COVID-19 mRNA Vaccines for Individuals Aged 12 Years and Older

Pfizer/Comirnaty™ Vaccine and Moderna/Spikevax™ Vaccine

Public Health Factsheet
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Manitoba

Immunization is one of the most important accomplishments in public health. Over the past 50 years, immunization has led to the elimination, containment and control of diseases that were once very common in Canada.[1] Vaccines help our immune system recognize and fight bacteria and viruses that cause diseases.

After vaccination, continue to focus on the fundamentals. Go to manitoba.ca/covid19/fundamentals/focus-on-the-fundamentals.html for more information.

How do mRNA vaccines work?

COVID-19 mRNA vaccines are used to prevent COVID-19. mRNA vaccines teach our cells how to make a protein that will trigger an immune response without using the live virus that causes COVID-19. Once triggered, our body then makes antibodies. Antibodies protect us from being infected if the real virus does enter our body in the future.

RNA stands for ribonucleic acid, which is a molecule that gives cells instructions for making proteins. **Messenger RNA (mRNA) vaccines contain the genetic instructions** for making the SARS-CoV-2 spike protein. This protein is found on the surface of the virus that causes COVID-19.

mRNA vaccines cannot change a person's DNA. When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein. After the protein piece is made, the cell breaks down the instructions and gets rid of them.

The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn't belong there and begins to build an immune response by making antibodies. It takes about two weeks for your body to fully respond to the vaccine. **You cannot get COVID-19 from the vaccine and it cannot offer protection against the flu or other viruses or bacteria.**

There are two mRNA COVID-19 vaccines available for Manitobans aged 12 years and older: Pfizer/Comirnaty™ and Moderna/Spikevax™. These two COVID-19 mRNA vaccines are given by injection (needle) into a muscle of the upper arm.

The evidence indicates that these vaccines are very effective at preventing severe illness, hospitalization and death from COVID-19, including against the Alpha and Delta variants of concern. In addition, vaccinated people are less likely to:

- spread COVID-19 to others
- have COVID-19 with or without symptoms

At first, Health Canada had issued both the Pfizer and Moderna vaccines a market authorization with conditions to support early access to the vaccines. This authorization gave Canadians access to safe and effective vaccines more quickly than typical circumstances. On September 16, 2021, Health Canada approved Pfizer/Comirnaty™ and Moderna/Spikevax™ under the Food and Drug Regulations (i.e., they are no longer issued market authorizations with conditions for early access as sufficient data was available to approve them under normal regulatory processes). On November 9 and 12, 2021, Health Canada approved the use of a booster/third dose of Pfizer/Comirnaty™ (0.3 mL) and Moderna/Spikevax™ (0.25 mL), respectively, at least six months after the last dose in individuals aged 18 years and older.

[1] The Public Health Agency of Canada

Is the vaccine safe?

Health Canada conducted a rigorous scientific review of the available medical evidence to assess the safety of the COVID-19 mRNA vaccines. Health Canada did not identify any major safety concerns, and continues to monitor post-marketing studies. More than four hundred million doses of mRNA COVID-19 vaccines have been administered to teens/adults worldwide.

The safety signals of blood clots after vaccination that has been seen rarely with the viral vector vaccines (AstraZeneca/Vaxzevria™ and Janssen) has not been detected to date with the mRNA vaccines.

Myocarditis/pericarditis (inflammation of the heart muscle/lining around the heart) has been rarely reported following immunization with the mRNA vaccines, mostly in young males less than 30 years of age, more often after the second dose of vaccine and usually within a week following vaccination. Data on myocarditis/pericarditis risk following a third dose is limited but suggests a lower risk than what has been seen following dose two. The majority of cases have responded well to treatment and recovered quickly.

As with other vaccines and medicines, some people may experience adverse reactions or side effects. Most side effects are not serious and should go away on their own and within a day or two after getting the vaccine.

Who should get the COVID-19 vaccine?

Everyone in Manitoba 12 years of age and older is recommended to receive the COVID-19 mRNA vaccine. Eligible individuals 12 to 29 years of age are recommended to get Pfizer/Comirnaty™.

A limited supply of the viral vector COVID-19 vaccines (AstraZeneca/Vaxzevria™ and Janssen) are available in Manitoba but given the lower effectiveness and safety concerns, Pfizer/Comirnaty™ and Moderna/Spikevax™ are preferentially recommended for use in Manitoba.

COVID-19 vaccines can be given to teens/adults at the same time as other (live or inactivated) vaccines.

People who live with a medical condition (e.g., heart failure, liver disease, chronic kidney disease) can get the vaccine. If you are immunosuppressed because of disease or treatment, have an autoimmune condition, are pregnant and/or breastfeeding, refer to the appropriate factsheet for more information: manitoba.ca/covid19/vaccine/resources.html**.**

Talk to your immunizer or health care provider if you have any questions about your medical conditions or if you are uncertain if you are immunosuppressed or have an autoimmune condition. Your immunizer can give you more information based on what we know from clinical trial data and real-world studies.

How many doses do I need, and which vaccine should I get and when?

All individuals without contraindications after the first dose of any type of vaccine, are recommended to receive a second dose of mRNA vaccine eight weeks after the first dose. Based on individual circumstances, first and second doses can be given 28 days apart.

A booster/third dose is **recommended** for people aged 18 years and older at increased risk of serious illness from COVID-19, their caregivers and close/household contacts. However, anyone who is 18 years of age and older who wants to further reduce their individual risk, can get a booster/third dose. To assess the individual risks and benefits of getting a booster/third dose, consider your:

- risk of getting really sick from COVID-19 and experiencing complications
- risk of exposure
- risk of declining protection from dose 1 and 2, particularly when:
    - your first two doses were administered closely together (emerging data suggests eight weeks between dose 1 and dose 2 provides better protection against COVID-19)
    - a long time has passed since you received your last dose (e.g., greater than six months)
- risk as it pertains to vaccine safety, particularly around the limited evidence of myocarditis/pericarditis (inflammation of the heart muscle/lining around the heart) following a third dose.

- use in Canada and worldwide: the National Advisory Committee on Immunization (NACI)[2] recommends a third dose for certain populations (e.g., residents of personal care homes). Early data from some countries indicates booster/third doses may enhance protection and is as safe as the second dose.

For the most current third/booster dose information including a list of individuals who are **recommended** to get a booster/third dose, go to: manitoba.ca/covid19/vaccine/eligibility-criteria.html.

Subsequent doses should be with the same mRNA vaccine as the last dose (i.e., if you received Pfizer/Comirnaty™ for your second dose, you should receive Pfizer/Comirnaty™ for your third dose) unless you are between 12 and 29 years of age and therefore recommended to receive Pfizer/Comirnaty™. If the same mRNA vaccine is not available, was with a viral vector vaccine (AstraZeneca/Vaxzevria™ or Janssen) or other non-mRNA vaccine, or the last dose is unknown, another mRNA vaccine will be offered. Generally, booster/third doses should be given 6 months after your last COVID-19 vaccine.

People who are moderately to severely immunocompromised are recommended to receive a total of four doses of an mRNA vaccine. Your doctor can provide more information including about when is the best time to get immunized, based on a review of your medical history and individual circumstances.

Who should NOT get the COVID-19 mRNA vaccine?

Anyone 11 years old or younger should not be given the adult formulation of Pfizer/Comirnaty™ (30 mcg) or, Moderna/Spikevax™.

As a precautionary measure, individuals who experienced myocarditis or pericarditis following vaccination with any dose of an mRNA COVID-19 vaccine, should defer further COVID-19 vaccination until more information is available. People who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team prior to vaccination.

An allergy referral is required before vaccination if you are allergic to an active substance or any ingredients of Pfizer/Comirnaty™ or Moderna/Spikevax™, or if you have had a severe allergic reaction after the first dose of mRNA vaccine. An allergic reaction can be life-threatening. For information about any of the COVID-19 vaccine ingredients, please review the vaccine manufacturer's product monograph at manitoba.ca/vaccine or speak with your health care provider. There are two ingredients that are potential allergens known to cause possible allergic reactions, including serious reactions:

1. Polyethylene glycol (PEG) is an ingredient in both Pfizer/Comirnaty™ or Moderna/Spikevax™ and may be found in a multitude of products including bowel preparation products for colonoscopies, laxatives, cough syrup, cosmetics, contact lens care solutions, skin care products, certain medications and as an additive in some food and drinks. People with PEG allergies may also be allergic to polysorbate 80. **If you are allergic to PEG or polysorbate 80, regardless of the severity of reaction, speak with your health care provider before immunization.**
2. Tromethamine (trometamol or Tris) is an ingredient of Moderna/Spikevax™ and may be found in certain medications. **If you are allergic to tromethamine, regardless of the severity of reaction, speak with your health provider before getting immunized with the Moderna vaccine.**

Allergic reactions generally happen shortly after the vaccine is administered. **You must be observed for a minimum of 15 minutes after immunization.**

You can be immunized if you have allergies not related to the vaccine, such as allergies to foods, insect stings or seasonal/environmental allergies. Talk to your immunizer or health care provider about all of your allergies before vaccination.

If you have a fever or any symptoms that could be due to COVID-19, you should not be vaccinated at that time. If you were infected with COVID-19, you should get immunized after your symptoms are gone and your period of isolation is over. Talk with your health care provider if you have any new or lingering symptoms of COVID-19. Your health care provider will advise you when you are able to receive the vaccine.

[2] The National Advisory Committee on Immunization (NACI) is an independent committee of recognized experts that provides informed advice on the use of vaccines in Canada. After Health Canada approves a vaccine, NACI critically evaluates all available evidence to make recommendations about its optimal use.

If you were previously infected with COVID-19 and received a monoclonal antibody treatment (e.g., Sotrovimab, Casirivimab, Imdevimab), wait 90 days before getting the COVID-19 vaccine.

What are some possible side effects of the COVID-19 vaccine?

In general, the side effects observed during the clinical trials were similar to other vaccines. The side effects were generally mild or moderate, and went away a few days after vaccination. They included things like:

- pain, redness and swelling at the site of injection
- body chills
- feeling tired and feverish
- headache
- muscle and joint pain
- nausea and vomiting

These are common side effects of the vaccines and are not a risk to your health. Over-the-counter medicines like acetaminophen (e.g., Tylenol®) or ibuprofen (e.g., Advil®) may be considered to help manage these adverse events (like pain or fever, respectively), if they occur **after vaccination**.

For a full list of possible side effects, please review the vaccine manufacturer's product monograph at: manitoba.ca/vaccine or speak with your health care provider.

As with all vaccines, more serious side effects such as allergic reactions are possible. However, these are rare.

The signs and symptoms of myocarditis/pericarditis can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. If you experience any of these symptoms, go to the nearest emergency department or health centre.

It is important to stay in the immunization clinic for 15 minutes after getting any vaccine in the unlikely event of a severe allergic reaction. You may need to stay in the clinic for 30 minutes if you have had a serious allergic reaction to a vaccine in the past. This can include hives, difficulty breathing, or swelling of the throat, tongue or lips. This can happen up to an hour after you get vaccinated. If this happens after you leave the immunization clinic, call 911 or go to the nearest emergency department or health centre for immediate attention.

Report any serious or unexpected adverse reactions to a health care provider, or call Health Links – Info Santé at 204-788-8200 or 1-888-315-9257 (toll free in Manitoba).

Preparing for your vaccination

Be sure to follow the signs and instructions at the immunization clinic (e.g., stay two metres away from other people), and remember to stay home if you are sick.

- Wear a short-sleeve shirt.
- Be sure you have eaten regularly that day.
- Bring and wear your mask.
- Bring any personal identification required by the immunization clinic, such as your Manitoba Health Family Registration Card.
- Bring your completed and signed COVID-19 Vaccine Consent Form, available at ProtectMB.ca/Resources.

Your record of protection

All immunizations, including the COVID-19 vaccine, are recorded on your immunization record in Manitoba's immunization registry. This registry:

- allows health care providers to find out which immunizations you (or the people you care for) have received or need to have
- may be used to produce immunization records or notify you or your health care provider if a particular immunization has been missed

- allows Manitoba Health and Seniors Care as well as public health officials to monitor how well vaccines work in preventing disease

The Personal Health Information Act protects your information and the information for any people you provide care for. You can choose to have this personal health information hidden from health care providers. For additional information, please contact your local public health office or speak with a health care provider.

For information and to obtain your Manitoba Immunization Card, Manitoba immunization record or Pan-Canadian Proof of Vaccination Credential (PVC), go to: manitoba.ca/covid19/vaccine/immunizationrecord/residents.html.

Where can I find more information?

For more information about COVID-19 or the COVID-19 vaccines, talk to your health care provider. You can also call Health Links – Info Santé in Winnipeg at 204-788-8200 or 1-888-315-9257 (toll free in Manitoba).

Or visit:

Province of Manitoba: manitoba.ca/covid19/index.html

Government of Canada: canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html