Formulation/Presentation Guide</u></a>	Guide to storage, handling, and preparation of the vaccine across formulations/presentations
<a href="#"><u>Checklist for storage, handling, and preparation of the Pfizer-BioNTech COVID-19 Vaccine</u></a>	Materials checklist for storing, handling, and preparing the vaccine

### COVID-19 vaccination resources from [CDC.gov](https://www.cdc.gov)\*

<a href="#"><u>COVID-19 Vaccination Clinical &amp; Professional Resources</u></a>	Clinical information for COVID-19 vaccination administration, including patient education
<a href="#"><u>Building Confidence in COVID-19 Vaccines</u></a>	Series of COVID-19 vaccine confidence resources to help strengthen patient trust in the vaccines
<a href="#"><u>Your COVID-19 Vaccination</u></a>	Comprehensive patient information about COVID-19 vaccines, including frequently asked questions

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### COVID-19 vaccination resources from [American Academy of Pediatrics \(healthychildren.org\)](https://www.healthychildren.org)\*

<a href="#"><u>The Science Behind COVID-19 Vaccines: Parent FAQs</u></a>	Answers to frequently asked questions about COVID-19 vaccines for children
<a href="#"><u>COVID Vaccine Checklist for Kids Age 5-11</u></a>	Includes a checklist of things parents can do to prepare their child for COVID-19 vaccination
<a href="#"><u>How should I talk with my child about the COVID vaccine?</u></a>	Includes a video of conversation tips from professor and practicing pediatrician, Shaquita Bell, MD, FAAP

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Please see additional Important Safety Information and Indication & Authorized Uses on pages 2 and 3. 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 respective EUA Fact Sheets.

## 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 ( $\geq 10\%$ ) 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%).

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%).

### 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

*Authorized Use continued on next page.*

**Please see additional Important Safety Information and Indication & Authorized Uses on pages 2 and 3. 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 respective EUA Fact Sheets.**

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

### Authorized Use

- 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

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 Important Safety Information and Indication & Authorized Uses on pages 2 and 3.**

**Before administration of the vaccine, please click or visit [covidvaccine-us.com](https://covidvaccine-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 \(5 through 11 years of age\)](#)



Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany  
Marketing Authorization Holder

Manufactured by  
Pfizer Inc.  
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.

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