

December 8, 2022

**IMPORTANT PRESCRIBING INFORMATION**

**Subject: Moderna COVID-19 Vaccine, Bivalent –  
New Vial Presentation Available to Provide Booster Doses for  
Ages 6 Months Through 5 Years of Age**

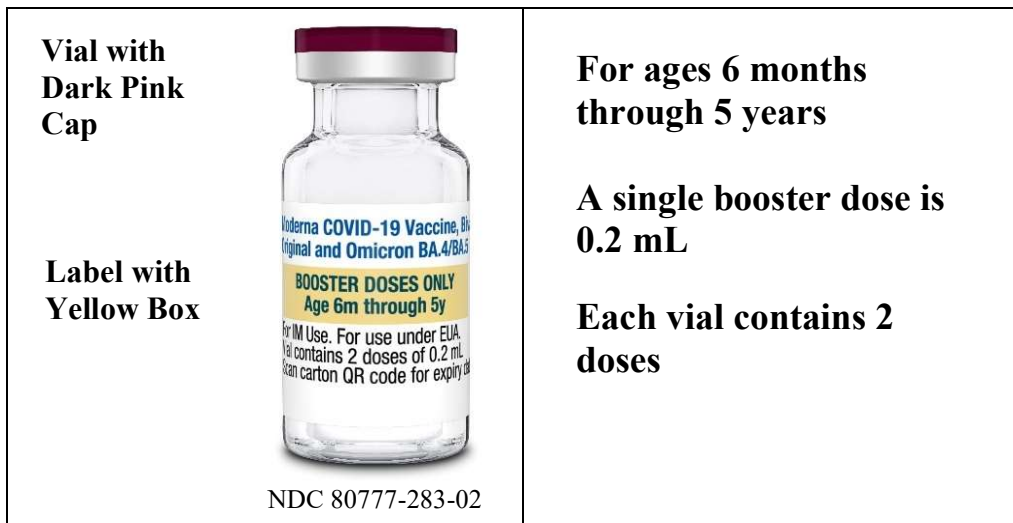
**Dear Healthcare Provider:**

On December 8, 2022, FDA authorized Moderna COVID-19 Vaccine, Bivalent for use as a single booster dose in individuals 6 months through 5 years of age administered at least 2 months after completion of primary vaccination with Moderna COVID-19 Vaccine.

This letter is to alert you that Moderna COVID-19 Vaccine, Bivalent for individuals 6 months through 5 years of age is supplied in a multiple-dose vial with a dark pink cap and a label with a yellow box. The volume of a single booster dose for ages 6 months through 5 years is **0.2 mL**.

It is important to carefully read the labels to differentiate between this and other Moderna COVID-19 vaccines.

The vial and label for Moderna COVID-19 Vaccine, Bivalent for use in individuals 6 months through 5 years of age are shown in the figure below.




**Thaw Time and Discard Time**

Thaw time and discard time for Moderna COVID-19 Vaccine, Bivalent supplied in a multiple-dose vial with a dark pink cap and a label with a yellow box for use in individuals 6 months through 5 years of age are different than those for Moderna COVID-19 Vaccine, Bivalent authorized for use in individuals 6 years of age and older and presentations of Moderna COVID-19 Vaccine authorized for use in individuals 6 months of age and older.

Specifically, for Moderna COVID-19 Vaccine, Bivalent supplied in a multiple-dose vial with a dark pink cap and a label with a yellow box for use in individuals 6 months through 5 years of age:

- Thaw before use:
  - Refrigerator: Thaw between 2°C to 8°C (36°F to 46°F) for 45 minutes. Let each vial stand at room temperature for 15 minutes before administering; or
  - Room temperature: Thaw between 15°C to 25°C (59°F to 77°F) for 15 minutes.
- After the first booster dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine, Bivalent vial label. Discard vial after 8 hours. Do not refreeze.

To access the most recent vaccine Fact Sheets, please scan the QR code or visit the website provided below. A copy of the Fact Sheet for Moderna COVID-19 Vaccine, Bivalent authorized for use in individuals 6 months through 5 years of age is also attached to this letter.

Website	Telephone number
<p data-bbox="240 787 763 819"><a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></p> 	<p data-bbox="998 787 1242 856">1-866-MODERNA (1-866-663-3762)</p>

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

Please share this letter with relevant personnel in your organization. Should you have any questions about the use of Moderna COVID-19 Vaccine, Bivalent, you can either contact the Moderna Medical Information Contact Center at 1-866-MODERNA (1-866-663-3762) or visit [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua) for additional resources.

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

Sincerely,

*Paul Burton*

Paul Burton, MD, PhD, FACC, MRCS Chief Medical Officer, Moderna

*Enclosure: Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Moderna COVID-19 Vaccine, Bivalent - Booster Dose - 6 Months Through 5 Years of Age*