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

Pfizer-BioNTech COVID-19 Vaccine

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older (purple cap and gray cap) can be used interchangeably without presenting any safety or effectiveness concerns, but **should not be used** for individuals **5 through 11 years of age**, because of the potential for vaccine administration errors, including dosing errors.

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.

Selected 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).

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

Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.

BIONTECH Pfizer

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

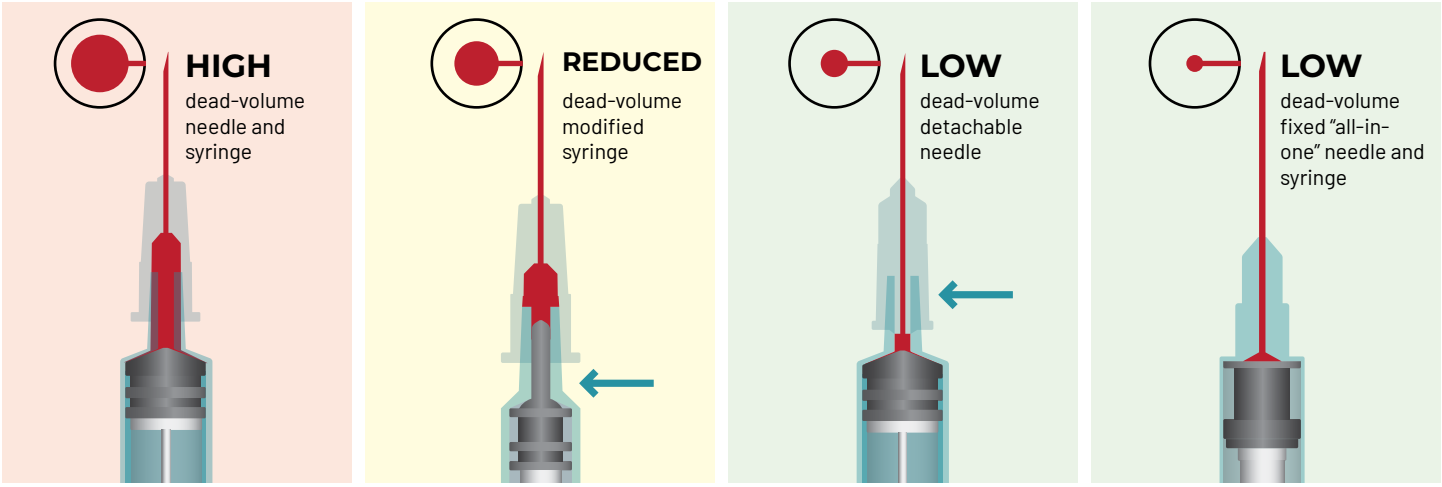
Vaccine vials for the 12 years of age and older **DILUTE BEFORE USE Purple Cap** and 12 years of age and older **DO NOT DILUTE Gray Cap** contain 6 doses of 0.3 mL of vaccine, while vaccine vials of 5 though 11 years of age **DILUTE BEFORE USE Orange Cap** contain 10 doses of 0.2 mL of vaccine.

Low dead-volume syringes and/or needles can be used to extract 6 doses from the Purple Cap and Gray Cap vials and 10 doses from the Orange Cap vial.[1]

Use of low dead-volume (LDV) syringes and/or needles may maximize the potential number of vaccine doses and minimize vaccine wastage[2]

Low dead-volume (also called low dead-space) is the amount of fluid remaining within the syringe and needle after an injection is completed[3]

Characteristics of LDV syringes and needles[4]



Withdrawal of 6 (Purple Cap or Gray Cap Vials) or 10 (Orange Cap Vial) 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 (Purple Cap or Gray Cap Vials) or 10 (Orange Cap Vials) doses of the vaccine

Compatible LDV syringe and/or needle pairings may successfully withdraw achieve 6 (Purple Cap or Gray Cap Vials) or 10 (Orange Cap Vials) doses of the vaccine dependent on presentation vial, but not all syringe combinations have been assessed or have a low dead-volume that is small enough to allow extraction of all doses.[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 (Purple Cap or Gray Cap Vials) or 10 (Orange Cap Vials) doses of the vaccine. For further information, please contact the manufacturer directly.

Please see Important Safety Information and Indication & Authorized Use on pages 3 and 4.
Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the 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 (≥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 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.

Indication & Authorized Use continued on next page.

Please see Important Safety Information and Indication & Authorized Use on pages 3 and 4.
Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.

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

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

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 10 mcg modRNA third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise
- 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 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 30 mcg modRNA single 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

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 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 30 mcg modRNA single 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

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

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) 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. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; December 16, 2021. **2.** Jarrahian 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.

BIONTECH Pfizer

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.