

**INFORMATION****Moderna Spikevax® Bivalent Original/  
Omicron BA.4/5 COVID-19 Vaccine** Rev. July 2023

**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.

People who were diagnosed with COVID-19 after completing their primary vaccine series were significantly less likely to be hospitalized or to die, particularly if they received an additional dose(s).

**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.
- The effectiveness and protectiveness of this vaccine is assumed to be similar to Moderna's 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 6 months and older for a primary series. These are off label recommendations as Health Canada has not approved the vaccine for use as a primary series.
- Individuals 6 years and older as a booster dose.

**Who should not have this COVID-19 vaccine?**

**Do not attend a public immunization clinic** if you/your child have any new or worsening respiratory symptoms (fever, cough, sore throat, runny nose).

**Check with your healthcare provider or a public health nurse before you get this vaccine if you:**

- have received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19
- received the smallpox/mpox vaccine in the past 4 weeks or plan to get it in the next 4 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 a health care provider to determine the optimal time to receive the COVID-19 vaccine if you/your child:

- are receiving treatment with immunosuppressive medications, or
- have an autoimmune disease that affects the neurological system.

Always tell your healthcare provider if you/your child have allergies or have had a side effect from a vaccine, medication or other product in the past.

**How is the vaccine administered?**

- Depending on the client's age, the vaccine is given as a needle in the muscle of the upper arm or outer thigh.
- 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/mpox vaccine is recommended.

**What are common reactions to this vaccine?**

- In studies, people who received Moderna Spikevax 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/your child's health, they may make you/your child 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:

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| » pain, redness or swelling where the needle was given (resolves in up to 7-10 days) | » nausea/vomiting     |
| » swollen and tender lymph nodes in the underarm                                     | » headache            |
| » muscle aches/stiffness   | » fever, chills, rash |
|  | » tiredness           |
|  | » joint pain          |

- There were no vaccine-related cases of myocarditis or pericarditis reported during Moderna Spikevax bivalent vaccine studies in adults. Health Canada monitors for reports of myocarditis and pericarditis as more people receive the bivalent 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/your child develop any of these symptoms.
- It is important to note that you/your child cannot get COVID-19 infection from the vaccine.
- If you have any concerns about the symptoms you/your child 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 very careful to prevent the spread of COVID-19 when offering immunizations. Examples of extra safety measures include the following:

- You/your child will be asked about any COVID-19 symptoms when you/ 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/your child are feeling well. Longer waiting times of 30 minutes may be recommended if there is concern about a possible vaccine allergy. You/your child may be asked by the health care provider to wait in the clinic, or if an adult is with your

child and they have a warm, dry place to wait (such as in a vehicle), you/your child 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.

- **Upon leaving 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 should I/my child return for another vaccine dose?

- **Primary series:** Return for the second dose at the optimal time of 8 weeks after the first dose (minimum 21 days). Eligible high-risk individuals should receive 3 doses as their primary series with 4-8 weeks between each dose.
- **Booster dose for ages 5 years and older:** After the last dose in a primary series, it is recommended to return for one bivalent booster dose after 6 months. This is important to ensure the vaccine continues to work well.
- Seniors, immune compromised adults and adults living in personal care homes and long-term care facilities are recommended to get a second bivalent booster dose 6 months after their first bivalent booster dose.
- A person is considered up-to-date on their vaccinations if they have received the last dose they are eligible for.
- Ask your healthcare provider or visit <https://www.saskatchewan.ca/covid19-vaccine> for booster dose information.

### What does this vaccine contain?

- **Medicinal ingredients:** elasomeran mRNA SARS-CoV-2 and davesomeran Omicron variant, B.1.1.529 (BA.4.5).  
Non- medicinal ingredients: Acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), lipid SM-102, PEG2000-DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection.

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.