

September 11, 2023



IMPORTANT PRESCRIBING INFORMATION

**Subject: Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)
Authorized for 6 months through 11 years of age**

**COMIRNATY® (COVID-19 Vaccine, mRNA) (2023-2024 Formula)
Approved for 12 years of age and older**

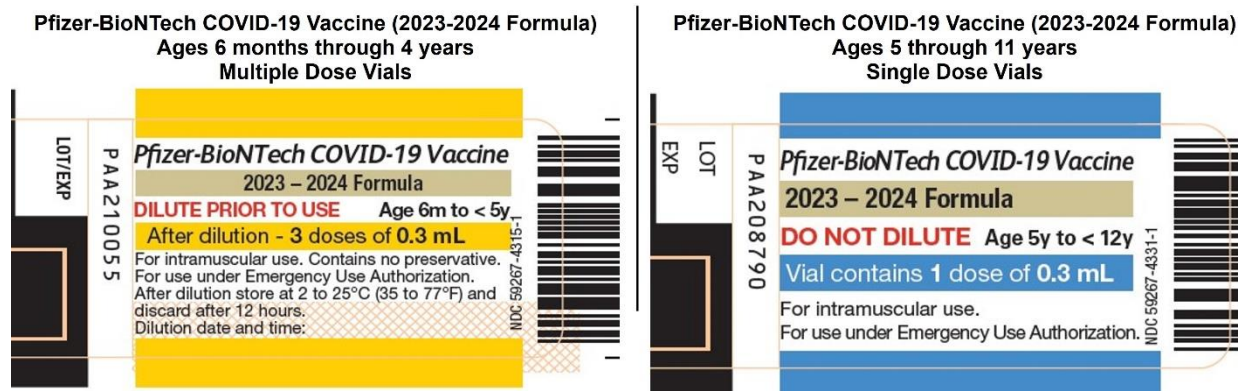
Dear Healthcare Provider,

The purpose of the letter is to inform vaccination providers that, on 09/11/2023, the US Food and Drug Administration:

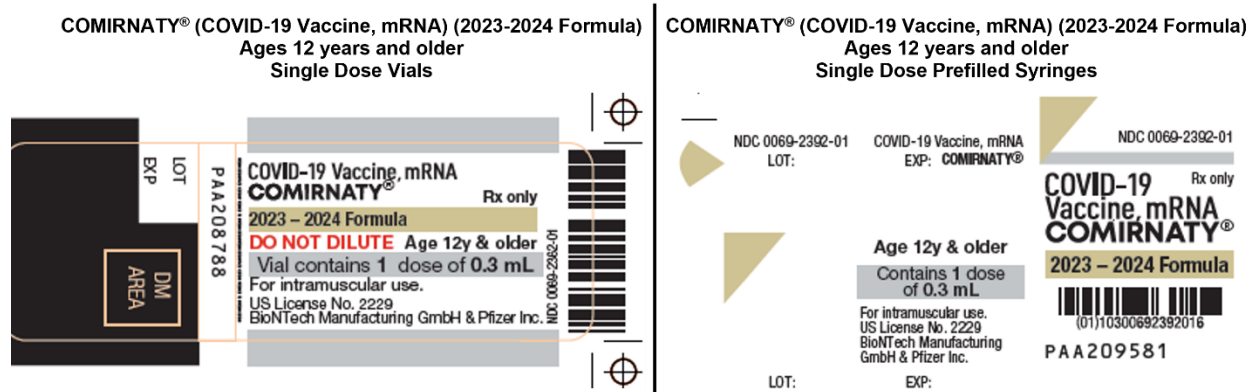
- Authorized emergency use of the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) for individuals 6 months through 11 years of age,
- Approved COMIRNATY® (COVID-19 Vaccine, mRNA) (2023-2024 Formula) for individuals 12 years of age and older,
- Removed authorization of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 6 months of age and older in the U.S.

The COVID-19 vaccines (2023-2024 Formula) are monovalent and encode the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5.

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula), authorized for 6 months through 11 years, is supplied in 2 presentations: one for ages 6 months through 4 years and one for ages 5 through 11 years.



COMIRNATY® (COVID-19 Vaccine, mRNA) (2023-2024 Formula), approved for ages 12 years and older, is supplied in single dose vials and single dose prefilled syringes.



For more information, refer to the Fact Sheet for Healthcare Providers Administering Vaccine for the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) and Prescribing Information for COMIRNATY® (COVID-19 Vaccine, mRNA) (2023-2024 Formula) that can be accessed using the QR code and website below.



www.cvdvaccine-us.com

Should you have any questions about the use of the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) and COMIRNATY® (COVID-19 Vaccine, mRNA) (2023-2024 Formula) you can contact Pfizer at 1(877) 829-2619.

Sincerely,

Alejandro Cane, MD, PhD

United States / International Developed Markets Vaccines & Antivirals Lead