

LOW DEAD-VOLUME (LDV) SYRINGES AND/OR NEEDLES GUIDE

Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)*

*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and they can be used interchangeably without presenting any safety or effectiveness concerns. Although they may be manufactured in different facilities, the products offer the same safety and effectiveness.

The 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) for use in individuals 12 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.

Selected Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

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>).

GLOBAL: Drives to <http://labeling.pfizer.com/ShowLabeling.aspx?id=15623>

Please see Important Safety Information and Indications & Authorized Use on pages 3 and 4.

Before administration of the vaccine, please see full [Prescribing Information](#) (16+ years of age), [EUA Fact Sheet for Vaccination Providers](#) (12+ years of age), and [Recipients and Caregivers Fact Sheet](#) (12+ years of age).



GLOBAL Drives to <http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf>

GLOBAL Drives to <http://labeling.pfizer.com/ShowLabeling.aspx?id=14472&format=pdf>
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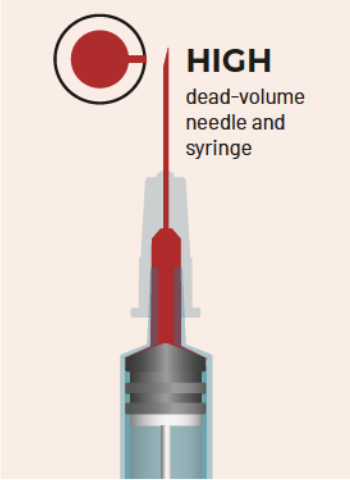
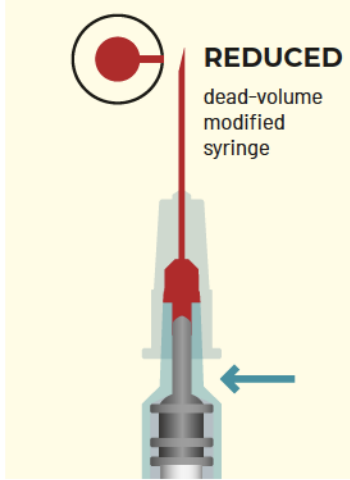
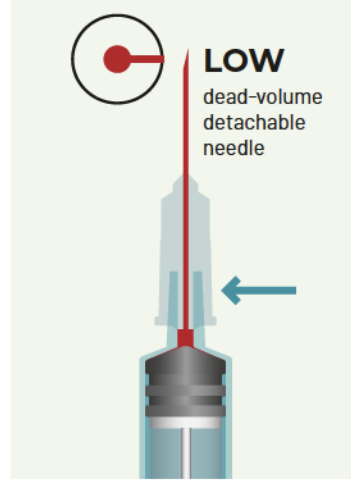
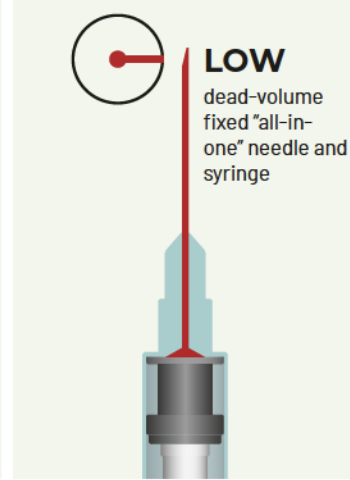
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After dilution, vials of the vaccine contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial.¹

Use of low dead-volume (LDV) syringes and/or needles may maximize the potential number of vaccine doses and minimize vaccine wastage²

i **Low dead-volume** (also called low dead-space) is the amount of fluid remaining within the syringe and needle after an injection is completed³

Characteristics of LDV syringes and needles⁴

 <p>HIGH dead-volume needle and syringe</p>	 <p>REDUCED dead-volume modified syringe</p>	 <p>LOW dead-volume detachable needle</p>	 <p>LOW dead-volume fixed "all-in- one" needle and syringe</p>
Withdrawal of 6 doses is unlikely with standard detachable needles with standard syringe	LDV SYRINGES have plungers molded to the luer cone , allowing fluid to be cleared from the syringe tip during injection	LDV NEEDLES have an extension of the needle that fits through the opening of some standard syringes, allowing for a reduction in dead space	FIXED-NEEDLE SYRINGES have low dead volumes and will, in most cases, achieve 6 doses of the vaccine

Compatible LDV syringe and/or needle pairings may successfully withdraw 6 doses of the vaccine, but not all combinations have been assessed or have a low dead volume that is small enough to allow extraction of a sixth dose.⁴

The Centers for Disease Control and Prevention (CDC) is partnering with McKesson to provide ancillary kits containing needles and syringes for use with all COVID-19 vaccines. Please reach out to your state, local, or tribal health department and/or the CDC for more information. Pfizer makes no guarantee of the type or quality of the needles and syringes within the ancillary kits or the capability to withdraw 6 doses. For further information, please contact the manufacturer directly.

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



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Before administration of the vaccine, please see full [Prescribing Information](#) (16+ years of age), [EUA Fact Sheet for Vaccination Providers](#) (12+ years of age), and [Recipients and Caregivers Fact Sheet](#) (12+ years of age).

FDA-CBER-2021-5683-0952228

Important Safety Information and Indication & Authorized Use

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

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, including this vaccine. 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.

In clinical studies 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 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 evaluating administration of a booster dose in participants 18 through 55 years of age, the most commonly reported adverse reactions ($\geq 10\%$) following the dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), and joint pain (25.3%).

In a clinical study of adolescents 12 through 15 years of age, the most commonly reported adverse reactions 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%).

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

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

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

- a two-dose primary series in individuals 12 through 15 years
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

Authorized Use information continued on next page.

Before administration of the vaccine, please see full [Prescribing Information \(16+ years of age\)](#), [EUA Fact Sheet for Vaccination Providers \(12+ years of age\)](#), and [Recipients and Caregivers Fact Sheet \(12+ years of age\)](#).

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

Authorized Use (cont'd)

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older to provide:

- a two-dose primary series in individuals 12 years of age and older
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

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Please see Important Safety Information on page 3.

Before administration of the vaccine, please see full [Prescribing Information \(16+ years of age\)](#), [EUA Fact Sheet for Vaccination Providers \(12+ years of age\)](#), and [Recipients and Caregivers Fact Sheet \(12+ years of age\)](#).

References: 1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; 2021. 2. Jarrahan C, Rein-Weston A, Saxon G, et al. Vial usage, device dead space, vaccine wastage, and dose accuracy of intradermal delivery devices for inactivated poliovirus vaccine (IPV). *Vaccine*. 2017;35:1789-1796. 3. Kesten JM, Ayres R, Neale J, et al. Acceptability of low dead space syringes and implications for their introduction: a qualitative study in the West of England. *Int J Drug Policy*. 2017;39:99-108. 4. Data on File. Pfizer Inc. New York, NY.



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Marketing Authorization Holder

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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.

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