2020/12/23

IMPORTANT: Access to Canadian-specific labelling information during the initial distribution of the Moderna COVID-19 Vaccine.

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.

Innomar Strategies Inc. (the Canadian importer and distributor) is initially distributing the Moderna COVID-19 Vaccine 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

- On December 23, 2020, Moderna COVID-19 Vaccine (COVID-19 mRNA Vaccine) (DIN 02510014) was authorized in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.
- Moderna COVID-19 Vaccine is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in persons 18 years of age and older.
- At this time, Moderna Biopharma Canada Corporation (Moderna) is providing vaccine supplies with global English-only labels on the vials and cartons in order to expedite the global distribution of Moderna COVID-19 Vaccine.
- Health Canada has imposed terms and conditions on the authorization of the vaccine requiring that Moderna develop Canadian-specific labelling in French and English for the vaccine vials and cartons. Moderna has agreed that vaccine supplies with Canadian-specific labelling in French and English will be available as soon as feasible given the need to ensure a rapid global supply.
What is the issue?
Moderna COVID-19 Vaccine 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 earlier access to vaccine supplies in the context of the global pandemic, Moderna is providing, at this time, vaccine vials and cartons labelled with the global label. This label is presented in English-only and is missing some important Canadian-specific information normally found on Health Canada approved labels (see the Information for healthcare professionals section).

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

Healthcare professionals are advised that:

- Important Canadian-specific information is absent from the vial and carton labels (see the Information for healthcare professionals section).
- The Canadian Product Monograph, 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 https://www.ModernaCovidVaccine.com, should be referenced for complete product information.
- The Canadian-specific labelling information including the Product Monograph and training materials can be accessed at https://www.ModernaCovidVaccine.com, 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.
- Moderna will develop Health Canada approved vial and carton labels in French and English, and make them available on the https://www.ModernaCovidVaccine.com website in the coming weeks.
- Paper copies of the Canadian Product Monograph and Patient Handout in French and English will be available at the points of use for healthcare professionals and patients.
- Paper copies of the Health Canada approved vial and carton labels in French and English will also be made available, once finalized in the coming weeks, for reference by healthcare professionals at the points of use.
Background information

Moderna COVID-19 Vaccine is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in persons 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 Moderna COVID-19 Vaccine with vial and carton labels that are in English-only for the initial global distribution of the vaccine. This allows earlier access to the vaccine for the Canadian population ahead of the Canadian-labelled Moderna COVID-19 Vaccine being available, and facilitates the global deployment of this vaccine across many countries given the high demand.

Moderna COVID-19 Vaccine with global labels is the same as the Health Canada authorized Moderna COVID-19 Vaccine 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. The Canadian Product Monograph for Moderna COVID-19 Vaccine, which is approved by Health Canada and available in French and English, should be used for complete product information. The Product Monograph is available on Health Canada’s Drug Product Database, on the federal government’s covid-vaccine.canada.ca website, or at https://www.ModernaCovidVaccine.com.

The use of Moderna COVID-19 Vaccine 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

In order to provide rapid access to Moderna COVID-19 Vaccine for Canadians, Moderna will provide product vials and cartons labelled in English-only for a limited time period.

Healthcare professionals are advised that:

- The approved Canadian Product Monograph, 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 https://www.ModernaCovidVaccine.com, 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

- The Canadian-specific information can be accessed at https://www.ModernaCovidVaccine.com, 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.

- Paper copies of the Canadian Product Monograph and Patient Handout will be available at the points of use for this vaccine.

- Moderna will develop Health Canada approved vial and carton labels in French and English, and make them available on the https://www.ModernaCovidVaccine.com website in the coming weeks for reference by healthcare professionals. Once finalized, a paper copy of these labels will also be made available for reference at the points of use.

- For any medical questions, contact Moderna Medical Information at 1-866-MODERNA (1-866-663-3762), or email medinfo@modernatx.com.

- For any other general inquiries, contact Moderna Customer Service 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 Moderna COVID-19 Vaccine 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 a global English-only label 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 French and English on the federal government’s covid-vaccine.canada.ca website.

Health Canada has worked with Moderna to prepare this alert for the Moderna COVID-19 Vaccine. 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 Moderna COVID-19 Vaccine 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 V6C2X8

**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](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**
Carla Vinals
VP, Regulatory Affairs Strategy, Infectious Disease Moderna Therapeutics, Inc.

**Digitally signed by Carla Vinals**
Date: 2020.12.23 09:44:47 -05'00'
Appendix A – Vial and carton labels for Moderna COVID-19 Vaccine with English-only labelling

Vial

<table>
<thead>
<tr>
<th>Store and transport frozen at -25°C to -15°C. Read the package leaflet before use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scan for package leaflet or visit: <a href="http://www.ModernaCovidVaccine.com">www.ModernaCovidVaccine.com</a></td>
</tr>
<tr>
<td>Moderna COVID-19 Vaccine</td>
</tr>
<tr>
<td>0.20 mg/mL Suspension for Injection</td>
</tr>
<tr>
<td>COVID-19 mRNA vaccine</td>
</tr>
<tr>
<td>Intramuscular Use</td>
</tr>
<tr>
<td>Multiple-dose vial (10 doses of 0.5 mL)</td>
</tr>
<tr>
<td>Moderna Biotech Spain SLU</td>
</tr>
</tbody>
</table>
**Moderna COVID-19 Vaccine**

<table>
<thead>
<tr>
<th>0.20 mg/mL Suspension for Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 mRNA vaccine</td>
</tr>
<tr>
<td>Intramuscular Use</td>
</tr>
</tbody>
</table>

- 10 multiple-dose vials (each vial contains 10 doses of 0.5 mL)
- Each multiple-dose vial contains 10 doses (0.5-mL each). Also contains Lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), PEG2000-DMG, tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, sucrose, water for injection.

- Store and transport 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.

Scan here for package leaflet or visit [www.ModernaCovidVaccine.com](http://www.ModernaCovidVaccine.com)

Moderna Biotech Spain SLU
Calle Monte Esquinza 30, Bajo Izquierda
28010, Madrid, Spain