

IMPORTANT PRESCRIBING INFORMATION

Subject: Pfizer BioNTech COVID-19 Vaccine, Bivalent – New Vial Presentation Available to Provide a Single Booster Dose for Ages 5 through 11 Years

Dear Healthcare Provider,

On October 12, 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 5 through 11 years of age 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.

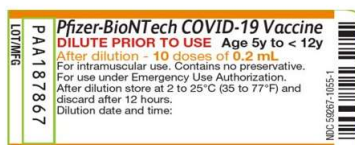
This letter is to alert you that the Pfizer-BioNTech COVID-19 Vaccine for individuals 5 through 11 years of age, and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, for individuals 5 through 11 years of age are both supplied in multiple dose vials with orange caps and labels with orange borders.

It is important to carefully read the labels to differentiate between the vaccines:
The Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 5 through 11 years of age to provide a **primary series**.

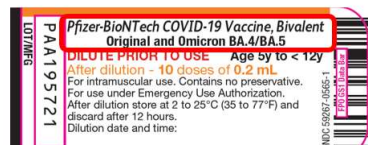
The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use in individuals 5 through 11 years of age to provide a single **booster dose**.

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

Pfizer-BioNTech COVID-19 Vaccine Primary Series Only



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



Pfizer-BioNTech COVID-19 Vaccine, Bivalent
Original and Omicron BA.4/BA.5

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 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