Frequently Asked Questions

Explore these topics to find the answers to some of the most common questions we get from healthcare professionals. Can’t find the answer to your question? Give us a call at 1-866-MODERNA (1-866-663-3762).

The use of COVID-19 Vaccine Moderna is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 Interim Order (IO). Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada’s IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

The current COVID-19 Vaccine Moderna vial and carton labels are not Canadian-specific as global, English-only labels are being used for the Canadian market.

For more information, please see the Health Product Risk Communication.

COVID-19 Vaccine Moderna (mRNA-1273 SARS-CoV-2 vaccine) is indicated 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.

Please find helpful resources for COVID-19 Vaccine Moderna below. Check back as we update with additional educational content as it becomes available.

Drug Identification Number (DIN): 02510014

### General

**Who is Moderna?**

Moderna, Inc. is a biotechnology company developing messenger RNA (mRNA) therapeutics and vaccines to investigate and potentially create a new class of medicines for patients. Moderna was established in 2010 and is headquartered in Cambridge, Massachusetts.

If you would like more information on Moderna, you can visit our website, www.ModernaTX.com.

**What does it mean that the vaccine is based on mRNA technology?**

A vaccine based on messenger RNA (mRNA) technology, such as COVID-19 Vaccine Moderna, does not use inactivated virus, attenuated virus, or any other kind of virus. COVID-19 Vaccine Moderna uses mRNA to provide a blueprint for your cells to build your body’s defense against the virus. This allows the body to generate an antibody response, and to retain the information in memory immune cells, in order to attack the virus if the vaccinated individual is exposed to the virus.
What side effects are seen with this vaccine?

The safety profile of COVID-19 Vaccine Moderna is based on data generated from an ongoing Phase 3 placebo-controlled clinical study on subjects ≥ 18 years of age.

Solicited adverse reactions were reported more frequently among vaccine subjects than placebo subjects. The most frequently reported adverse reactions after any dose were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%) and chills (45.4%). The majority of local and systemic adverse reactions had a median duration of 1 to 3 days.

Overall, there was a higher reported rate of solicited adverse reactions in younger age groups; the incidence of lymphadenopathy (axillary swelling/tenderness), fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, fever was higher in adults 18 to 64 years of age than in those 65 years of age and above. Solicited adverse reactions were also more frequent after the second dose, compared to the first one, including grade 3 local and systemic adverse reactions.

Anaphylaxis has been reported following COVID-19 Vaccine Moderna administration. Please see the full Product Monograph for more information on adverse reactions.

The vaccine was incorrectly handled. Can it still be used?

COVID-19 Vaccine Moderna should be stored and handled under the freezer and refrigerator conditions as described in the Storage, Stability and Disposal section of the Product Monograph.

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.

After the first dose has been withdrawn, the vial should be stored between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

If for any reasons, some vials may have experienced a temperature excursion, use our Temperature Excursion Tool for further instructions.

How do I know that the vaccine I received is not counterfeit?

Moderna is committed to safety and ensuring that people have accurate information about investigational COVID-19 Vaccine Moderna, including how it is accessed and administered.

Moderna is actively monitoring for fraudulent offers of illegitimate COVID-19 Vaccine Moderna to protect individuals from products that might be dangerous and lead to serious and life-threatening harm.

COVID-19 Vaccine Moderna is not sold online.

The authenticity of products acquired outside of the legitimate supply chain cannot be verified by Moderna. If you suspect the COVID-19 Vaccine Moderna you have purchased may be counterfeit, please call Moderna Medical Information at 1-866-MODERNA (1-866-663-3762).

The vaccine appears to be defective or damaged. What can I do?

If you have defective or damaged vaccine, please contact Moderna Medical Information at 1-866-MODERNA (1-866-663-3762).

COVID-19 Vaccine Moderna is a white to off-white dispersion. It may contain white or translucent product-related particulates.

Inspect COVID-19 Vaccine Moderna vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

Packages and vials that have not been stored and handled with the appropriate freezer and refrigeration requirements as outlined in the Product Monograph should be discarded.
What is known about the safety of the vaccine for special populations (children, pregnant women, elderly people)?

**Children:** The safety and efficacy of COVID-19 Vaccine Moderna in individuals under 18 years of age has not yet been established.

**Pregnant women:** The safety and efficacy of COVID-19 Vaccine Moderna in pregnant women have not yet been established.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to COVID-19 Vaccine Moderna during pregnancy. Women who are vaccinated with COVID-19 Vaccine Moderna during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

**Breastfeeding women:** It is unknown if COVID-19 Vaccine Moderna is excreted in human milk. A risk to the newborns/infants cannot be excluded. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for immunization against COVID-19.

**Elderly people:** Clinical studies of COVID-19 Vaccine Moderna include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.

In clinical studies, there was a higher reported rate of solicited adverse reactions in younger age groups; the incidence of lymphadenopathy (axillary swelling/tenderness), fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, fever was higher in adults 18 to 64 years of age than in those 65 years of age and above. Solicited adverse reactions were also more frequent after the second dose, compared to the first one, including grade 3 local and systemic adverse reactions.

What should I do if a patient only receives one dose?

COVID-19 Vaccine Moderna was designed and studied to be given as a series of two doses 1 month apart. There are no available data on a single dose.

All effort should be made to ensure that all vaccine recipients receive 2 doses. Provide a COVID-19 vaccination card to recipients as documentation of the first dose of Moderna COVID-19 Vaccine and to remind them when a second dose should be administered.

How do I report adverse events from vaccination?

Managing marketed health product-related side effects depends on healthcare professionals and patients reporting them. Any serious or unexpected side effects in patients receiving COVID-19 Vaccine Moderna should be reported to your local Health Unit.

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory and send it to your local Health Unit.

In addition, you can report side effects to Moderna at 1-866-MODERNA (1-866-663-3762).

Is mask wearing and social distancing necessary after the first dose? After the second dose?

As with any vaccine, COVID-19 Vaccine Moderna may not fully protect all those who receive it. Even after having had both doses of the vaccine, patients should continue to follow the recommendations of local public health officials to prevent the spread of COVID-19.

Are there any risks with concomitant vaccines?

There are no data to assess the concomitant administration of COVID-19 Vaccine Moderna with other vaccines. Do not mix COVID-19 Vaccine Moderna with other vaccines/products in the same syringe.

Are there any known contraindications?

COVID-19 Vaccine Moderna is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.
REPORTING ADVERSE EVENTS

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PRODUCT CONCERNS

All designated vaccination sites need to maintain security around the storage of COVID-19 Vaccine Moderna within their facilities.

Make sure that vials of COVID-19 Vaccine Moderna arrive and are stored in their original packaging. If you suspect that the COVID-19 Vaccine Moderna you have purchased may be counterfeit, if there are any irregularities with packaging, and/or with the arrival of the shipments, please contact us at 1-866-663-3762 or visit www.modernatx.com, or report a complaint to Health Canada.