

Importation of Moderna COVID-19 Vaccine with up to 15 Doses per Vial and English-only Vial and Carton Labels (US-Labelled Supply)



10/09/2021

Audience

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners, and healthcare professionals at identified points of use.

NUPCO is distributing COVID-19 Vaccine Moderna doses directly to vaccination locations where administration of the vaccine will occur, as outlined by provincial and territorial governments and public health authorities.

Key messages

- **Further to the June 26, 2021 Conditional Approval of the COVID-19 Vaccine Moderna, ModernaTx, Inc. is providing US-labelled vaccine supplies with English-only vial and carton labels (see Appendix A) in order to expedite the distribution of the vaccine in Saudi Arabia.**
- **Moderna COVID-19 Vaccine with US labels is the same as the Saudi Food & Drug Authority (SFDA) authorized COVID-19 Vaccine Moderna in all aspects (i.e., formulation, strength, route of administration).**
- **Healthcare professionals are advised that:**
 - **The US-labelled supply is being offered in an 8 mL vial fill containing 15 of 0.5 mL each. This is different from the SFDA authorized product which comes in vials containing 10 doses of 0.5 mL each.**
 - **Information regarding the vaccine name, description of pharmaceutical form, volume of vial fill and storage conditions are different on the US labels. Continue to reference the SFDA approved labelling for [all product information](#) for use in Saudi Arabia.**
 - **The expiration date is not printed on the US vial and carton labels. Healthcare professionals must verify the expiration date prior to vaccination. The expiration date for the corresponding lots can be**

found [on this website](#). Please follow the instruction to retrieve the expiration date.

What is the issue

COVID-19 Vaccine Moderna was authorized for use in accordance with SFDA regulation. As an extraordinary measure to provide access to vaccine supplies in the context of the global pandemic, Moderna is providing US-labelled vaccine supply on a temporary basis.

The US-labelled vaccine, named 'Moderna COVID-19 Vaccine', is supplied in a carton of 10 multiple-dose vials with 8 mL fill volume and contain a greater number of doses (15 doses).

Products affected

U.S. Vaccine Name	Dosage Form, Strength, and Route of Administration	Country of Origin and Identifying Code	Manufacturer	Importer and Supplier in Saudi Arabia
Moderna COVID-19 Vaccine	Suspension for Intramuscular Injection 10 multiple-dose vials (each vial contains maximum of 15 doses of 0.5 mL)	USA NDC 80777-273-15 (vial) NDC 80777-273-98 (carton)	Moderna US, Inc.	NUPCO

Expiration Date of Moderna COVID-19 Vaccine manufactured in US

The expiry date is not printed on the vial and carton labels (see Appendix A). To find the expiration date for Moderna COVID-19 Vaccine lots manufactured in US, please click on the following link and follow the instruction:

<https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup#vialLookupTool>

Background information

COVID-19 Vaccine Moderna is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

As an extraordinary measure to provide access to vaccine supplies in the context of

the global pandemic, SFDA has authorized the importation and sale of US-labelled Moderna COVID-19 Vaccine with vial and carton labels that are in English-only. The availability of US-labelled Moderna vaccine will be offered on an exceptional basis. The first lots are available for import to Saudi Arabia in the week of August 23, 2021.

Information regarding the vaccine name, description of pharmaceutical form, volume of vial fill and storage conditions are different on the US labels. Continue to reference the SFDA approved labelling for [all product information for use in Saudi Arabia](#).

SFDA has approved the following interim US-labelled Moderna COVID-19 Vaccine Product Presentation:

- Carton of 10 multiple-dose vials with 8 mL fill volume.
- Each vial contains 15 doses (0.5 mL).

The US Moderna COVID-19 Vaccine with English-only labels is the same as the SFDA authorized COVID-19 Vaccine Moderna in all aspects (i.e., formulation, strength, route of administration) and should be used in Saudi Arabia for the same indication and per the same vaccination schedule.

Information for healthcare professionals

Healthcare professionals should be aware that there are no changes to the product. The indication, dosage, route of administration, strength, formulation, and non-medicinal ingredients in the US-labelled product are the same as the current SFDA authorized COVID-19 Vaccine Moderna.

Healthcare professionals are advised that:

- The US-labelled Moderna COVID-19 Vaccine has a different carton and vial label. Continue to reference the [SFDA approved product information](#) for use in Saudi Arabia.
- The expiry date is not printed on the vial and carton labels (see Appendix A). **The expiration date for the corresponding lots can be found [on this website](#). Please follow the instruction to retrieve the expiration date.**
- There are no changes to the dosage and administration, other than the total number of doses per vial.
- There are no changes to the storage, stability and disposal of the vaccine. The US-labelled Moderna COVID-19 Vaccine should be stored and discarded in accordance with the SFDA approved information.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving COVID-19 Vaccine Moderna should be reported to your local Health Unit.

There is a need to report any suspected adverse reactions to:

- **The National Pharmacovigilance Center (NPC); Saudi Food and Drug Authority (SFDA) via:**

The National Pharmacovigilance Centre (NPC) SFDA call center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <http://ade.sfda.gov.sa/>

You can also report any suspected adverse reactions to:

- **Pharmacovigilance department in Tabuk Pharmaceuticals:**

E-mail: pv.info@tabukpharmaceuticals.com

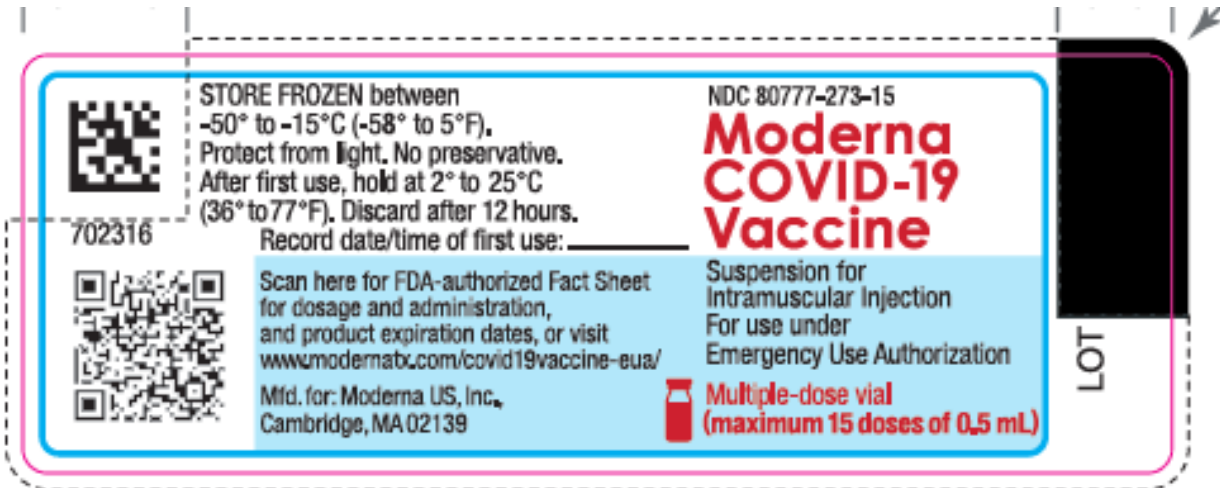
Tel: +966 4774946; Ext 233

Original signed by

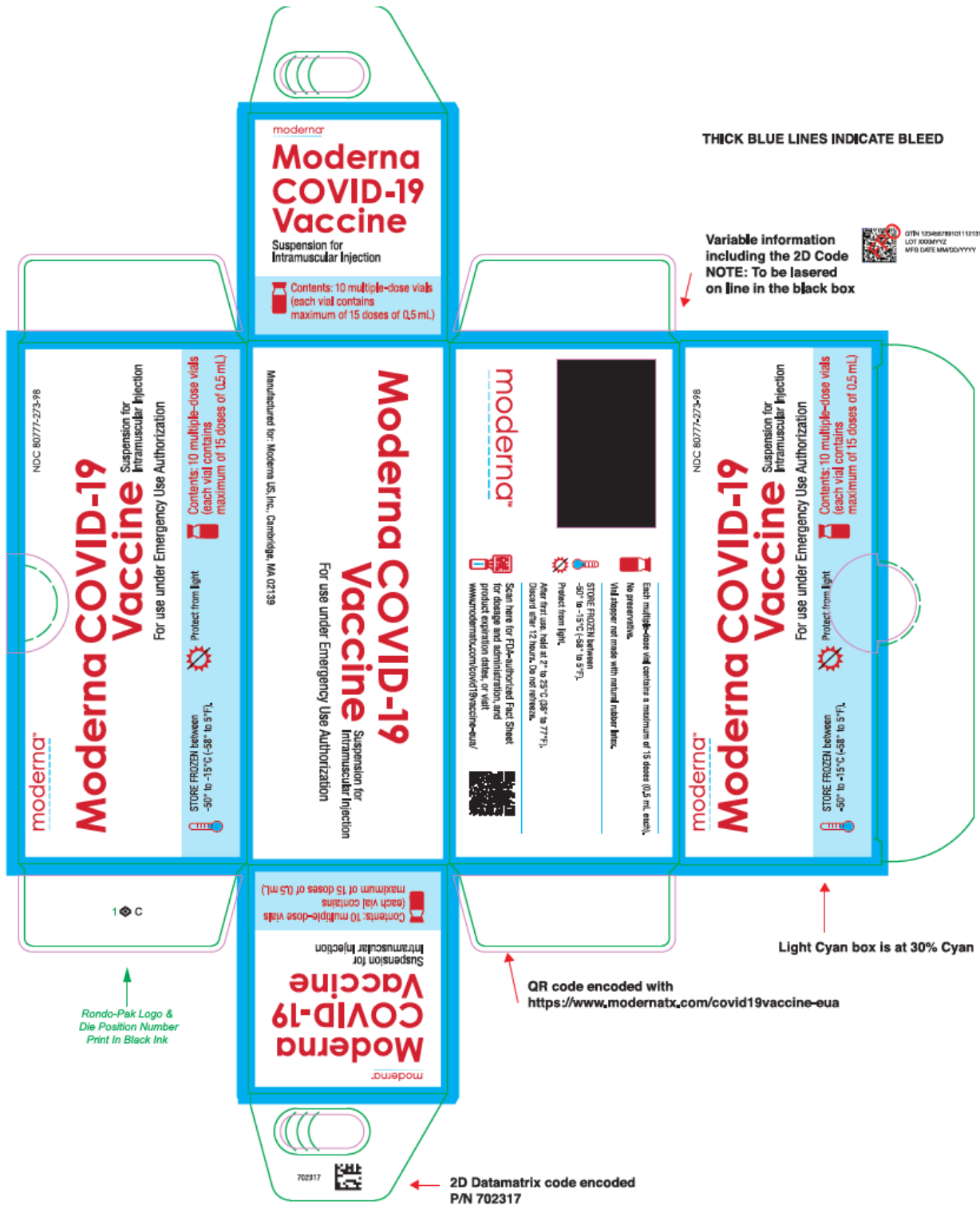
Paolo Dametto, PhD
Sr. Manager – International Regulatory Affairs
Moderna Switzerland GmbH

Appendix A – Vial and Carton Labels for Moderna COVID-19 Vaccine with English-only Labelling (US-labelled supply)

U.S. VIAL LABEL

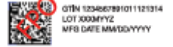


U.S. CARTON LABEL



THICK BLUE LINES INDICATE BLEED

Variable information including the 2D Code
NOTE: To be lasered on line in the black box



NDC 80771-273-96

Moderna COVID-19 Vaccine
Suspension for Intramuscular Injection
For use under Emergency Use Authorization

STORE FROZEN between -50° to -15°C (-58° to 5°F)
Protect from light
Contents: 10 multiple-dose vials (each vial contains maximum of 15 doses of 0.5 mL)

Manufactured for: Moderna US, Inc., Cambridge, MA 02139

Moderna COVID-19 Vaccine
Suspension for Intramuscular Injection
For use under Emergency Use Authorization

moderna™



Scan here for FDA-authorized Fact Sheet for dosage and administration, and product expiration dates, or visit www.modernatx.com/covid19vaccine-eua/

After first use, hold at 2° to 25°C (36° to 77°F). Discard after 12 hours. Do not refreeze.

Protect from light.

STOCK FROZEN between -50° to -15°C (-58° to 5°F).

Each multiple-dose vial contains a maximum of 15 doses (0.5 mL each), no preservatives.

Vial stopper not made with natural rubber latex.

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Rondo-Pak Logo & Die Position Number
Print In Black Ink

QR code encoded with <https://www.modernatx.com/covid19vaccine-eua>

Light Cyan box is at 30% Cyan

702317

2D Datamatrix code encoded P/N 702317