Important Safety Information on COVID-19 Vaccine Moderna - Updated English-only Global Vial and Carton Labels and Post-Market Adverse Reaction Information

moderna

2021/02/22

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

- **The COVID-19 Vaccine Moderna (mRNA-1273 SARS-CoV-2 vaccine) Product Monograph (PM) has been updated with post-market adverse reaction information identified during pharmacovigilance activities. Anaphylaxis has been reported following COVID-19 Vaccine Moderna administration outside of clinical trials. This new information does not change the benefit-risk profile of this product.**
- **The COVID-19 Vaccine Moderna PM and global English-only vial and carton labels are also being updated with new product labelling information, including brand name change. These product labelling updates are administrative in nature (see table under Information for healthcare professionals section and Appendix A).**
- **There are no changes to the product and COVID-19 Vaccine Moderna remains the same in all aspects as initially authorized by Health Canada (i.e., formulation, strength, route of administration, storage and handling) and should be used in Canada for the same indication and per the same vaccination schedule.**
- **The updated PM, which is available in French and English on Health Canada's Drug Product Database, the federal government's covid-vaccine.canada.ca website or at www.ModernaCovid19Global.com should be used for complete product information. Updated vial and carton labels with English-only labelling (see Appendix A) are also available on the federal government's covid-vaccine.canada.ca website.**

What is the issue?
The COVID-19 Vaccine Moderna was authorized on December 23, 2020, for use in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. Since the time of authorization, new information pertaining to post-market adverse reactions has been identified following COVID-19 Vaccine Moderna administration outside of clinical trials. In addition, the PM and global English-only vial and carton labels have been updated with new product labelling information.

Products affected
COVID-19 Vaccine Moderna, 0.2 mg/mL dispersion for intramuscular injection, multiple dose vials. Each vial contains 10 doses (each dose is 0.5 mL).
DIN: 02510014

Manufacturer: Moderna Therapeutics Inc.
Canadian Importer and Distributor: Innomar Strategies Inc.

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.

The COVID-19 Vaccine Moderna PM has been updated with post-market adverse reaction information identified during pharmacovigilance activities. Anaphylaxis has been reported following COVID-19 Vaccine Moderna administration outside of clinical trials. This new information does not change the benefit-risk profile of this product.

In addition, the COVID-19 Vaccine Moderna PM, and global English-only vial and carton labels have been updated with new product labelling information including a revised brand name, product common name, pharmaceutical dosage form, company address, company website address, and QR codes, alternative names for non-medicinal ingredients, as well as the addition of new statements. These product labelling updates are administrative in nature.

There are no changes to the product and COVID-19 Vaccine Moderna remains the same in all aspects as initially authorized by Health Canada (i.e., formulation, strength, route of administration, storage and handling) and should be used in Canada for the same indication and per the same vaccination schedule.

Health Canada has authorized updates to the COVID-19 Vaccine Moderna PM to reflect this new information. Health Canada has also authorized updates to the global vial and carton labels.

The PM for the COVID-19 Vaccine Moderna, which is approved by Health Canada and available in French and English, should be used for complete product information. The PM is available on Health Canada's Drug Product Database, on the federal government's covid-vaccine.canada.ca website, or at

www.ModernaCovid19Global.com. Updated vial and carton labels with English-only labelling (see Appendix A) are also available on the federal government's covid-vaccine.canada.ca website.

As an extraordinary measure to provide earlier access to vaccine supplies in the context of the global pandemic, Health Canada authorized the importation, sale, and advertising of the COVID-19 Vaccine Moderna with vial and carton labels that are in English-only and meant for the initial global distribution of the vaccine. The terms and conditions imposed by Health Canada, which includes a requirement for Moderna to develop Canadian-specific labelling in French and English for the vaccine vials and cartons, continue to apply. For more information on this issue, please consult the previously issued communication published on the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. Also in accordance with the terms and conditions imposed by Health Canada, Moderna Therapeutics Inc. is required to submit adverse reaction reports without delay and monthly safety reports for COVID-19 Vaccine Moderna.

The use of COVID-19 Vaccine Moderna is permitted under an interim authorization in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

Patients should be advised of the nature of the authorization.

Information for healthcare professionals
Healthcare professionals should be aware that anaphylaxis has been reported following COVID-19 Vaccine Moderna administration outside of clinical trials. This new information does not change the benefit-risk profile of this product.

Healthcare professionals are advised that:

- as with all vaccines, appropriate medical treatment, training for immunizers, and supervision should always be readily available in case of a rare anaphylactic event following the administration of this vaccine.
- close observation for at least 15 minutes is recommended following vaccination with COVID-19 Vaccine Moderna.
- a second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine Moderna.

Healthcare professionals are also advised that the COVID-19 Vaccine Moderna PM, and global English-only vial and carton labels have been updated with new product labelling information as indicated in the table below. These product labelling updates are administrative in nature.

Administrative Labelling Updates		
	Previous	**New**
Brand Name	Moderna Covid-19 Vaccine	Covid-19 Vaccine Moderna
Common Name	COVID-19 mRNA Vaccine	COVID-19 mRNA Vaccine (nucleoside modified)
Pharmaceutical Form	suspension	dispersion
Alternative names for non-medicinal ingredients	Tromethamine Tromethamine Hydrochloride Sodium acetate	Trometamol Trometamol Hydrochloride Sodium acetate trihydrate
Website URL and QR Codes	www.ModernaCovidVaccine.com	www.ModernaCovid19Global.com
Statements	N/A	"Read the package leaflet before use" "Discard Date/Time"
Company Address	Moderna Biotech Spain SLU	Moderna Biotech Spain **SL**

There are no changes to the product and COVID-19 Vaccine Moderna remains the same in all aspects as initially authorized by Health Canada (i.e., formulation, strength, route of administration, storage and handling) and should be used in Canada for the same indication and per the same vaccination schedule.

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, in collaboration with Moderna, has updated the PM for the COVID-19 Vaccine Moderna to reflect this new information. Health Canada has also authorized updates to the global vial and carton labels.

Health Canada continues to closely monitor reports of anaphylactic reactions associated with the COVID-19 Vaccine Moderna. Health Canada will take action if any new safety issues are confirmed.

Health Canada has worked with Moderna to prepare this alert for the COVID-19 Vaccine Moderna. 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 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:

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Carlota Vinals
Digitally signed by Carlota Vinals
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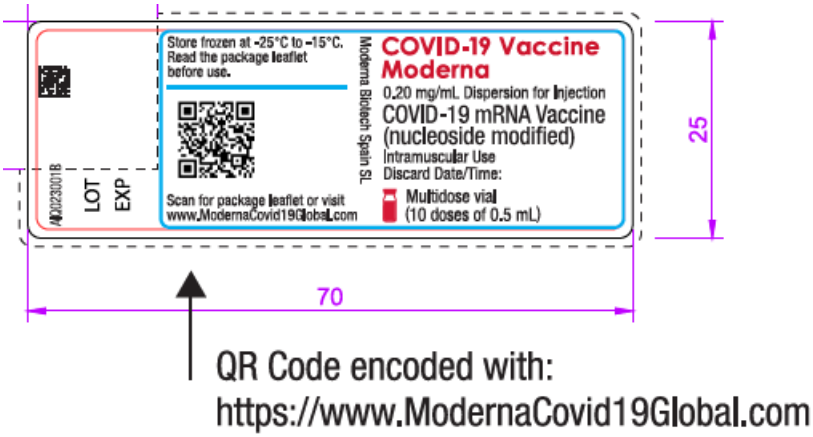
Carla Vinals
VP, Regulatory Affairs Strategy, Infectious Disease
Moderna Therapeutics, Inc.

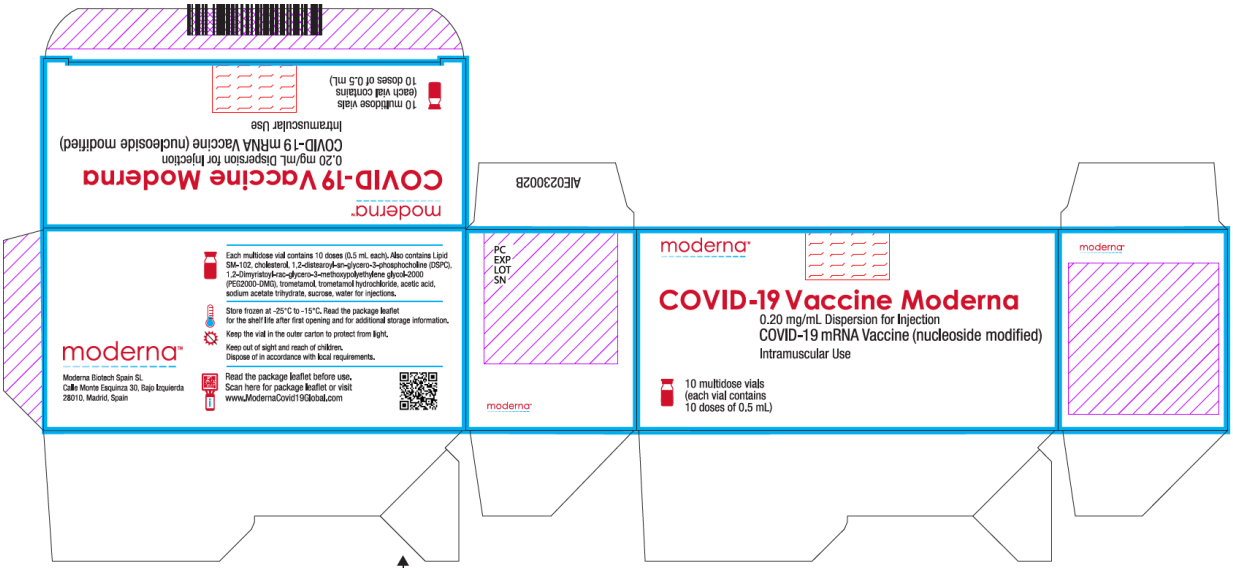
Appendix A – Updated vial and carton labels for COVID-19 Vaccine Moderna with English-only labelling

VIAL LABEL



Store frozen at -25°C to -15°C. Read the package leaflet before use.
Scan for package leaflet or visit: www.ModernaCovid19Global.com
COVID-19 Vaccine Moderna
0.20 mg/mL Dispersion for Injection
COVID-19 mRNA Vaccine (nucleoside modified)
Intramuscular Use
Discard Date/Time
Multidose vial (10 doses of 0.5 mL)
Moderna Biotech Spain SL

CARTON LABEL



COVID-19 Vaccine Moderna
0.20 mg/mL Dispersion for Injection
COVID-19 mRNA Vaccine (nucleoside modified)
Intramuscular Use
10 multidose vials (each vial contains 10 doses of 0.5 mL)
Each multidose vial contains 10 doses (0.5-mL each). Also contains Lipid SM-102, cholesterol, 1,2distearoyl-sn-glycero-3-phosphocholine (DSPC), PEG2000-DMG, tromethamol, tromethamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injection.
Store frozen at -25°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.
Read the package leaflet before use. Scan here for package leaflet or visit: www.ModernaCovid19Global.com
Moderna Biotech Spain SL Calle Monte Esquinza 30, Bajo Izquierda 28010, Madrid, Spain