

# IMPORTANT PLEASE READ INFORMATION

## Moderna Spikevax® bivalent Original/ Omicron COVID-19 Vaccine

September 8, 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 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.

**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.

### 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 the COVID-19 virus. The vaccine uses messenger RNA (mRNA) to help our bodies make protection against the virus.
- In studies, this vaccine produced high antibody levels in those who were previously immunized with a booster dose or had previous COVID-19 disease.
- 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 18 years and older as a booster dose, for those who have previously received a primary COVID-19 immunization series and regardless of the number of booster doses previously received.

### 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 like it
- are younger than 18 years of age
- have received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19

- Received the smallpox/monkey pox vaccine in the past 4 weeks or plan to get it in the next 4 weeks.
- 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 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?

- In studies, people who received Moderna bivalent Original/Omicron vaccine were monitored after receiving the vaccine and few serious side effects have been found to-date. People who receive the vaccine in studies continue to be monitored for any long-term side effects. 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. In the study, side effects included the following:

» pain, redness or swelling where the needle was given (up to 9-11 days later)	» nausea/vomiting
» swollen and tender lymph nodes in the underarm	» headache
» muscle aches/stiffness	» fever, chills, rash
	» tiredness
	» joint pain

- There have been reports of myocarditis and/or pericarditis in those aged 12 years and older after immunization with 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.
- There were no vaccine-related cases of myocarditis or pericarditis reported during Moderna bivalent vaccine studies in adults. 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. However, this was not seen during studies for this vaccine.
- 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. 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 and your child 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 and your child 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/your child feels unwell while waiting. You/your child should not leave the clinic (or clinic parking lot) for at least 15 to 30 minutes after receiving the vaccine, based on the recommendation of the health care provider.
- **Once you leave the clinic, call 9-1-1 right away if you/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 the 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 to return for the next vaccine dose

- Only 1 dose of this vaccine is required as a booster dose.

### What does this vaccine contain?

- Medicinal ingredient: elasomeran mRNA SARS-CoV-2 and Imelasomeran Omicron variant, B.1.1.529. Non-medicinal ingredients: e SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino) octanoate), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.

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.