

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

COVID-19 Vaccine Moderna

mRNA-1273 SARS-CoV-2 vaccine for injection

Health Canada has authorized the sale of this COVID-19 vaccine under an Interim Order.

Read this carefully before you start taking **COVID-19 Vaccine Moderna**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **COVID-19 Vaccine Moderna**.

What is COVID-19 Vaccine Moderna used for?

COVID-19 Vaccine Moderna is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to adults aged 18 years and older.

How does COVID-19 Vaccine Moderna work?

COVID-19 Vaccine Moderna works by causing the body to produce its own protection (antibodies) against the SARS-CoV-2 virus that causes the COVID-19 infection. COVID-19 Vaccine Moderna uses a molecule called messenger ribonucleic acid (mRNA) to deliver the set of instructions that cells in the body can use to make antibodies to help fight the virus that causes COVID-19.

The vaccine is given by injection with a needle in the upper arm and will require two doses given 4 weeks apart.

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

Individuals may not be optimally protected until after receiving the second dose of the vaccine.

You cannot get COVID-19 from this vaccine.

What are the ingredients in COVID-19 Vaccine Moderna?

Medicinal ingredients: mRNA-1273 SARS-CoV-2

Non-medicinal ingredients:

- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC),
- acetic acid,
- cholesterol,
- PEG2000 DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol),
- lipid SM-102,
- sodium acetate trihydrate,
- sucrose,
- trometamol
- trometamol hydrochloride,
- water for injection.

COVID-19 Vaccine Moderna comes in the following dosage forms:

White to off-white dispersion for injection, 0.20 mg/mL, provided in a multidose vial of 10 doses of 0.5mL, each dose containing 100 micrograms of mRNA.

Do not use COVID-19 Vaccine Moderna if:

- you are allergic to the active substance or any of the other ingredients of this vaccine
- you have had an allergic reaction to a previous dose of COVID-19 Vaccine Moderna
- you currently have symptoms that could be due to COVID-19. Talk with your healthcare professional about your symptoms and getting a COVID-19 test. Your healthcare professional will advise you when you are able to receive the vaccine

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take COVID-19 Vaccine Moderna. Talk about any health conditions or problems you may have, including if you:

- Have any allergies or previous problems following administration of COVID-19 Vaccine Moderna such as an allergic reaction or breathing problems
- Have a bleeding problem, bruise easily or use a blood thinning medication
- Have a high fever or severe infection
- Have any serious illness
- Have a weakened immune system due to a medical condition or are on a medicine that affects your immune system.
- Are pregnant, think you may be pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There is no information on the use of COVID-19 Vaccine Moderna with other vaccines. Tell your healthcare professional if you have recently received any other vaccine.

How is COVID-19 Vaccine Moderna given:

- Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm
- During and after each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

Usual dose:

COVID-19 Vaccine Moderna will be given to you as two 0.5 mL injections. Each injection will be given on a separate visit 1 month apart. It is very important that you return for the second injection, or the vaccine may not work as well.

Overdose:

In the event of suspected overdose with COVID-19 Vaccine Moderna, contact your regional poison control centre.

Missed Dose:

If you forget to go back to your healthcare professional at the scheduled time for your next dose, ask your healthcare professional for advice.

What are possible side effects from using COVID-19 Vaccine Moderna?

Like all vaccines, COVID-19 Vaccine Moderna can cause side effects

The following are common or very common side effects of COVID-19 Vaccine Moderna. Most of these side effects are mild and do not last long. Tell your doctor if you have side effects that bother you:

- Pain at the injection site
- Tiredness
- Headache
- Muscle ache and stiffness
- Chills
- Fever
- Swelling or redness at the injection site
- Nausea and/or vomiting
- Enlarged lymph nodes

These are not all the possible side effects you may have when taking COVID-19 Vaccine Moderna. If you experience any side effects not listed here, tell your healthcare professional.

Should you develop any serious symptoms or symptoms that could be an allergic reaction, seek medical attention immediately. Symptoms of an allergic reaction include:

- hives (bumps on the skin that are often very itchy)
- swelling of the face, tongue or throat
- difficulty breathing

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Moderna Therapeutics Inc. cannot provide medical advice.

For healthcare professionals: 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.

Storage:

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Your doctor or pharmacist is responsible storing, supplying and administering this vaccine, as well as disposing of any unused product correctly.

Keep out of reach and sight of children.

If you want more information about COVID-19 Vaccine Moderna:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.modernacovid19global.com/ca/>, or by calling 1-866-MODERNA(1-866-663-3762).

This leaflet was prepared by Moderna Therapeutics Inc.

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