

INFORMATION

Pfizer BioNTech Comirnaty® Vaccine (6 months – 4 years) Rev. March 28, 2023

Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine. A parent/guardian must be present for the immunization of children 11 years old and younger.

- COVID-19 is an infectious disease caused by a coronavirus (SARS-CoV-2). The virus that causes COVID-19 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes.
- It is important to note that infected people can spread the infection even if they have no symptoms.
- Symptoms of COVID-19 can include cough, shortness of breath, fever, chills, tiredness and loss of smell or taste. Some children infected with the virus have no symptoms at all, while others have symptoms that range from mild to severe.
- People who were diagnosed with COVID-19 after completing their primary vaccine series were significantly less likely to be hospitalized or to die.
- Cases of COVID-19 in children are rising in Canada but less than 1% of infected children develop serious disease. Children may not become as sick as adults, however children with mild symptoms may feel unwell for a long time after a COVID-19 infection.
- Children with other health conditions, such as obesity, diabetes and asthma, might be at higher risk of serious illness with COVID-19. Children who have congenital heart disease, genetic conditions or conditions affecting the nervous system or metabolism also might be at higher risk of serious illness with COVID-19.

How does this vaccine protect against COVID-19?

- The vaccine causes our body to produce protection (antibodies) to help keep us from becoming sick if we are exposed to the COVID-19 virus. The vaccine uses messenger RNA (mRNA) to help our body make protection against the virus.
- As with any vaccine, this vaccine may not fully protect all those who receive it (especially for immunocompromised individuals) and it is not known how long you will be protected.

Who can receive this COVID-19 vaccine at this time?

- Children age 6 months to 4 years are eligible to receive this vaccine.

Who should not have the COVID-19 vaccine?

Do not attend a public immunization clinic if your child has any new or worsening respiratory symptoms (fever, cough, sore throat, runny nose).

Check with your healthcare provider or a public health nurse before your child gets this vaccine if they:

- have an allergy to any of the vaccine ingredients;
- had a severe or unusual side effect after this vaccine or one like it;
- have had multi-inflammatory syndrome (MIS-C) after COVID-19 disease or a previous dose of COVID-19 vaccine;

- have received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19;
- have a history of myocarditis (inflammation of the heart) or pericarditis (inflammation of the outer lining of the heart) after a previous vaccine dose;

Contact your child's health care provider to determine the optimal time to receive the COVID-19 vaccine if:

- they are receiving treatment with immunosuppressive medications.
- they have an autoimmune disease that affects the neurological system.
- they have a history of myocarditis and/or pericarditis unrelated to COVID-19 vaccination and are under active care.

Always tell your child's healthcare provider if they have allergies or if they have had a side effect from a vaccine, medication or other product in the past.

How is the vaccine administered?

- Depending on the child's age, the vaccine is given as a needle in the muscle of the upper arm or outer thigh.

What are common reactions to this vaccine?

- Side effects can develop up to 3 days after receiving the vaccine. Although these side effects are not serious to your child's health, they may make them feel unwell for a day or two; they will go away on their own.
- There have been reports of myocarditis (inflammation of the heart) and pericarditis (inflammation of the outer lining of the heart) after immunization with mRNA COVID-19 vaccines. Recent Canadian data shows that these events occur more often in adolescents (+12 years) and adults under 30 years of age, in males more than in females, and more often after second doses than after first doses. **These events were not seen in Pfizer BioNTech's pediatric vaccine studies**, however there is a possible risk that these could occur and Health Canada will monitor this.
- These types of side effects are expected and can indicate the vaccine is working to produce protection.
- Side effects may include:

- » pain, redness and swelling where the needle was given
- » fever, chills
- » rash (6 months to less than 2 years)
- » diarrhea
- » swelling of the lymph glands
- » headache
- » decreased appetite (6 months to less than 2 years)
- » tiredness
- » feeling weak or lack of energy/sleepy
- » irritability
- » excessive sweating, night sweats
- » vomiting
- » dizziness
- » joint pain
- » muscle pain

- A skin condition called erythema multiforme is an allergic reaction that can occur following immunization with mRNA COVID-19 vaccines. Symptoms are round red, raised areas on the skin that can appear all over the body, and on the fingers and toes. These patches often look like “targets” (dark circles with purple-grey centers). The skin condition may reoccur and usually lasts for 2 to 4 weeks each time.
- Very rare reports of Bell’s palsy (weakness or paralysis on 1 side of the face that is often temporary) following immunization have been reported in adults. Symptoms usually resolve within one month.
- Rarely allergic reactions can occur after receiving a vaccine. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of the face, tongue or throat, or difficulty breathing. The clinic staff are prepared to manage an allergic reaction should it occur. Seek immediate medical care if your child develops any of these symptoms.
- It is important to note that you/your child **cannot get COVID-19 infection from the vaccine.**
- **If you have any concerns about the symptoms your child develops after receiving the vaccine, call 811. If your child received their vaccination from a pharmacist, please consult them first when possible.**

For more information please speak with the person providing the vaccine or contact your local public health office, your physician, nurse practitioner, or by calling 811.

What measures have been put in place to safely provide immunizations during COVID-19?

Health care providers are very careful to prevent the spread of COVID-19 when offering immunizations. Examples of extra safety measures include the following:

- You will be asked about any COVID-19 symptoms when you arrive at the clinic. People with symptoms of COVID-19 should not attend the clinic.
- You will be asked to wear a mask while at the clinic, as well as to clean your hands, and to stay at least 2 metres (6 feet) from others (except those you live with).
- The staff will also be wearing personal protective equipment and will be cleaning their hands before and after each client.
- Other measures may also be put in place in clinics. Be sure to read and follow any signs or instructions provided.

What should you do after receiving the vaccine?

- You and your child will be asked to **wait at least 15 minutes after receiving the vaccine** to be sure they are feeling well. Longer waiting times of 30 minutes may be recommended if there is concern about a possible vaccine allergy. You and your child may be asked by the health care provider to wait in the clinic, or if you and your child have a warm, dry place to wait (such as in a vehicle), you may be asked to wait outside of the clinic. Inform a health care provider right away if your child feels unwell while waiting. Your child should not leave the clinic (or clinic parking lot) for at least 15 to 30 minutes after receiving their vaccine, based on the recommendation of the health care provider.
- **Upon leaving the clinic, call 9-1-1 right away if your child develops any serious symptoms or symptoms of an allergic reaction** such as hives (bumps on the skin that are often very itchy), swelling of their face, tongue or throat, or difficulty breathing.
- Continue to follow the recommendations of local public health officials to prevent spread of COVID-19, which may include wearing a mask, staying at least 2 metres from others and limiting / avoiding contact with others outside your household.
- Keep your child’s immunization record with information about the COVID-19 vaccine in a safe place.

When should my child return for their next vaccine dose?

- The optimal time to return for their second dose is 8 weeks after the first dose (minimum of 21 days). The third dose of a primary series is given 8 weeks after the second dose.
- Immunocompromised children require four dose given 4-8 weeks apart.
- Emerging evidence shows that a stronger immune response and a reduced risk of myocarditis may result when the 8 week interval is used.
- Your child is considered up-to-date on their vaccinations if they have received the last dose they are eligible for.

What does Pfizer/BioNTech 6 months to 4 years vaccine contain?

- Each 0.2 mL dose of COMIRNATY 6 months to 4 years vaccine contains 3 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2, ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)-2000]- N, N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, cholesterol, sodium chloride, sucrose, tromethamine, tromethamine hydrochloride, water for injection. Preservative and latex-free.

