

**Important Safety Information on the Distribution of
SPIKEVAX Bivalent (elasomeran/imelasomeran) COVID-19 Vaccine
with English-only Vial and Carton Labels**



2022/09/02

Audience

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners, healthcare professionals at vaccination sites.

Key messages

- **On September 1, 2022, Health Canada authorized Moderna's SPIKEVAX Bivalent (elasomeran/ imelasomeran) Original / Omicron mRNA COVID-19 vaccine (DIN 02530252), which encodes for the Spike (S) protein of SARS-CoV-2 original variant and Omicron variant (B.1.1.529).**
- **SPIKEVAX Bivalent vaccine is indicated as a booster dose for active immunization against coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.**
- **In order to provide rapid access to SPIKEVAX Bivalent, Moderna will distribute product vials and cartons with English-only labels with the brand name "SPIKEVAX 0 (Zero)/ O (Omicron)" (see Appendix A), for a period of time.**
- **Existing monovalent vaccine supply of SPIKEVAX (elasomeran), 0.10 mg/mL, 2.5 mL multidose vial and 0.20 mg/mL, 5 mL multidose vial, continue to be available at this time.**
- **Healthcare professionals are advised that:**
 - **While the Canadian brand name is SPIKEVAX Bivalent, initial shipments are being distributed with English-only labels with the brand name "SPIKEVAX™ 0 (Zero) / O (Omicron)."**
 - **The bivalent SPIKEVAX™ 0 (Zero) / O (Omicron), 0.10 mg/mL, 2.5 mL shares the same coloured vial cap (royal blue) to monovalent SPIKEVAX 0.10 mg/mL, 2.5 mL. To avoid medication errors, pay careful attention to the vial and carton label.**
 - **Important Canadian-specific information is absent from the vial and carton labels (see the Information for healthcare professionals section).**

- **The Canadian-specific labelling information including the SPIKEVAX Bivalent Product Monograph and training materials can be accessed at 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 Bivalent Product Monograph in English and French is also available on Health Canada's [Drug Product Database](#).**
- **Moderna will develop Canadian-specific vial and carton labels for SPIKEVAX Bivalent in English and French, and make them available on the modernacovid19global.com/ca website at a future date.**

What is the issue?

Health Canada authorized SPIKEVAX Bivalent (elasomeran/imelasomeran) on September 1, 2022. In order to provide rapid access to SPIKEVAX Bivalent, Moderna will distribute product vials and cartons labelled in English only with the brand name "SPIKEVAX 0 (Zero) / O (Omicron)" for a period of time. As a result, important Canadian-specific information is absent from these labels (see the Information for healthcare professionals section).

The **bivalent** SPIKEVAX™ 0 (Zero) / O (Omicron), 0.10 mg/mL, 2.5 mL shares the same coloured vial cap (royal blue) to **monovalent** SPIKEVAX 0.10 mg/mL, 2.5 mL. To avoid medication errors, pay careful attention to the vial and carton label.

Products affected

SPIKEVAX Bivalent (elasomeran/imelasomeran) (0.10 mg/mL), 2.5 mL multidose vial, dispersion for intramuscular injection, 5 doses of 0.5 mL each.

DIN: 02530252

Manufacturer: ModernaTX, Inc.

Canadian Importer and Distributor: Innomar Strategies

Background information

SPIKEVAX Bivalent (elasomeran/imelasomeran) Original/Omicron mRNA vaccine is indicated as a booster dose for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 18 years of age and older.

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of SPIKEVAX Bivalent with vial and carton labels that are in English only with the brand name "SPIKEVAX 0 (Zero) / O (Omicron)" for the initial global distribution of the vaccine.

The Canadian Product Monograph for SPIKEVAX Bivalent, which is approved by Health Canada and available in English and French, should be used for complete

product information when using SPIKEVAX™ 0 (Zero) / O (Omicron).

Information for healthcare professionals

Healthcare professionals are advised that:

- On September 1, 2022, Health Canada authorized SPIKEVAX Bivalent (elasomeran/imelasomeran) COVID-19 vaccine.
- In order to provide rapid access to SPIKEVAX Bivalent, Moderna will distribute product vials and cartons labelled in English only with the brand name "SPIKEVAX 0 (Zero) / O (Omicron)" for a period of time.
- The **bivalent** SPIKEVAX™ 0 (Zero) / O (Omicron), 0.10 mg/mL, 2.5 mL shares the same coloured vial cap (royal blue) to **monovalent** SPIKEVAX 0.10 mg/mL, 2.5 mL. To avoid medication errors, pay careful attention to the vial and carton label.
- The Canadian-specific information, including the SPIKEVAX Bivalent Product Monograph and training materials, can be accessed at 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](https://www.covid-vaccine.canada.ca) website. The Canadian SPIKEVAX Bivalent Product Monograph in English and French, which is also available on Health Canada's [Drug Product Database](#), should be used for complete product information.
- The following important Canadian-specific information is absent from the 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
 - Canadian brand name SPIKEVAX Bivalent

Action taken by Health Canada

Health Canada is permitting the use of global English-only labels with the brand name SPIKEVAX™ 0 (Zero) / O (Omicron) for a limited period. Health Canada has imposed terms and conditions requiring Moderna to provide vaccine supplies with Canadian-specific labels as soon as possible. Health Canada has made full labelling information available in English and French on the federal government's [covid-vaccine.canada.ca](https://www.covid-vaccine.canada.ca) website.

Health Canada 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 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 Bivalent 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:

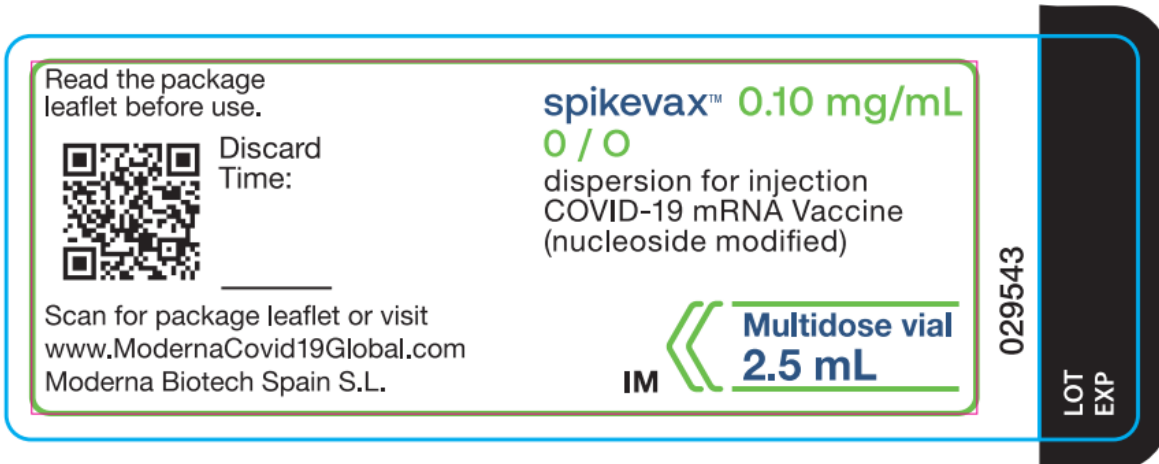
Biologic and Radiopharmaceutical Drugs Directorate
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Original signed by

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ModernaTX, Inc.

Appendix A – Vial and carton labels for SPIKEVAX Bivalent (elasomeran/imelasomeran) with English-only labelling

SPIKEVAX™ 0 (Zero) / O (Omicron) Vial Label*



Read the package leaflet before use.	spikevax™
Discard Time: _____	0.10 mg/mL
	0 / O
Scan for package leaflet or visit www.ModernaCovid19Global.com Moderna Biotech Spain S.L.	dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)
	IM
	Multidose vial
	2.5 mL
	LOT
	EXP

*The vial label presents an abbreviated version of the brand name, SPIKEVAX™ 0 (Zero) / O (Omicron). The vial label contains the brand name SPIKEVAX™ and '0 / O' as an abbreviation of 'Zero / Omicron'. The 2-D matrix code may not appear on all vial labels with the SPIKEVAX™ 0 / O band name.

SPIKEVAX™ 0 (Zero) / O (Omicron) Carton Label



<p>Moderna spikevax™ 0 (Zero) / O (Omicron) dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Intramuscular use</p>	<p>0.10 mg/mL 10 multidose vials each vial contains 2.5 mL</p>
<p><i>Black box contains:</i> PC EXP LOT</p> <p>Moderna™ Moderna Biotech Spain, S.L. Calle del Principe de Vergara 132 Pit 12, Madrid 28002, Spain</p>	<p>Each multidose vial contains 2.5 mL. Excipients: Lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.</p>

Store frozen at -50°C to -15°C. Read the package leaflet for the shelf life after first opening and for additional storage information.

Keep the vial in the outer carton to protect from light.

Keep out of sight and reach of children.

Dispose of in accordance with local requirements.

Read the package leaflet before use.

Scan here for package leaflet or visit

www.ModernaCOVID-19Global.com