

INFORMATION

Pfizer/BioNTech **Pediatric (5-11 years)**

Comirnaty® COVID-19 Vaccine February 15, 2022

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). COVID-19 was recognized for the first time in December 2019 and has since spread around the world to cause a pandemic. 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.
- [About 7% of people diagnosed with COVID-19 in Canada](#) require hospitalization and about 2% of people 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.
- currently have any symptoms that could be due to COVID-19, they should not go out to get vaccinated because they could spread the infection to others. Talk with your health care provider, or call 811, about their symptoms and getting a COVID-19 test. Your health care provider will advise you when they are able to receive the vaccine.
- have a history of myocarditis (inflammation of the heart) or pericarditis (inflammation of the outer lining of the heart) after a previous mRNA 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 are eligible to receive this vaccine.

Who should not have the COVID-19 vaccine?

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

How is the vaccine administered?

- The vaccine is given as a needle in the upper arm muscle and requires two doses.
- For children five to 11 years in Saskatchewan, co-administration of COVID-19 vaccines and other vaccines may occur with parental consent. This differs from the national recommendations that children receive the pediatric Pfizer-BioNTech COVID-19 vaccine at least 14 days before or after another vaccine. The national recommendation is a precaution to help to determine if a side effect that may arise is due to the COVID-19 vaccine or another vaccine.

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:
- There have been reports of myocarditis (inflammation of the

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

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 next 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.

What does Pfizer/BioNTech pediatric vaccine contain?

Each 0.2 mL dose of COMIRNATY5-11 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) 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.

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.



SCREENING

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1. Is your child feeling ill today?

2. Has your child had a previous COVID -19 infection?

- » Individuals should wait to receive a vaccine until they no longer have acute symptoms of COVID-19 and are no longer infectious to others as long as there are no contraindications to the vaccine.

3. Is your child allergic to any components in the vaccine including polyethylene glycol (PEG)?

- » Polyethylene glycol (PEG) can be found in some products such as cosmetics, skin care products, laxatives, cough syrups, bowel preparation products for colonoscopy, and some foods and drinks.

4. Does your child have a history of myocarditis (inflammation of the heart) or pericarditis (inflammation of the lining of the heart) not related to COVID-19 immunization?

- » For these children, a history of myocarditis and/or pericarditis is not a contraindication but the child and caregiver should consult with their clinical care team for recommendations. If the child is no longer under active care, they may receive the vaccine.

5. Does your child have a history of myocarditis (inflammation of the heart) or pericarditis (inflammation of the lining of the heart) after getting a dose of an mRNA COVID-19 vaccine?

- » As a precautionary measure, additional mRNA COVID-19 vaccine doses should be deferred in individuals who developed myocarditis or pericarditis following a dose of an mRNA COVID-19 vaccine until more information is available. If an individual is at high risk of being infected with COVID-19 due to community transmission or of severe illness due to an underlying condition, then a decision to get an additional dose should be made in consultation with the individual's physician (cardiologist if possible) with the individual's informed consent.

6. Does your child have any problems with their immune system or are they taking any medications/ treatment that can affect their immune system (e.g., high dose steroids, chemotherapy)?

- » The vaccine immune response may not be as strong for children with immune system conditions due to disease or treatment compared to children who do not have immune system conditions.
- » Stem cell transplant recipients MUST consult their specialist prior to immunization with COVID-19 vaccine.
- » For transplant recipients, it is preferred to contact your health care provider to determine the optimal time to receive the COVID-19 vaccine.

7. Does your child have an autoimmune disease?

- » For children with any autoimmune condition that involves the neurological system it is preferred they and their parents discuss this with their primary physician or specialist prior to immunization with COVID-19 vaccine

8. Has your child received monoclonal antibodies or convalescent plasma for prevention or treatment of COVID-19 infection?

- » Vaccination with a dose of COVID-19 vaccine should be delayed for at least 90 days after treatment.

9. Has your child had a tuberculin (TB) skin test or need TB blood work (IGRA) done?

- » COVID-19 vaccination should not be delayed because of testing for tuberculosis (TB) infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon-gamma release assay (IGRA), can be done before, after, or during the same encounter as COVID-19 vaccination.

10. Does your child have a bleeding disorder or are they taking any medications that could affect blood clotting?

- » If yes, apply direct pressure (without rubbing) to the injection site for 5 minutes or longer following immunization.

11. Has your child ever had multi-inflammatory syndrome (MIS-C) unrelated to COVID-19 vaccination?

- » If yes, they may be vaccinated once they have recovered or once it has been more than 90 days since the diagnosis, whichever is longer.

12. Has your child ever felt faint or fainted after a past vaccination or medical procedure?

- » If yes, consider having them lie down for the immunization.

13. Did your child have any side effects after a previous dose of COVID-19 vaccine?

- » If client had a serious or allergic reaction to a previous dose of COVID-19 vaccine, they should not be vaccinated until it is determined to be safe by an allergist or other health care provider.

14. Has your child had a serious reaction to this vaccine or any other vaccine in the past?

- » If a child had a serious or allergic reaction to any other vaccine in the past or multi-inflammatory syndrome (MIS-C) after a previous COVID-19 vaccines dose, they should not be vaccinated until it is determined to be safe by a Medical Health Officer.

AFTER CARE

Pfizer/BioNTech Pediatric (5-11 years) Comirnaty® COVID-19 Vaccine February 15, 2022

What should my child do after receiving the vaccine?

- Wait for at least 15 minutes after receiving their vaccine. A longer waiting time of 30 minutes may be recommended if there is concern about a possible vaccine allergy. Though uncommon, fainting or allergic reactions can occur after vaccination. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of your face, tongue or throat, or difficulty breathing. The clinic staff are prepared to manage these events should they occur.
- Your child may be asked to wait in the clinic or outside the clinic (such as in a vehicle) if an adult is with them. If they are asked to wait outside, inform the health care provider if they do not have a warm, dry place to wait.
- Inform a health care provider at the clinic if your child feels unwell while waiting. If waiting in a vehicle, you can honk your horn to get their attention.
- If waiting inside the clinic, be sure to leave your and your child's masks on if at all possible and remain at least 2 metres away from anyone not part of your household.
- Use the alcohol-based hand rub to clean your and your child's hands before leaving the clinic.

What should be expected in the next few days?

- 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; side effects will go away on their own.
- The most common side effect is pain where the needle was given; swelling where the needle was given may also occur. A cool, damp cloth or wrapped ice pack where the vaccine was given may help.
- Some local reactions may occur 7 days or more after immunization and include a rash, tenderness and extensive swelling where the injection was given. This is a known reaction that resolves on its own within 7-10 days.
- Other temporary side effects may include fever, diarrhea, vomiting, tiredness, headache, muscle pain, joint pain and chills.
- If needed, medication (such as acetaminophen or ibuprofen) may be given to manage side effect such as pain. Check with your health care provider if you need advice about medication for your child.
- Serious side effects after receiving the vaccine are rare. However, should your child develop any serious symptoms or symptoms that could be an allergic reaction, call 9-1-1 right away. Symptoms of an allergic reaction include:
 - » Hives (bumps on the skin that are often very itchy)
 - » Swelling of the face, tongue or throat
 - » Difficulty breathing

- In Pfizer's pediatric studies, myocarditis (inflammation of the heart) and pericarditis (inflammation of the outer lining of the heart) did not happen following immunization with this vaccine. However, it is important to go to Emergency or call 911 right away if your child has any of the following symptoms any time after vaccination:
 - » chest pain
 - » shortness of breath
 - » irregular heartbeat, or a very fast or pounding heartbeat
- Very rare reports of Bell's palsy (weakness or paralysis on one side of the face that is often temporary) following immunization have been reported in a small number of adults. Symptoms usually resolve within a month. If you have any concerns about this or other symptoms your child develops after receiving the vaccine, call 811. If your child was immunized by a pharmacist, please consult them first when possible.
- If your child still needs to receive another dose, tell the person providing the next dose about any side effects your child experienced after a previous dose.

When should my child return for their next vaccine dose?

- **Return for their next dose of Pfizer/BioNTech's pediatric vaccine at the optimal time of 8 weeks after their previous dose (minimum 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.
- Make an appointment or follow the instructions of the health care provider to ensure your child receives their second dose at the right time.
- Tell the person providing the next dose about any side effects your child experienced after a previous dose.

Things to remember

- 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 this sheet or other immunization record in a safe place. You can also download the [CANimmunize](#) app to keep track of this and other vaccines for your child. Sign up for [MySaskHealthRecord](#), a secure website that enables Saskatchewan citizens to quickly and easily access their personal health information including immunization history.