

IMPORTANT PLEASE READ

INFORMATION

Pfizer/BioNTech 12+ Years Comirnaty® COVID-19 Vaccine Revised June 2, 2022

Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine.

- COVID-19 is an infectious disease caused by a new 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 people 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. Even people with mild symptoms may feel unwell for a long time after a COVID-19 infection.
- » If you 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 belong to one of the following groups:
 - » anyone receiving treatment with immunosuppressive medications, and
 - » anyone with an autoimmune disease that affects the neurological system.

Always tell your healthcare provider if you have allergies or if you have 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 upper arm muscle.

All Health Canada approved COVID-19 vaccines can be given at the same time as other non-COVID-19 vaccines; no intervals are needed before or after COVID-19 vaccine 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 health, they may make you 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:

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| » pain, redness or swelling where the needle was given | » tiredness |
| » headache | » fever, chills |
| » muscle pain, stiffness | » joint pain |
| » enlarged lymph nodes in the underarm | » burning, prickling, and numbness in the body, limbs and face |

- There have been reports of myocarditis and/or pericarditis after immunization with mRNA COVID-19 vaccines in Canada and internationally. Based on international reports as of August 19, 2021, cases of myocarditis and/or pericarditis occur more often in adolescents and adults under 30 years of age, more often in males than in females, and more often after a second dose of an mRNA vaccine than after a first dose. Recently, a higher rate of cases of myocarditis and/or pericarditis has been reported after the administration of the Moderna's Spikevax® vaccine compared to the Pfizer-BioNTech Comirnaty® vaccine, **although verification of this potential difference is ongoing.**

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 a large study where people were given 2 doses of the vaccine, the vaccine was shown to work very well at preventing people from becoming sick with COVID-19. The immunized group of people was much less likely (95% 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?

- Individuals 12 years and older are eligible to receive this vaccine.

Who should not have the COVID-19 vaccine?

- Those younger than 12 years old.
- Check with your healthcare provider or a public health nurse before you get this vaccine if you:
 - » have an allergy to any of the vaccine ingredients
 - » had a severe or unusual side effect after this vaccine or one like it
 - » have received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19
 - » If you have any symptoms that could be due to COVID-19, you should not go out to get vaccinated because you could spread the infection to others. Talk with your health care provider, or call 811, about your symptoms and getting a COVID-19 test. Your health care provider will advise you when you are able to receive the vaccine.

- Rare cases of tinnitus (ringing or other noises in one or both ears) or hearing loss have been reported after receiving a COVID-19 vaccine. The majority of the reports have happened following vaccination with the Pfizer-BioNTech COVID-19 vaccine.
- A skin condition called erythema multiforme is an allergic reaction that can occur following immunization with this vaccine. 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 a small number of people in Canada and internationally. 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 your 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 note 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 your 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.



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 should you do after receiving the vaccine?

- You will be asked to **wait at least 15 minutes after receiving the vaccine** to be sure you are feeling well. Longer waiting times of 30 minutes may be recommended if there is concern about a possible vaccine allergy. You may be asked by the health care provider to wait in the clinic, or if an adult is with you and you have a warm, dry place to wait (such as in your vehicle), you may be asked to wait outside of the clinic. Inform a health care provider right away if you feel unwell while waiting. You should not leave the clinic (or clinic parking lot) for at least 15 to 30 minutes after receiving your vaccine, based on the recommendation of the health care provider.
- **Once you leave the clinic, call 9-1-1 right away if you develop any serious symptoms or symptoms of an allergic reaction** such as hives (bumps on the skin that are often very itchy), swelling of your 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.

When should I return for my next vaccine dose?

- For people aged 12 and older, evidence shows that an 8-week interval is optimal between first and second doses but the minimum interval of 28 days will still be provided if people choose the shorter interval.
- After the last dose in a primary series, it is recommended that people aged 12 and older return for a booster dose after 4 months. This is very important to ensure the vaccine continues to work well.
- Others are eligible for additional/booster doses. Please ask your healthcare provider for more information or visit <https://www.saskatchewan.ca/covid19-vaccine>.
- The booster recommendation for ages 12-15 years is known as “off-label”, which means that boosters are not yet noted in the vaccine product monograph information for this age group, but this will be reviewed by Health Canada.
- Pfizer’s Comirnaty is the recommended mRNA vaccine for those 30 years old and younger.

What does Pfizer/BioNTech Comirnaty® vaccine contain?

- Medicinal ingredient: mRNA. Non-medicinal ingredients: ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6, 1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[[poly(ethylene glycol)[PEG]-2000]-N, N-ditetradecylacetamide, 1, 2-Distearoyl-sn-glycero-3-phosphocholine, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, water for injection, sodium chloride, sucrose.