

**Important Information on the
Shelf Life Extension for the SPIKEVAX™
(elasomeran) COVID-19 Vaccine with
Printed Expiry Dates on Vial and Carton Labels**



2022/01/11

Audience

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

Key messages

- **Health Canada has authorized a shelf-life extension, from 7 months to 9 months, for SPIKEVAX / COVID-19 Vaccine Moderna 5 mL vials. This 2-month extension may be retroactively applied to vials that are currently on the market with printed expiry dates between February 2022 and August 2022 (see Products affected section), as long as the approved storage conditions have been maintained.**
- **Healthcare professionals are advised that:**
 - **The expiration date of vaccines must be verified prior to vaccination.**
 - **The Canadian-specific labelling information, including the SPIKEVAX Product Monograph and training materials, can be accessed at www.modernacovid19global.com/ca, or by scanning the QR code on the English-only vial and carton labels. This information is also available on the federal government's covid-vaccine.canada.ca website. The Canadian SPIKEVAX Product Monograph in French and English is also available on Health Canada's [Drug Product Database](#).**

What is the issue?

On December 23, 2021, Health Canada authorized a shelf-life extension, from 7 months to 9 months, for SPIKEVAX / COVID-19 Vaccine Moderna 5 mL vials. This 2-month extension may be retroactively applied to vials that are currently on the market with printed expiry dates between February 2022 and August 2022, as long as the approved storage conditions have been maintained.

Products affected

SPIKEVAX (elasomeran mRNA vaccine) (100 mcg / 0.5mL), dispersion for intramuscular injection, multidose vial (5 mL).

DIN: 02510014

Manufacturer: ModernaTx, Inc.

Canadian Importer and Distributor: Innomar Strategies Inc.

Vials of SPIKEVAX/ COVID-19 Vaccine Moderna, currently on the market, with printed expiry dates of 15 February 2022 through 31 August 2022:

Printed Expiry Date*	Updated Expiry Date
February 2022	April 2022
March 2022	May 2022
April 2022	June 2022
May 2022	July 2022
June 2022	August 2022
July 2022	September 2022
August 2022	October 2022

**Note: Printed expiry date appears in the format of DD/MM/YYYY on vial and carton labels.*

Background information

SPIKEVAX 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 12 years of age and older.

Health Canada has authorized a 2-month shelf-life extension for SPIKEVAX / COVID-19 Vaccine Moderna, which is supported by scientific evidence. This 2-month shelf-life extension may be retroactively applied to vials currently on the market with a printed expiry date between February 2022 and August 2022 (see Products affected section).

The storage conditions of -25°C to -15°C (-13°F to 5°F) remain unchanged. Within the 9-month shelf-life, unopened vials may be stored refrigerated at 2°C to 8°C (36°F to 46°F), protected from light, for a maximum of 30 days. Within this period, up to 12 hours may be used for transportation. Once thawed, the vaccine should not be re-frozen.

The last vials to be subject to this retroactive shelf-life extension will be those with a printed expiry date of August 2022 (manufactured in January 2022).

The new 9-month shelf-life will be printed on labels of SPIKEVAX beginning with vials manufactured as of February 2022. All vials with a printed expiry date of November 2022 onwards will reflect the authorized 9-month shelf-life.

Information for healthcare professionals

Healthcare professionals are advised that:

- On December 23, 2021, Health Canada authorized a shelf-life extension, from 7 months to 9 months, for the 5 mL vials of the SPIKEVAX / COVID-19 Vaccine Moderna. This 2-month extension may be retroactively applied to vials of SPIKEVAX currently on the market with printed expiry dates between February 2022 and August 2022 (see Products affected section), as long as the approved storage conditions have been maintained.
- Health Canada had previously authorized a 2-month shelf-life extension (from 7 months to 9 months) for certain lots of US-labelled vaccine supplies of SPIKEVAX (previously Moderna COVID-19 Vaccine). For additional information about the expiration date for those lots, please review the [Health Product Risk Communication dated October 29, 2021](#).
- The expiration date of vaccines must be verified prior to vaccination.
- The Canadian SPIKEVAX Product Monograph, in French and English, is available on Health Canada's [Drug Product Database](#) and should be used for complete product information.
- The Canadian-specific information, including the SPIKEVAX Product Monograph and training materials, can be accessed at www.modernacovid19global.com/ca, or by scanning the QR code on carton and vial labels. This information is also available on the federal government's covid-vaccine.canada.ca website.

Action taken by Health Canada

Health Canada is permitting a retroactive application of the authorized 2-month shelf-life extension, from 7 to 9 months, for SPIKEVAX / COVID-19 Vaccine Moderna 5 mL vials with printed expiry dates between February 2022 and August 2022.

Health Canada is communicating this important information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](#) on the Healthy Canadians Web Site. This communication update 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 SPIKEVAX 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: brdd.dgo.enquiries@hc-sc.gc.ca

Original signed by

Leslie Madden, BSc, MBA, LLM
Director, Head of Regulatory Affairs Canada
ModernaTx, Inc.