

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

Public Health Factsheet

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Pfizer/Comirnaty™ Vaccine and Moderna/Spikevax™ Vaccine

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-onthe-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 approved and available in Manitoba: Pfizer/Comirnaty™ and Moderna/Spikevax™. These two COVID-19 mRNA vaccines are given by injection (needle) into a muscle of the upper arm.

Evolving evidence indicates that two-doses of these vaccines remain effective at preventing severe illness and hospitalization for most people. However over time and with the Omicron variant, two doses becomes less effective at preventing mild illness, and we also see reduced protection against severe illness for older people and those with multiple health conditions. A third dose improves protection against severe illness for high risk groups and provides some additional protection against mild illness for everyone. It is currently unknown how long protection from a third dose will last, particularly against Omicron. People who are vaccinated remain less likely to spread COVID-19 to others, even if they are infected.

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.

Over the past year, post-marketing studies have found the following rare reactions following vaccination, which are estimated to occur in less than 0.1 per cent of vaccinated people:

1. Myocarditis/pericarditis (inflammation of the heart muscle/lining around the heart) has been rarely reported following immunization with the mRNA vaccines. It has occurred mostly in males less than 30 years of age, more often after the second dose of vaccine, usually within a week following vaccination and less common with Pfizer/Comirnaty™ compared to Moderna/Spikevax™. Data on myocarditis/pericarditis risk following a third dose is limited but suggests a lower risk than what has been seen following dose two. Vaccine related myocarditis/pericarditis is a much milder

¹The Public Health Agency of Canada

condition than infection related myocarditis/pericarditis. The majority of cases have responded well to treatment and recovered quickly.

2. Bell's palsy (weakness or paralysis on one side of the face) has been very rarely reported following immunization with the mRNA vaccines. In the majority of cases, it's temporary however in very rare cases, Bell's palsy can be permanent.

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

Regulatory Approval in Canada

At first, Health Canada issued both the Pfizer and Moderna vaccines market authorizations with conditions to support early access to these new COVID-19 vaccines. This authorization gave Canadians access to safe and effective vaccines more quickly than typical circumstances. Since then, data has become available to approve these vaccines under normal regulatory processes.

- September 16, 2021: Health Canada approved Pfizer/Comirnaty™ and Moderna/Spikevax™ under the Food and Drug Regulations (e.g., they no longer required temporary market authorizations).
- November 9, 2021: Health Canada approved the use of Pfizer/Comirnaty™ (0.3 mL) as a booster dose administered at least six months after the last dose in adults aged 18 years and older.
- November 12, 2021: Health Canada approved the use of Moderna/Spikevax™ (0.25 mL) as a booster dose administered at least six months after the last dose in adults aged 18 years and older.
- **Use outside of the above indications (e.g., booster doses for individuals younger than 18 years of age) is not approved by Health Canada and is considered off-label at this time.**

Who should get the COVID-19 mRNA vaccine, and which vaccine should I get?

Everyone in Manitoba 12 years of age and older is recommended to receive the COVID-19 mRNA vaccine.

For all doses, all adolescents and young adults between the ages of 12 and 29 are recommended to receive Pfizer/Comirnaty™ due to a lower risk of myocarditis/pericarditis with Pfizer/Comirnaty™ compared to Moderna/Spikevax™ in this age group.

Adults 30 years and older can get either mRNA vaccine (Pfizer/Comirnaty™ or Moderna/Spikevax™). It is recommended to get the same mRNA vaccine for dose 1 and dose 2, if available. However, getting a combination of mRNA vaccines is both safe and effective, and either (Pfizer/Comirnaty™ or Moderna/Spikevax™) can be offered if:

- the same mRNA vaccine is not available
- your previous dose was with a non-mRNA vaccine (e.g., AstraZeneca/Vaxzevria™, Janssen)
- the last dose is unknown

Adults 30 years and older can get either mRNA vaccine (Pfizer/Comirnaty™ or Moderna/Spikevax™) for the booster dose (regardless of the COVID-19 vaccine previously given).

Recommendations for Individuals who are Moderately to Severely Immunocompromised

Individuals 12 years and older with a weakened immune system are recommended to receive a total of four doses. Individuals aged 12 to 29 years are recommended to receive Pfizer/Comirnaty™.

Adults 30 years and older should get the same mRNA vaccine for dose 1, dose 2 and dose 3, if available. The booster dose (dose 4) can be given with either mRNA vaccine (Pfizer/Comirnaty™ or Moderna/Spikevax™), regardless of the COVID-19 vaccine previously given. Talk to your doctor about which vaccine might be right for you, as some evidence suggests that Moderna/Spikevax™ (100 mcg) may produce a better immune response among people who are immunocompromised.

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 or have an autoimmune condition, refer to the appropriate factsheet for more information: manitoba.ca/covid19/vaccine/resources.html.

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

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 dose:

- **is recommended** for adults aged 18 years and older at increased risk of serious illness from COVID-19, their caregivers and close/household contacts.
- **is available** for adults aged 18 years and older who want to further reduce their individual risk.
- **may be offered** to adolescents aged 12 to 17 years who may be at higher risk of serious illness from COVID-19, including those who:
 - a. have a chronic health condition
 - b. are living in a congregate setting (e.g., shelters, group homes, quarters for migrant workers, correctional facilities)
 - c. belong to a racialized and/or marginalized community disproportionately affected by COVID-19
- **is not currently recommended** for adolescents aged 12 to 17 who are not at a higher risk of serious illness from COVID-19.

For the most current booster dose information including details on who may be at increased risk of serious illness, go to www.manitoba.ca/covid19/vaccine/eligibility-criteria.html.

To assess the individual risks and benefits of getting a booster dose, consider:

- **your risk of getting sick from COVID-19 and experiencing complications.** Emerging evidence suggests that overall the risk of serious illness from Omicron may be lower compared to other variants of concern, although this continues to evolve. Based on past experience, some groups of people continue to be at increased risk of experiencing serious illness from Omicron.
- **your risk as it pertains to vaccine safety** (e.g., limited evidence of rare cases of myocarditis/pericarditis following a booster dose).
- **what is known and unknown at this time** (e.g., it is unknown what future variants of concern may emerge, and how the vaccine will work against them).
- **the evolving and limited evidence on the effectiveness of a booster dose.** Current evidence suggests a booster dose improves protection from Omicron among adults but there is currently limited evidence on the effectiveness of a booster dose against Omicron among teens 12 to 17 years of age. It is currently unknown how long protection from a third dose will last.

Speak with your immunizer or health care provider if you have questions about your individual risks and benefits of getting a booster dose.

Individuals aged 50 years and older as well as adults who live in a First Nations community, can get their booster dose five months after the last dose. All other individuals are advised to wait six months after the last dose.

Adolescents and adults 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 about when it's the best time to get immunized, based on a review of your medical history and individual circumstances. You can also find **Information for Individuals who are Immunosuppressed and/or have an Autoimmune Condition** here www.manitoba.ca/asset_library/en/covidvaccine/immunosuppressed-autoimmune-vaccine-factsheet.pdf.

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 would prefer not to defer vaccination should talk to their immunizer or health care provider about the risks and benefits of proceeding with vaccination. 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](https://www.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 were infected with COVID-19 (e.g., confirmed by a positive PCR test), you're recommended to wait two to three months after your infection before getting your next dose of vaccine. But at minimum, you need to wait until your symptoms are gone and your period of isolation is over.

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](https://www.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.

The signs and symptoms of Bell's palsy tend to appear suddenly, and can include mild weakness to total paralysis on one side of the face affecting facial muscle movement, headache, loss of feeling in the face, hypersensitivity to sound in the affected ear or loss of sense of taste on the tongue. If you experience any of these symptoms, contact your health provider.

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).

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](https://www.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](https://www.manitoba.ca/covid19/index.html)

Government of Canada: [canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html](https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html)
