

September 11, 2023

**IMPORTANT PRESCRIBING INFORMATION**

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

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

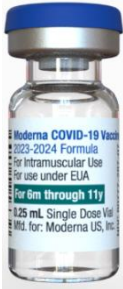
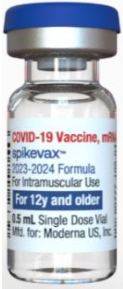

**Dear Healthcare Provider:**

The purpose of this letter is to inform vaccination providers that, on September 11, 2023, the U.S. Food and Drug Administration:


- authorized Moderna COVID-19 Vaccine (2023-2024 Formula) for Emergency Use in individuals 6 months through 11 years of age.
- approved SPIKEVAX (COVID-19 Vaccine, mRNA) (2023-2024 Formula) for use in individuals 12 years of age and older.
- removed authorization for use of Moderna COVID-19 Vaccine, Bivalent for use 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.

Moderna COVID-19 Vaccine (2023-2024 Formula) authorized for ages 6 months through 11 years is supplied in single dose vials. SPIKEVAX (2023-2024) Formula approved for ages 12 years and older is supplied in single dose vials and single dose pre-filled syringes (see table below).

Moderna COVID-19 Vaccine (2023-2024 Formula) 6 Months Through 11 Years of Age	SPIKEVAX (COVID-19 Vaccine, mRNA) (2023-2024 Formula) 12 Years of Age and Older	
 <p><b>0.25 mL single dose vial</b></p>	 <p><b>0.5 mL single dose vial</b></p>	 <p><b>0.5 mL single dose pre-filled syringe</b></p>
<p><b>NDC 80777-287-07</b> Individual single dose vial</p> <p><b>NDC 80777-287-92</b> Carton of 10 single dose vials</p>	<p><b>NDC 80777-102-04</b> Individual single dose vial</p> <p><b>NDC 80777-102-95</b> Carton of 10 single dose vials</p>	<p><b>NDC 80777-102-01</b> Individual single dose pre-filled syringe</p> <p><b>NDC 80777-102-96</b> Carton of 10 single dose pre-filled syringes</p> <p><b>NDC 80777-102-93</b> Carton of 10 single dose, blister-sealed pre-filled syringes</p>

For more information, refer to the Fact Sheet for Healthcare Providers Administering Vaccine for Moderna COVID-19 Vaccine (2023-2024 Formula) and prescribing information for SPIKEVAX (COVID-19 Vaccine, mRNA) (2023-2024 Formula), which are attached to this letter or can be accessed through the websites provided below.

Website	Telephone number
Moderna COVID-19 Vaccine <a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a> 	1-866-MODERNA (1-866-663-3762)
SPIKEVAX (COVID-19 Vaccine, mRNA) <a href="http://www.spikevax.com">www.spikevax.com</a>	

Please share this letter with relevant personnel in your organization. Should you have any questions about the use of Moderna COVID-19 Vaccine (2023-2024 Formula) or SPIKEVAX (COVID-19 Vaccine, mRNA) (2023-2024 Formula), 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) or [www.spikevax.com](http://www.spikevax.com) or for additional resources.

Sincerely,

*Francesca Ceddia*

Francesca Ceddia, MD  
Chief Medical Officer a.i.

*Enclosures: Fact Sheet for Healthcare Providers Administering Vaccine for Moderna COVID-19 Vaccine (2023-2024 Formula) and Prescribing Information for SPIKEVAX (COVID-19 Vaccine, mRNA) (2023-2024 Formula)*