March 22, 2021

Francesca De Plato
Ospedale Civile di Teramo, Piazza Italia.
64100 Teramo
Italy

Dear Dr De Plato,

Thank you for your inquiry regarding COVID-19 Vaccine Moderna. The following information is enclosed in response to your medical inquiry.

• Dosage And Administration

The European Medicines Agency-approved Summary of Product Characteristics (SmPC) is attached for your information.

COVID-19 Vaccine Moderna has been granted a Conditional Marketing Authorization by the European Commission, based upon the recommendation of the European Medicines Agency. The European Medicines Agency will review new information on this medicinal product as it becomes available and this SmPC will be updated as necessary.

The enclosed information is supplied to you in response to your unsolicited inquiry. It is intended for educational purposes only and is not an endorsement of the use of COVID-19 Vaccine Moderna in a manner inconsistent with the attached SmPC. It should not be altered, duplicated, or further disseminated.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system and include batch/Lot number if available.

If we may be of further assistance, please do not hesitate to contact us.

Sincerely,

Medical Information
Moderna
www.modernatx.com
MDIT21-00055

DOSAGE AND ADMINISTRATION

COVID-19 Vaccine Moderna has been granted a Conditional Marketing Authorization by the European Commission, based upon the recommendation of the European Medicines Agency. The European Medicines Agency will review new information on this medicinal product as it becomes available and the SmPC will be updated as necessary.

Method of administration[1]

- The vaccine should be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm.
- Do not administer this vaccine intravascularly, subcutaneously or intradermally.
- The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

Steps prior to administration[1]

- The COVID-19 Vaccine Moderna multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the desired number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes or at room temperature between 15° to 25°C (59° to 77°F) for 1 hour. After thawing, let vial stand at room temperature for 15 minutes before administering.
- After thawing, do not refreeze.
- The COVID-19 Vaccine Moderna is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the COVID-19 Vaccine Moderna vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5mL.

Steps during Administration

- Administer the COVID-19 Vaccine Moderna intramuscularly as a series of two doses (0.5 mL each) 28-days apart.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the COVID-19 Vaccine Moderna vial label. Withdraw 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another. The vaccine should be used immediately and be discarded after 6 hours. Do not refreeze.

Special precautions for disposal and other handling[1]

The vaccine should be prepared and administered by a trained healthcare professional using aseptic techniques to ensure sterility of the dispersion.

The vaccine comes ready to use once thawed.

Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal.

COVID-19 Vaccine Moderna vials are multidose.

Ten (10) doses (of 0.5mL each) can be withdrawn from each vial.

An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL can be delivered.

Supplemental Information

Multiple-dose Vials [2]

If an additional 0.5 mL dose can be obtained from a single vial, there is no prohibition on using it.
Do not use vaccine obtained from two or more vials to comprise a dose of vaccine.

Any unused vaccine or waste materials should be disposed of in accordance with local requirements.

Needle Size and Syringes [2]

A 2.5-4cm needle and a 1-mL to 3-mL disposable syringe may be used. A single 22G-25G needle can be used both prepare (draw up) and administer the vaccine.

The syringe should have markings to enable 0.5 mL volume to be measured accurately. Common disposable syringes made of polypropylene or polycarbonate are suitable for use. The syringes must be sterile, non-pyrogenic and intended for human-use.

Pre-filling syringes

According to the Chemistry, Manufacturing and Control (CMC) department in Moderna: [2]

Syringes may be pre-filled, provided their content is administered within 6 hours of the first time the source vial is pierced. Chemical and physical in-use stability has been demonstrated for 6 hours at 2°C to 25ºC after initial puncture. From a microbiological point of view, the product should be used immediately and be discarded after 6 hours. Pre-loaded syringes can be either stored in the refrigerator at 2° to 8°C (36° to 46°F) or left at ambient room temperature at 15° to 25°C (59° to 77°F) up to 6 hours. Keep out of direct sunlight.

Alternate site of injection [3]

In the ongoing clinical trials with COVID-19 Vaccine Moderna, subjects have been preferentially vaccinated via the intramuscular route in their non-dominant deltoid muscle. An alternative injection site would be the deltoid muscle of the dominant arm.

Alternate route of administration [1, 2]

There are no data on the safety or efficacy of inadvertent subcutaneous injection of the vaccine. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

Deviation from the recommended dose-regimen [1-5]

- COVID-19 Vaccine Moderna should be administered as two 0.5 mL doses by intramuscular injection 28-days apart.

Deviation from the recommended Interval between the first and second dose [1]

- A dosing window of –7 to +14 days for administration of the second dose (scheduled at day 29) was allowed for inclusion in the COVE study per protocol analysis set. 98% of vaccine recipients received the second dose 25 days to 35 days after dose 1 (corresponding to -3 to +7 days around the interval of 28 days).

Deviation from the recommended 100 mcg dose

- Phase 1 and 2 studies assessed the administration of 25 mcg, 50 mcg and 250 mcg doses.
- In the event of a deviation from the interval between doses or deviation from the recommended dose, the vaccine recipient should be followed closely for safety outcomes, but the dose should not be repeated, as data are not available on the administration of 3 doses of the Moderna COVID-19 Vaccine.

References:

1. Moderna, Inc. COVID-19 Vaccine Summary of Product Characteristics Including Patient Information Leaflet. Moderna, Inc., Cambridge, MA, USA: January 06, 2021.
2. Data on File, Moderna Chemistry, Manufacturing and Control
3. Phase 1 study: Open-label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults (NCT04283461)
4. A Phase 2a, Randomized, Observer-Blind, Placebo Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-COV-2 Vaccine in Adults Aged 18 Years and Older (NCT04405076)
5. The COVE study: a phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-Cov-2 vaccine in adults aged 18 years and older (NCT04470427)