

INFORMATION

Pfizer Comirnaty® Bivalent Original & Omicron BA.4/5 COVID-19 Vaccine (12+ years)

Revised October 13, 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). 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.
- 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.

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.
- The effectiveness and protectiveness of this vaccine is assumed to be similar to Pfizer BioNTech's studies of its original COVID-19 and bivalent Omicron BA.1 vaccines.
- 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 you will be protected.

Who can receive this COVID-19 vaccine?

- Individuals 12 years and older as a booster dose.
- Note: Moderna's Comirnaty bivalent vaccine is preferentially recommended for moderately to severely immunocompromised individuals 12 years and older.

Who should not have this 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
- had a severe or unusual side effect after this vaccine or one
- received the smallpox/monkey pox vaccine in the past 4 weeks or plan to get it in the next 4 weeks.
- plasma for treatment or prevention of COVID-19.
- are younger than 12 years of age
- Do not attend a public immunization clinic if you have any new or worsening respiratory symptoms (fever, cough, sore throat, runny nose) or if you have tested positive for COVID-19, until you are symptom-free or 5 days have passed since your test.
- 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 a 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 muscle of the upper arm. COVID-19 vaccines can be given at the same time as other non-COVID-19 vaccines; however an interval of 4 weeks between mRNA COVID-19 vaccines and the smallpox/monkey pox vaccine is recommended.

What are common reactions to this vaccine?

- Side effects can develop up to 3 days 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 side effects are expected and can indicate the vaccine is working to produce protection.
- Expected side effects include:

» pain, redness or swelling where the needle was given (up to 10 days later)	» diarrhea
» swollen and tender lymph nodes in the underarm	» fever, chills, rash
» muscle aches/stiffness	» tiredness
» decreased appetite	» joint pain
» nausea/vomiting	» excessive sweating/night sweats
» headache	» feeling weak or lack of energy/sleepy

- There have been reports of myocarditis and/or pericarditis in those aged 12 years and older after immunization with original mRNA COVID-19 vaccines. Cases 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. Health Canada will monitor for reports of myocarditis and pericarditis as more people receive the bivalent 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.
- 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 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 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 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/your child 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 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.

What does Pfizer/BioNTech Comirnaty® vaccine contain?

- Original formulation gray cap Medicinal ingredient: mRNA. Non-medicinal ingredients: 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.
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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.