

September 12, 2023

Information About English-Only Non-Canadian Vial and Carton Labels
SPIKEVAX® XBB.1.5 (andusomeran mRNA vaccine)
Drug Identification Number (DIN): 02541270

Dear Vaccination Provider,

The purpose of this letter is to inform Canadian vaccination providers of the following:

- In order to provide rapid access to the vaccine, Moderna will distribute **SPIKEVAX XBB.1.5 (andusomeran mRNA vaccine)** COVID-19 vaccine product vials and cartons labeled in English only for a period of time (see Appendix A).
- 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
 - all corresponding text in French
- The Canadian Product Monograph for SPIKEVAX XBB.1.5, which is approved by Health Canada and available in English and French, should be used for complete product information.

The Canadian-specific labelling information including the SPIKEVAX XBB.1.5 Product Monograph can be accessed at modernacovid19global.com/ca, or by scanning the QR code which is also found on the English-only vial and carton labels.

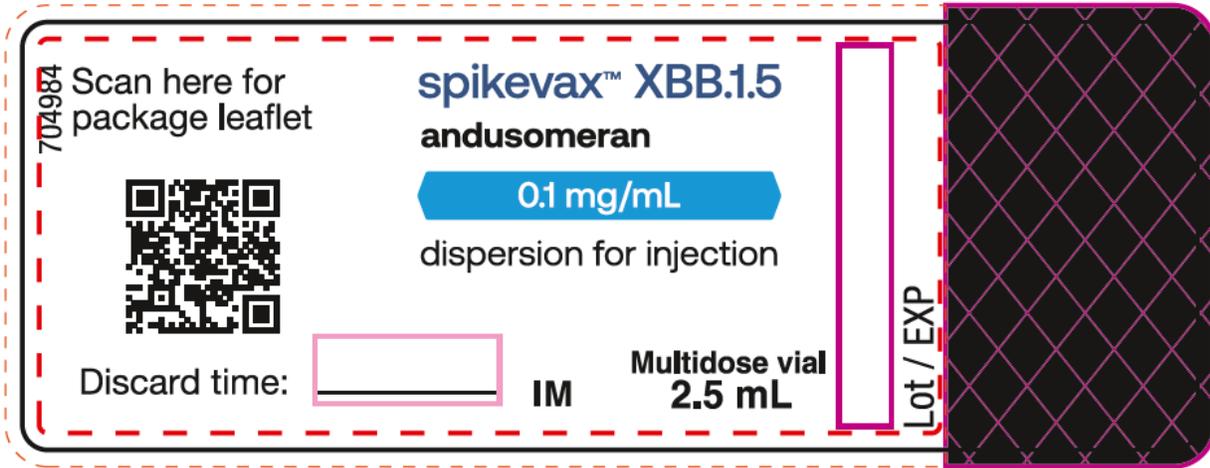


Sincerely,

Leslie Madden, BSc, MBA, LLM
Senior Director, Head of Regulatory Science & Quality Assurance
Moderna Biopharma Canada Corp.

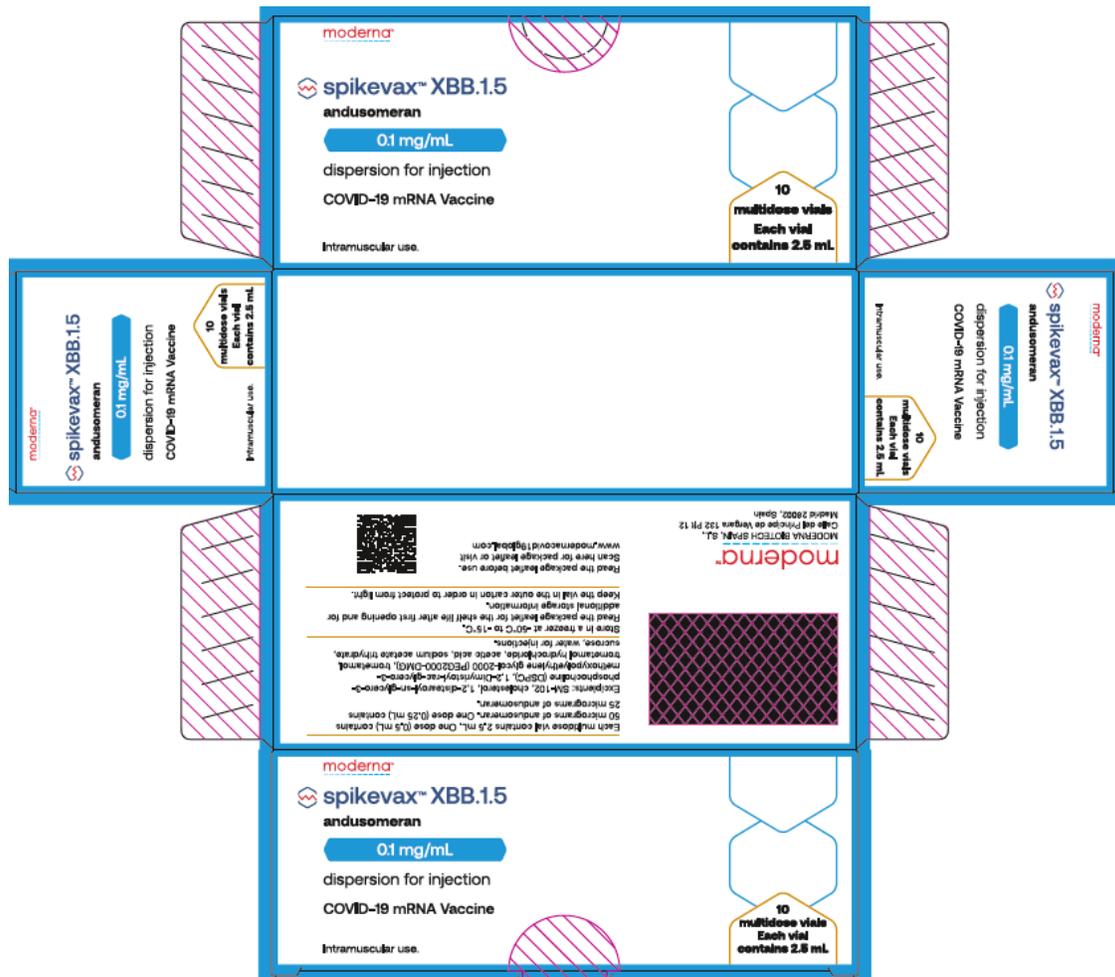
Appendix A – Vial and Carton Labels for SPIKEVAX XBB.1.5 (andusomeran mRNA vaccine)

SPIKEVAX XBB.1.5 – English-Only Vial Label



[2D matrix code*] 704984	spikevax™ XBB.1.5 andusomeran
Scan here for package leaflet [QR code]	0.1 mg/mL dispersion for injection
Discard Time: _____	IM Multidose vial 2.5 mL
	LOT / EXP

SPIKEVAX XBB.1.5 – English-Only Carton Label



<p>Moderna spikevax™ XBB.1.5 andusomeran 0.1 mg/mL dispersion for injection COVID-19 mRNA Vaccine Intramuscular use.</p>	<p>10 multidose vials Each vial contains 2.5 mL</p>
<p><i>Black box contains:</i> LOT EXP Moderna™ Moderna Biotech Spain, S.L. Calle del Principe de Vergara 132 Plt 12, Madrid 28002, Spain</p>	<p>Each multidose vial contains 2.5 mL. One dose (0.5 mL contains 50 micrograms of andusomeran. One dose (0.25 mL contains 25 micrograms of andusomeran. Excipients: 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> <p>Store in a freezer at -50°C to -15°C.</p> <p>Read the package leaflet for the shelf life after first opening and for additional storage information.</p> <p>Keep the vial in the outer carton to protect from light.</p> <p>Read the package leaflet before use.</p> <p>Scan here for package leaflet or visit www.ModernaCOVID-19Global.com [QR code]</p>