

August 31, 2022



IMPORTANT PRESCRIBING INFORMATION

**Subject: Pfizer BioNTech COVID-19 Vaccine, Bivalent –
New Vial Presentation Available to Provide Booster Doses for Ages 12 years and older**

Dear Healthcare Provider,

On August 31, 2022, the US Food and Drug Administration authorized emergency use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent, for use in individuals 12 years of age and older as a single booster dose administered at least 2 months after either:

- completion of primary vaccination with any authorized or approved monovalent¹ COVID-19 vaccine, or
- receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent contains an Omicron component to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2.

This letter is to alert you that COMIRNATY® (COVID-19 Vaccine, mRNA), one formulation of the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, are all supplied in multiple dose vials with gray caps and labels with gray borders.

It is important to carefully read the labels to differentiate between the vaccines:

COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine are for use in individuals 12 years of age and older to provide a **primary series**.

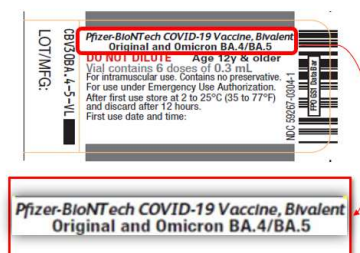
The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use in individuals 12 years of age and older to provide a single **booster dose**.

The labels for the multiple dose vials of each vaccine are shown below.

**Pfizer-BioNTech COVID-19 Vaccine or
Comirnaty® (COVID-19 Vaccine, mRNA)**
Primary Series Only



**Pfizer-BioNTech COVID-19 Vaccine, Bivalent
(Original and Omicron BA.4/BA.5)**
Booster Dose Only



¹ Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

Storage and handling requirements for these vaccines are identical.

Vaccination providers must report certain information associated with the administration of the vaccine to VAERS in accordance with the authorized Fact Sheet.

Should you have any questions about the use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, you can either contact Pfizer-BioNTech at 1(877) 829 2619 or visit www.cvdvaccine-us.com for additional resources.

This letter is not intended as a complete description of the benefits and risks related to the use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Please refer to the authorized Pfizer-BioNTech COVID-19 Vaccine, Bivalent Fact Sheet.

Sincerely,



Alejandro Cane, MD, PhD

North America Vaccines Medical Scientific Affairs Lead