

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



2021/10/29

**UPDATED INFORMATION – October 29, 2021**

Further to the Health Canada communications below issued on June 14, 2021 (and updated on June 24, 2021, and August 3, 2021), Health Canada has authorized a 2-month shelf life extension (from 7 months to 9 months) for certain lots of the SPIKEVAX (previously COVID-19 Moderna vaccine). This extension applies to lots of US-labelled vaccine supplies with English-only vial and carton labels. These lots with their extended expiry dates are identified in the "Products Affected" section in the table below. One previously listed lot (015E21A) has been removed from the table because it was not distributed in Canada.

SPIKEVAX (previously COVID-19 Moderna vaccine) has now been issued a Notice of Compliance under the *Food and Drug Regulations*, replacing the previous authorization under the Interim Order. The vaccine is now authorized under the brand name SPIKEVAX (elasomern mRNA vaccine), for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

**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.

Innomar Strategies Inc. (the Canadian importer and distributor) 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 December 23, 2020 authorization of the COVID-19 Vaccine Moderna in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19, 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 Canada.**
- **Moderna COVID-19 Vaccine with US labels is the same as the Health Canada 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 14 doses (US label maximum 15 doses) of 0.5 mL each. This is different from the Health Canada authorized product which comes in vials containing 10 doses of 0.5 mL each.**
  - **Important Canadian-specific information is absent from the US-labelled vial and carton (see the 'Information for healthcare professionals' section below).**
  - **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 Canadian Product Monograph for all product information for use in Canada.**
  - **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 in the 'Products affected' section below. The expiration date information is also found at [www.modernacovid19global.com/ca](http://www.modernacovid19global.com/ca).**
  - **The Canadian Product Monograph, which is available in French and English on Health Canada's [Drug Product Database](http://www.drugproductdatabase.ca), the federal government's [covid-vaccine.canada.ca](http://covid-vaccine.canada.ca) website, or at [www.modernacovid19global.com/ca](http://www.modernacovid19global.com/ca), should be referenced for complete product information.**
  - **Other Canadian-specific labelling information can be accessed at [www.modernacovid19global.com/ca](http://www.modernacovid19global.com/ca). This information is also available on the federal government's [covid-vaccine.canada.ca](http://covid-vaccine.canada.ca) website.**
  - **Paper copies of the Canadian Product Monograph and the Patient Medication Information, in French and English, will be available as needed for healthcare professionals and patients.**

### **What is the issue**

COVID-19 Vaccine Moderna was authorized for use in accordance with the [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#). 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 (14 doses (with US label max. 15 doses)). The vial and carton labels are missing some important Canadian-specific information normally found on Health Canada approved labels (see the 'Information for healthcare professionals' section).

## Products affected

U.S. Vaccine Name	Dosage Form, Strength, and Route of Administration	Country of Origin and Identifying Code	Manufacturer	Importer and Supplier in Canada
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.	Innomar Strategies Inc.

U.S. COVID-19 Vaccine Moderna – Lot and Expiry Information			
Lot #	Expiry Date	Fill Volume	Doses per Vial
052C21A	10 Nov 2021	8 mL	14 (US label max. 15)
042D21A	07 Feb 2022	8 mL	14 (US label max. 15)
043D21A	09 Feb 2022	8 mL	14 (US label max. 15)
044D21A	10 Feb 2022	8 mL	14 (US label max. 15)
045D21A	11 Feb 2022	8 mL	14 (US label max. 15)
085D21A	19 Feb 2022	8 mL	14 (US label max. 15)
092D21A	13 Feb 2022	8 mL	14 (US label max. 15)
093D21A	14 Feb 2022	8 mL	14 (US label max. 15)
016E21A	01 Mar 2022	8 mL	14 (US label max. 15)
018E21A	03 Mar 2022	8 mL	14 (US label max. 15)
019E21A	02 Mar 2022	8 mL	14 (US label max. 15)
020E21A	04 Mar 2022	8 mL	14 (US label max. 15)
047E21A	06 Mar 2022	8 mL	14 (US label max. 15)
016F21A	21 Mar 2022	8 mL	14 (US label max. 15)

## Background information

COVID-19 Vaccine Moderna is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

As an extraordinary measure to provide access to vaccine supplies in the context of the global pandemic, Health Canada authorized the importation, sale, and advertising of US-labelled COVID-19 Vaccine Moderna 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 Canada the week of June 14th, 2021.

**The Product Monograph for COVID-19 Vaccine Moderna, which is approved by Health Canada and available in French and English, will not be updated to reflect the interim availability of U.S. supply. Continue to refer to the COVID-19 Vaccine Moderna PM on Health Canada’s [Drug Product Database](#), the federal government’s [covid-vaccine.canada.ca](https://www.covid-vaccine.canada.ca) website or at [www.ModernaCovid19Global.com/ca](https://www.ModernaCovid19Global.com/ca) for complete product information.**

Health Canada 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 14 doses (US label maximum 15 doses) (0.5 mL).

The US Moderna COVID-19 Vaccine with English-only labels is the same as the Health Canada authorized COVID-19 Vaccine Moderna in all aspects (i.e., formulation, strength, route of administration) and should be used in Canada 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 Health Canada 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 Canadian Product Monograph for all product information for use in Canada.
- The Canadian Product Monograph for COVID-19 Vaccine Moderna, which is available in French and English on Health Canada’s [Drug Product Database](#), the federal government’s [covid-vaccine.canada.ca](https://www.covid-vaccine.canada.ca) website, or at [www.modernacovid19global.com/ca](https://www.modernacovid19global.com/ca), should be referenced for complete product information.
- The following important Canadian-specific information is absent from the US vial and carton labels:
  - Drug Identification Number (DIN)
  - name and address of the Canadian DIN holder
  - name and address of the Canadian importer and distributor
  - all corresponding text in French
  - expiry date

- The expiry date is not printed on the vial and carton labels (see Appendix A). The expiry date for the corresponding lots are summarized in the table found in the 'Products affected' section above. The expiry date can also be obtained:
  - through the Canadian website [www.modernacovid19global.com/ca](http://www.modernacovid19global.com/ca), or
  - by scanning the smaller 2D QR code printed on the carton next to the lot number, or on the vial label next to the storage information, which links to the US website. A link is present at the top of the US website to direct Canadian users to the Canadian website (i.e. [www.modernacovid19global.com/ca](http://www.modernacovid19global.com/ca)).
- 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 Canadian Product Monograph.
- The Moderna Call Centre is available from 9am to 5pm EST, Monday through Friday, and can be reached at 1-866-MODERNA (1-866-663-3762).

### **Action taken by Health Canada**

On September 16, 2020, Canada's Minister of Health approved an [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#) to expedite the authorization for the importation, sale, and advertising of drugs used in relation to COVID-19 while taking into consideration urgent public health needs. The Interim Order will expire after one year. Health Canada authorized the use of COVID-19 Vaccine Moderna under the Interim Order on December 23, 2020, and this vaccine has been added to the "[List of authorized drugs, vaccines and expanded indications](#)" for COVID-19.

Health Canada is permitting the use of US English-only labels for a limited period.

Health Canada has made full labelling information available in French and English on the federal government's [covid-vaccine.canada.ca](http://covid-vaccine.canada.ca) website.

Health Canada has worked with Moderna to prepare this alert for the Moderna COVID-19 Vaccine and is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](#) on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

### **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 or Moderna.

**Moderna Biopharma Canada Corporation**

c/o SE Corporate Services Ltd., Suite 1700,  
Park Place, 666 Burrard Street,  
Vancouver, BC V6C 2X8

**Telephone: 1-866-663-3762**

**Fax: 1-866-599-1342**

**To correct your mailing address or fax number, contact Moderna Biopharma Canada Corporation at 1-866-MODERNA (1-866-663-3762).**

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory

(<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

For other health product inquiries related to this communication, contact Health Canada at:

Biologic and Radiopharmaceutical Drugs Directorate

E-mail: [hc.brdd.dgo.enquiries.sc@canada.ca](mailto:hc.brdd.dgo.enquiries.sc@canada.ca)

**Original signed by**

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ModernaTx, Inc.

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

## U.S. VIAL LABEL

**STORE FROZEN** between -50° to -15°C (-58° to 5°F).  
Protect from light. No preservative.  
After first use, hold at 2° to 25°C (36° to 77°F). Discard after 12 hours.

NDC 80777-273-15  
**Moderna COVID-19 Vaccine**

3-5924-553  
Record date/time of first use: \_\_\_\_\_

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

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

Suspension for Intramuscular Injection  
For use under Emergency Use Authorization

**Multiple-dose vial (maximum 15 doses of 0.5 mL)**

LOT

## U.S. CARTON LABEL

**Moderna COVID-19 Vaccine**  
Suspension for Intramuscular Injection

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/](http://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.

Each multiple-dose vial contains a maximum of 15 doses (0.5 mL each). No preservative.  
Vial stopper not made with natural rubber latex.

**STORE FROZEN** between -50° to -15°C (-58° to 5°F).  
Protect from light.

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

Contents: 10 multiple-dose vials (each vial contains maximum of 15 doses of 0.5 mL)

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