

COVID-19 mRNA Vaccine for Children 5 to 11 years old

Pfizer/Comirnaty™ Pediatric Vaccine

Public Health - Factsheet for
Parents & Guardians

November 2021

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 www.manitoba.ca/covid19/updates/prepareandprevent.html#fundamentals for more information.

How do mRNA vaccines work?

COVID-19 mRNA vaccines are used to prevent COVID-19. mRNA vaccines teach the body's cells how to make a protein that will trigger an immune response without using the live virus that causes COVID-19. Once triggered, the body then makes antibodies, which provides protection from being infected if the real virus enters the 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 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. The body's 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 the body to fully respond to the vaccine. **Your child cannot get COVID-19 from the vaccine and it cannot offer protection against the flu or other viruses or bacteria.**

On November 19, 2021, Health Canada approved the Pfizer/Comirnaty™ pediatric vaccine for children aged five to 11 years. At this time, Pfizer/Comirnaty™ is the only vaccine authorized for use in children aged five to 11 years in Canada.

The Pfizer/Comirnaty™ pediatric COVID-19 vaccine is given by injection (needle) into a muscle of the upper arm.

The first COVID-19 vaccines available in Canada were the mRNA vaccines: Pfizer/Comirnaty™ and Moderna/Spikevax™. These mRNA vaccines were first approved for use in December 2020 under a market authorization with conditions to support early access to the vaccines, in adults aged 18 years and older. In May 2021, Pfizer/Comirnaty™ was authorized for use in teens aged 12 years and older, with Moderna/Spikevax™ authorized in August 2021. On September 16, 2021, Health Canada approved Pfizer/Comirnaty™ and Moderna/Spikevax™ under normal regulatory processes.

Is the Pfizer/Comirnaty™ pediatric vaccine safe?

Health Canada conducted a rigorous scientific review of the available medical evidence including the Pfizer clinical trial data to assess the safety of the Pfizer/Comirnaty™ pediatric vaccine. Health Canada did not identify any major safety concerns, and continues to monitor post-marketing studies.

Myocarditis/pericarditis (inflammation of the heart muscle/lining around the heart) that has been rarely reported following immunization with the COVID-19 mRNA vaccines for teens/adults, more after the second dose, has not been detected to date with the Pfizer/Comirnaty™ pediatric vaccine. However, clinical trials and post-marketing studies are ongoing to monitor, detect and respond to potential safety signals that may arise, including myocarditis/pericarditis.

¹ The Public Health Agency of Canada

The safety signal of blood clots after vaccination that has been rarely seen with the viral vector vaccines (AstraZeneca/Vaxzevria™ and Janssen) has not been detected to date with the COVID-19 mRNA vaccines.

As with other vaccines and medicines, some children 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.

Does COVID-19 affect children?

All children have been affected throughout the pandemic, as they have experienced disruptions to their normal social activities.

While most children who get COVID-19 have no symptoms or experience only mild symptoms, some get really sick requiring care in the hospital. Since the start of the pandemic, there have been 27 Manitoba children aged five to 11 years hospitalized from COVID-19, with seven admitted to the ICU.

Is the Pfizer/Comirnaty™ pediatric vaccine for children the same as the vaccine given to teens/adults?

No. There are two different Pfizer/Comirnaty™ vaccines approved by Health Canada and available for use: one is for teens/adults aged 12 years and older, the other is for children aged five to 11 years. The two vaccines are made in the same way, but the Pfizer/Comirnaty™ pediatric vaccine for children aged five to 11 years uses a lower dose and a different ingredient known as a buffer, which is used to keep the vaccine stable.

- The vaccine for teens/adults is a 30 microgram dose while the vaccine for children is 10 micrograms. Smaller vaccine doses are often used for children.
- The pediatric vaccine uses a Tris/sucrose buffer while the teen/adult vaccine uses a phosphate buffer.

Who should get the Pfizer/Comirnaty™ pediatric vaccine?

Vaccines help prepare the body to fight potential future exposure to COVID-19 by getting your child's immune system ready.

The vaccine helps to protect your child and family, as well as people in your community.

All children aged five to 11 years of age are recommended to receive the Pfizer/Comirnaty™ pediatric vaccine. Children must be at minimum five years of age at the time of vaccination. Children who are nearly 12 years of age, may receive the Pfizer/Comirnaty™ pediatric vaccine (10 mcg) for dose 1, and then Pfizer/Comirnaty™ teen/adult vaccine (30 mcg) for dose 2.

Children with a chronic medical condition or living with a weakened immune system can get the vaccine. These children are at increased risk of developing more serious symptoms if they get COVID-19. Children on immunosuppressive therapy should talk to their health care provider about when the best time is to get vaccinated against COVID-19.

How many doses will my child need and when should they get the second dose?

At this time, children need two doses of the Pfizer/Comirnaty™ vaccine given at least eight weeks apart. In some situations, doses may be given closer together after discussing the risks and benefits with your child's health care provider or as recommended by the relevant public health authority. As we learn more about the Pfizer/Comirnaty™ pediatric vaccine, additional doses may be recommended.

Who should NOT get the Pfizer/Comirnaty™ pediatric vaccine?

At present, infants and children aged four years and younger should NOT get the Pfizer/Comirnaty™ pediatric vaccine. However, clinical trials studying the vaccine in younger children and infants are underway.

As a precautionary measure, if your child has a history of myocarditis/pericarditis, consult their health care provider prior to vaccination. Children who experience myocarditis/pericarditis after the first dose should wait to get the second dose until more information is available.

Children with a history of Multisystem Inflammatory Syndrome in Children (MIS-C) should delay vaccination until clinical recovery or until it has been at least 90 days since diagnosis, whichever is longer.

If your child is allergic to an active substance or any ingredients of the Pfizer/Comirnaty™ vaccine, an allergy referral is required before vaccination. An allergic reaction can be life-threatening. For information about any of the vaccine ingredients, please review the vaccine manufacturer's product monograph at [manitoba.ca/vaccine](https://www.manitoba.ca/vaccine) or speak with your child's immunizer or health care provider. There are two ingredients in the Pfizer/Comirnaty™ pediatric vaccine that are potential allergens known to cause possible allergic reactions, including serious reactions:

1. Polyethylene glycol (PEG) 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, specific medications and as an additive in some food and drinks. Children with PEG allergies may also be allergic to polysorbate 80. **If your child is allergic to PEG or polysorbate 80, regardless of the severity of reaction, speak with their health care provider before immunization.**
2. Tromethamine (trometamol or Tris) may be found in certain medications. **If your child is allergic to tromethamine, regardless of the severity of reaction, speak with your health provider before getting immunized.**

Allergic reactions generally happen shortly after the vaccine is administered. **That is why all children, teens and adults are routinely observed for a minimum of 15 minutes after immunization.**

Your child can be immunized if they have allergies not related to the vaccine, such as allergies to foods, medications, insect stings or seasonal/environmental allergies. Talk to your child's immunizer or health care provider about all of their allergies before vaccination.

The National Advisory Committee on Immunization (NACI)² recommends a precautionary approach of waiting 14 days before receiving or getting another vaccine, but recognizes that there may be individual circumstances when the 14-day waiting period can be shortened. If you have already scheduled an appointment for your child(ren) to receive other childhood vaccines or influenza vaccine before or after getting their COVID-19 vaccine, there is no need to cancel or delay their next appointment, even if it falls within 14 days of their COVID-19 vaccine.

Your child should wait to be vaccinated if they have a fever or other symptoms that could be due to COVID-19. If they have been infected with COVID-19, they should get immunized after their symptoms are gone and period of isolation is over. Talk with your child's immunizer or health care provider if they have any new or lingering symptoms of COVID-19. Your child's immunizer or health care provider will advise you on when your child can receive the vaccine.

What are the possible side effects of the Pfizer/Comirnaty™ pediatric 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, diarrhea and vomiting

These are common side effects of the vaccine and are not a risk to your child's 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**.

² 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.

Acetylsalicylic Acid (example: Aspirin®) should NEVER be given to children because it can cause a severe liver and brain disease called Reye's Syndrome.

As with all vaccines, more serious side effects are possible. However, these are rare.

The signs and symptoms of myocarditis/pericarditis that has been rarely reported following vaccination with the mRNA COVID-19 vaccines for teens/adults more often after the second dose of vaccine, and usually within a week following vaccination, include: shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. If your child experiences 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. Your child may need to stay in the clinic for 30 minutes if they 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 getting vaccinated. **If this happens after you and your child 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).

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

Preparing to get the Pfizer/Comirnaty™ pediatric vaccine

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 or your child is sick.

- Your child should wear a short-sleeve shirt.
- Be sure your child has eaten regularly that day.
- Bring and wear masks.
- Bring your child's personal identification required by the immunization clinic, such as the Manitoba Health Family Registration Card.
- Bring the completed and signed COVID-19 Vaccine Consent Form, available at: ProtectMB.ca/Resources.

Your child's record of protection

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

- allows health care providers to find out which immunizations your child has received or needs 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 child's 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 child's Manitoba Immunization Card, Manitoba immunization record or Pan-Canadian Proof of Vaccination Credential (PVC), go to: www.gov.mb.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
