

INFORMATION Pfizer Comirnaty® XBB.1.5 COVID-19 Vaccine

12+ years

Read this information carefully and ensure 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 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes.
- 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 people infected with the virus have no symptoms at all, while others have symptoms that range from mild to severe.

How does this vaccine protect against COVID-19?

- The vaccine causes our bodies to produce protection (antibodies) to help keep us from becoming sick if we are exposed to a COVID-19 virus. The vaccine uses messenger RNA (mRNA) to help our bodies make protection against the virus, which help keep us from becoming seriously ill if we are exposed to a COVID-19 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 your child will be protected.
- It is important to know that **your child cannot get COVID-19 infection from the vaccine.**

Who can receive this COVID-19 vaccine?

- **For those 12 years and older who have never received a COVID-19 vaccination**, one dose is recommended.
- **For those 12 years and older who have previously received a COVID-19 vaccination**, one dose is recommended, given at least six months after their last dose.
- Immunocompromised individuals may require additional doses.

Who should not have this COVID-19 vaccine?

- Children younger than 12 years of age.
- **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 a COVID-19 vaccine or other vaccine
 - received the smallpox/mpox vaccine in the past four weeks or plan to get it in the next four weeks.
 - 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.
- Contact your health care provider to determine the optimal time to receive the COVID-19 vaccine if you/ your child is receiving treatment with immunosuppressive medications or has an autoimmune disease that affects the neurological system.
- Stem cell transplant recipients **must consult** their healthcare provider prior to getting immunized.
- Always tell your healthcare provider if your you/ your child has allergies or has had a side effect from a vaccine, medication or other product in the past.

How is the vaccine administered?

- The vaccine is given as a needle in the muscle of the upper arm.

What are possible reactions to this vaccine?

- Side effects can develop up to three days after receiving the vaccine. Although these side effects are not serious to you/ your child's health, they may feel unwell for 1-2 days. These side effects are expected and can indicate the vaccine is working to produce protection.
- Expected side effects include:

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| • pain, redness and swelling where the needle was given (up to 10 days later) | • swollen and tender lymph nodes in the underarm |
| • muscle ache and stiffness | • excessive sweating/ night sweats |
| • nausea/ vomiting | • headache or dizziness |
| • diarrhea | • fever, chills or rash |
| • joint pain | • general weakness or lack of energy |
| • decreased appetite | • excessive drowsiness |

- Very rare cases of myocarditis (inflammation of the heart) and/or pericarditis (inflammation of the outer lining of the heart) following immunization with older COVID-19 vaccines were reported.

- 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 2-4 weeks each time.
- Very rare reports of Bell's palsy (weakness or paralysis on one side of the face that is often temporary) following immunization with mRNA COVID-19 vaccines have been reported. 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 you develop any of these symptoms.
- It is important to know that you cannot get COVID-19 infection from the vaccine.
- If you have any concerns about the symptoms you develop after receiving the vaccine, call 811. If you received their vaccination from a pharmacist, please consult them first, when possible.
- For more information, speak with the person providing the vaccine or contact your local public health office, your physician, nurse practitioner, or by calling 811.

Use **Acetaminophen** (all ages; Tylenol®, Tempra®) or **Ibuprofen** (6 months & older; Advil®, Motrin®) to treat fevers and pain. **Never give ASA** (Aspirin®) to children younger than 18 years old because of the serious risk of Reye's syndrome.

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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.

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

- You/ your child may be asked about any COVID-19 symptoms upon arrival at the clinic. People with symptoms of COVID-19 should not attend the clinic.

What should your child do after receiving the vaccine?

- It is important to stay in the clinic for 15 minutes after getting any vaccine because there is an extremely rare possibility of a life-threatening allergic reaction called anaphylaxis. This may include hives, difficulty breathing, or swelling of the throat, tongue or lips. This reaction can be treated, and occurs in less than one in one million people who get the vaccine. **If this happens after you leave the clinic, get medical attention or call 911 right away.**

Who needs another vaccine dose?

- Immunocompromised individuals may require additional doses.

Mature Minor Consent

- It is recommended that parents/guardians discuss consent for immunization with their children. Efforts are first made to get parental/guardian consent for immunizations. However, children at least 13 years of age up to and including 17 years of age, who are able to understand the benefits and possible reactions for each vaccine and the risks of not getting immunized, can legally consent to or refuse immunizations in Saskatchewan by providing mature minor informed consent to a healthcare provider.

What does this vaccine contain?

Medicinal ingredients: Raxtozinameran (mRNA) encodes for the viral spike (S) protein of SARS-CoV-2 Omicron XBB.1.5 strain. **Non-medicinal ingredients:** ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), LC-0159 = 2-[(polyethylene glycol)- 2000]-N,N-ditetradecylacetamide, cholesterol, DSPC = 1,2-distearoyl-sn-glycero-3- phosphocholine, sucrose, tromethamine, tromethamine hydrochloride, water for injection