

October 20, 2021

IMPORTANT PRESCRIBING INFORMATION

**Subject: Moderna COVID-19 Vaccine –
Booster Dose Volume (0.25 mL) and Vial Presentation**

Dear Vaccination Provider:

Moderna COVID-19 Vaccine is authorized for emergency use to prevent COVID-19 in individuals 18 years of age and older.

A booster dose was authorized on October 20, 2021, for specific populations described below.

The purpose of this letter is to alert vaccination providers that the volume of a booster dose is **0.25 mL**.

Primary Vaccination:

Each dose 0.5 mL

A primary series of this vaccine is two 0.5 mL doses administered intramuscularly 1 month apart. A third 0.5 mL primary series dose at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Vaccination:

One 0.25 mL dose

A booster dose may be administered intramuscularly at least 6 months after completing a primary series with the Moderna COVID-19 Vaccine to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

Use of Multidose Vials of Moderna COVID-19 Vaccine

The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:

- A multiple-dose vial containing 5.5 mL
- A multiple-dose vial containing 7.5 mL

Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.

When extracting only primary series doses, depending on the syringes and needles used, a maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL.

When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. **Do not puncture the vial stopper more than 20 times.**


If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.

Vaccine Administration Errors

Administration of the incorrect volume for any dose is a vaccine administration error. Please report vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS). See the Fact Sheet for Vaccination Providers for reporting instructions.

Additional Resources

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

Should you have any questions about the use of the Moderna COVID-19 Vaccine, 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 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. Please refer to the enclosed Fact Sheet.

Sincerely,

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

Enclosure: Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information