

## IMPORTANT PLEASE READ

# INFORMATION

## Pfizer/BioNTech COVID-19 Vaccine Revised August 9, 2021

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

The Pfizer/BioNTech vaccine was authorized for use by Health Canada under an [Interim Order](#) on December 9, 2020. An Interim Order allows authorization of the vaccine more rapidly to respond to a public health emergency while following requirements to ensure the health and safety of Canadians.

- **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.
- [1 in 13 people diagnosed with COVID-19 in Canada](#) require hospitalization and about 3 out of every 100 people die. Even people with mild symptoms may feel unwell for a long time after a COVID-19 infection.
- had a severe or unusual side effect after this vaccine or one like it
- are younger than 12 years old
- have had another vaccine in the last 2 weeks
- have had a tuberculosis (TB) skin test in the last 2-3 days or need TB blood work done
- 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.
- If you have a history of myocarditis (inflammation of the heart) or pericarditis (inflammation of the outer lining of the heart) after a first mRNA vaccine dose.
- If you are a stem cell transplant recipient you MUST consult your health care provider prior to receiving.
- If you belong to one of the following groups, it is preferred you contact your health care provider prior to receiving:
  - » have received a solid organ transplant.
  - » 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.

### How does the Pfizer / BioNTech vaccine protect against COVID-19?

- The vaccine causes our body to produce protection (such as **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 the COVID-19 vaccine at this time?

- Public health officials will provide information on which groups of people are able to receive the vaccine at this time based on several factors including who is at high risk of COVID-19 infection and severe disease, as well as the amount of vaccine available.

### Who should not have the COVID-19 vaccine?

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

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 and will require two doses.

### 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 | » enlarged lymph nodes in the underarm |
| » headache   | » tiredness                            |
| » muscle pain, stiffness                               | » fever, chills                        |
|  | » joint pain                           |

- Very rare cases of myocarditis and/or pericarditis following vaccination with mRNA COVID-19 vaccine have been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of the mRNA COVID-19 vaccine.
- 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 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

To ensure that a complete immunization record is maintained, immunizations will be documented into the electronic provincial immunization registry, known as Panorama. 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.

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 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.
- If possible, do not receive other vaccines for 28 days after a dose of COVID-19 vaccine or 14 days before your second dose however, in consultation with your health care provider there may be exceptions.
- **Keep your immunization record with information about the COVID-19 vaccine in a safe place.**

### When should I return for my second dose?

- If this is your first dose of the Pfizer/BioNTech COVID-19 vaccine, be sure to return for your second dose in a minimum of 28 days. This is very important to ensure the vaccine works well. You may be asked to book an appointment to receive the next dose. Bring your immunization record with you when you come for your next dose.

### What does this vaccine contain?

- Medicinal ingredient: mRNA. Non-medicinal ingredients: ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6, 1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene 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.

