



LABEL: COMIRNATY- covid-19 vaccine, mrna injection, suspension

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NDC Code(s): 0069-2025-01, 0069-2025-10, 0069-2025-25

Packager: Pfizer Laboratories Div Pfizer Inc

Category: VACCINE LABEL

DEA Schedule: None

Marketing Status: Biologic Licensing Application

DRUG LABEL INFORMATION

Updated May 18, 2022

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use COMIRNATY safely and effectively. See full prescribing information for COMIRNATY. COMIRNATY® (COVID-19 Vaccine, mRNA) suspension ...

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1 INDICATIONS AND USAGE

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 ...

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only. 2.1 Preparation for Administration - The storage, preparation, and administration information in this Prescribing Information apply to COMIRNATY for individuals ...

3 DOSAGE FORMS AND STRENGTHS

COMIRNATY is a suspension for injection. Each dose of COMIRNATY supplied in vials with gray caps and labels with gray borders is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer COMIRNATY to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the COMIRNATY [see Description (11)].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions - Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction ...

6 ADVERSE REACTIONS

In clinical studies, the most commonly reported ($\geq 10\%$) adverse reactions in participants 16 through 55 years of age following any dose were pain at the injection site (88.6%), fatigue (70.1%) ...

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy - There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to COMIRNATY during pregnancy. Women who are vaccinated with COMIRNATY during pregnancy ...

11 DESCRIPTION

COMIRNATY (COVID-19 Vaccine, mRNA) is a sterile suspension for injection for intramuscular use. COMIRNATY is supplied as a frozen suspension in multiple dose vials with gray caps and labels with ...

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action - The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S ...

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility - COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. In a ...

14 CLINICAL STUDIES

Efficacy in Participants 16 Years of Age and Older - Study 2 is an ongoing, multicenter, multinational, randomized, placebo-controlled, observer-blind, dose-finding, vaccine ...

16 HOW SUPPLIED/STORAGE AND HANDLING

COMIRNATY Suspension for Intramuscular Injection, multiple dose vials with gray caps and labels with gray borders are supplied in a carton containing 10 multiple dose vials (NDC 0069-2025-10) or ...

17 PATIENT COUNSELING INFORMATION

Inform vaccine recipient of the potential benefits and risks of vaccination with COMIRNATY. Inform vaccine recipient of the importance of completing the 2 dose vaccination series. There is a ...

SPL UNCLASSIFIED SECTION

Manufactured for - BioNTech Manufacturing GmbH - An der Goldgrube 12 - 55131 Mainz, Germany -
Manufactured by - Pfizer Inc., New York, NY 10017 - LAB-1490-1.0 - US Govt. License No. 2229

PRINCIPAL DISPLAY PANEL - 0.3 ML VIAL LABEL

COVID-19 Vaccine, mRNA - COMIRNATY® Rx only - DO NOT DILUTE - Vial contains 6 doses of 0.3 mL - For intramuscular use. Contains no preservative. Discard 12 hours after first use when stored at - 2 to ...

PRINCIPAL DISPLAY PANEL - 10 VIAL CARTON

NDC 0069-2025-10 - COVID-19 Vaccine, mRNA - COMIRNATY® Suspension for Injection, for Intramuscular Use - DO NOT DILUTE - 10 Multiple Dose Vials - Each vial contains 6 doses of 0.3 mL - BIONTECH - Pfizer - Rx ...

PRINCIPAL DISPLAY PANEL - 25 VIAL CARTON

NDC 0069-2025-25 - COVID-19 Vaccine, mRNA - COMIRNATY® Suspension for Injection, for Intramuscular Use - DO NOT DILUTE - 25 Multiple Dose Vials - Each vial contains 6 doses of 0.3 mL - BIONTECH - Pfizer - Rx ...

INGREDIENTS AND APPEARANCE

Product Information

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