

INFORMATION

Pfizer/BioNTech **Pediatric (5-11 years)** Comirnaty® COVID-19 Vaccine 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.
- Currently, about 4.8% of people diagnosed with COVID-19 in Canada require hospitalization and about 1% of people die. Even people with mild symptoms may feel unwell for a long time after a COVID-19 infection.
- People who were diagnosed with COVID-19 after completing their primary vaccine series were significantly less likely to be hospitalized or to die, particularly if they received an additional dose(s).
- 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.
- 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;
- belong to one of the following groups, you should contact their health care provider prior to receiving this vaccine:
 - » They are receiving treatment with immunosuppressive medications to determine the optimal time to receive the COVID-19 vaccine.
 - » All those with an autoimmune disease that affects the neurological system.
 - » Those who 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 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.
- In Pfizer’s pediatric study, 2 vaccine doses were shown to work very well at preventing children from becoming sick with COVID-19. The immunized group of people was much less likely (90.7% less likely) to become sick with COVID-19 in the weeks after vaccination compared to the group that did not receive the vaccine.

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

- Children age 5 to 11 years.

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;

How is the vaccine administered?

- The vaccine is given as a needle in the upper arm muscle.
- This COVID-19 vaccine can be given at the same time as other non-COVID-19 vaccines; no intervals are needed before or after administration.

What are common reactions to this vaccine?

- Side effects can develop in the day or two 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.
- These types of side effects are expected and can indicate the vaccine is working to produce protection. In the study, side effects included one or more of the following:

- » joint pain, muscle pain
- » fever, chills
- » diarrhea
- » tiredness
- » pain redness and swelling where the needle was given
- » swelling of the lymph glands
- » headache
- » vomiting
- » dizziness

- 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 the Pfizer BioNTech 5-11 years old pediatric vaccine studies**, however there is a possible risk that these could occur and Health Canada will monitor this.

- 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 a 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 being 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 later (minimum of 21 days). Eligible high-risk children should receive 3 doses as their primary series with 4-8 weeks between each dose.
- Emerging evidence shows that a stronger immune response and a reduced risk of myocarditis may result when the 8 week interval is used.
- After the last dose in a primary series, it is recommended they return for a bivalent booster dose after 6 months. This is important to ensure the vaccine continues to work well. Visit saskatchewan.ca/COVID19-vaccine for booster dose information.
- Pfizer-BioNTech Comirnaty® COVID-19 bivalent vaccine is the recommended booster vaccine for those age 5 to 11 years.
- 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 pediatric vaccine contain?

Each 0.2 mL dose of Comirnaty® 5-11 years vaccine contains 10 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2, ALC-0315 = ((4-hydroxybutyl) azanediy)bis (hexane-6,1-diy)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.

To ensure that a complete immunization record is maintained, immunizations will be documented into Panorama, the electronic provincial immunization registry. These immunization records may also be shared with health care professionals in order to provide public health services; assist with diagnosis and treatment; and to control the spread of vaccine preventable diseases. Panorama is a secure electronic system used in Saskatchewan to record and manage immunization records and the health information related to immunization for all Saskatchewan residents.

