**SAMPLE Information Sheet**

**Pfizer-BioNTech Comirnaty and Moderna Spikevax Omicron XBB.1.5 COVID-19 mRNA vaccines**

**Updated November 2023**

**Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before you or your child receives the vaccine.**

**What is COVID-19?**

* COVID-19 is an infectious disease caused by a coronavirus (SARS-CoV-2). COVID-19 was recognized for the first time in December 2019 and 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**](https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/symptoms.html#s) can include cough, shortness of breath, fever, chills, tiredness, diarrhea, vomiting 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.
* Even people with no or mild COVID-19 symptoms may feel unwell for a long time after a COVID-19 infection with symptoms such as tiredness, memory problems, shortness of breath, headache, and change in taste and smell. Prolonged symptoms after a SARS-CoV-2 infection are referred to as post-COVID-19 condition and can occur in adults and less commonly in children.
* Children are less likely to get severely ill than adults, but they can still get sick and require hospitalization, and rarely they can be admitted to the intensive care unit or can die from their infection. Children can also develop a rare complication called Multisystem Inflammatory Syndrome in Children (MIS-C) which often requires admission to an intensive care unit.

**How do the Pfizer-BioNTech Comirnaty and Moderna Spikevax vaccines protect against COVID-19?**

* The vaccines enable our body to produce protection (such as **antibodies**) to help keep us from becoming severely sick or hospitalized if we are exposed to the SARS-CoV-2 virus. The vaccines use a method called messenger RNA (mRNA) to help our body make protection against the virus. Being vaccinated can also help prevent post-COVID-19 condition.

**Who can and cannot receive the COVID-19 vaccine at this time?**

The National Advisory Committee on Immunization (NACI) has recommended that the mRNA vaccines (Pfizer-BioNTech Comirnaty and Moderna Spikevax) are preferred because they work very well and we are now very familiar with their safety profile.

**Table 1** indicates who should and should not receive the mRNA vaccines and provides some questions you may be asked before vaccination and possible recommendations based on your response. These recommendations are based on the advice of [NACI](https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid).

**Note: "you" refers to the individual being vaccinated**

**Table 1: Questions and possible recommendations with regard to receiving the Pfizer-BioNTech Comirnaty Omicron XBB.1.5 or Moderna Spikevax Omicron XBB.1.5 COVID-19 vaccines**

|  |  |
| --- | --- |
| **Questions** | **Possible recommendations** |
| **Are you feeling ill today?** | Vaccinations should be postponed in someone who may have COVID-19 to prevent spreading infection to others at the clinic.    Talk with your health care provider about any symptoms you may have. Your health care provider will advise you when the vaccine should be provided. |
| **Have you had a COVID-19 infection?** | It is important for people with previous COVID-19 infection to be vaccinated to help prevent becoming infected again. After a COVID-19 infection, NACI suggests waiting 8 weeks to start or complete the primary series (or 4 to 8 weeks for people who are immunocompromised). For those who are previously vaccinated, NACI suggests waiting 6 months after SARS-CoV-2 infection to receive a subsequent dose, although shorter intervals may be recommended by your health care provider.  If your child has had Multisystem Inflammatory Syndrome in Children (MIS-C), the vaccine can be given when all their symptoms have resolved or 3 months have passed from the start of their symptoms, whichever is longest. |
| **Did you have any side effects after any previous dose of COVID-19 vaccine?** | It may be possible for people with previous allergic reactions to a COVID-19 vaccine to receive that same type of vaccine again. Consult with your health care provider.  If you had myocarditis or pericarditis (inflammation of the heart or lining of the outside of the heart) after a previous dose of an mRNA vaccine, consult with your health care provider. A repeat COVID-19 vaccine is generally not recommended. If a repeat vaccine is offered, the Pfizer-BioNTech Comirnaty vaccine is the preferred vaccine. |
| **Are you allergic to polyethylene glycol (PEG)a** (which is contained in the Pfizer-BioNTech Comirnaty vaccine and Moderna Spikevax vaccines)?  *See footnotes for more details* | If you are allergic to polyethylene glycol (PEG), it may be possible for you to receive an mRNA vaccine. Consult with your health care provider. |
| **Are you allergic to tromethamine (trometamol or Tris)b** (which is contained in the Pfizer-BioNTech Comirnaty vaccine and Moderna Spikevax vaccines)?  *See footnotes for more details* | If you are allergic to tromethamine (trometamol or Tris), it may be possible for you to receive an mRNA vaccine. Consult with your health care provider. |
| **Do you have a suspected but unproven allergy to a vaccine component (polyethylene glycol [PEG]a, trometamol or Trisb)?**  *See footnotes for more details* | If "yes", you may receive an mRNA COVID-19 vaccine. You will be asked to wait in the clinic for 30 minutes after receiving the vaccine to make sure you are feeling well. |
| **Have you had an allergic reaction to another vaccine (another type of COVID-19 vaccine or a non-COVID-19 vaccine) or other medication given by injection or intravenously in the past?** | If "yes", you may receive an mRNA COVID-19 vaccine. You will be asked to wait in the clinic for 30 minutes after receiving the vaccine to make sure that you are feeling well. |
| **Are you or could you be pregnant?** | No safety concerns particular to pregnancy have been identified with the mRNA COVID-19 vaccines based on real world data. The benefit of vaccination in this population has been demonstrated to outweigh any potential theoretical risk. |
| **Do you have any problems with your immune system or take any medications that can affect the immune system** (e.g., high dose steroids, chemotherapy, some arthritis medications)?  *Ask the health care provider if you are not sure about your medical conditions* | People with problems with their immune systems may have a reduced immune response to the COVID-19 vaccine. An additional dose may be recommended for the primary series for immunocompromised individuals, compared to the age-based recommendations for those who are not immunocompromised. |
| **Do you have a bleeding disorder or take any medications that could affect blood clotting?**  *Ask the health care provider if you are not sure about your medical conditions* | If “yes”, the health care worker may hold the site where the needle is given for longer to prevent bleeding and bruising. |
| **Are you feeling particularly anxious or afraid of the needle?** | Let the health care provider know if you are feeling particularly anxious or concerned. They can take steps to help you feel more comfortable receiving the vaccine. |
| **Have you ever felt faint or fainted after a past vaccination or medical procedure?** | If “yes”, the health care provider may vaccinate you lying down to prevent fainting. |
| **Footnotes:**   1. Polyethylene glycol (PEG) can rarely cause allergic reactions and is found in products such as over the counter (e.g., cough syrup, laxatives) and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens solutions, and products such as ultrasound gel. Note that this is not a complete list. PEG can also be found in foods or drinks but has not been reported to cause allergic reactions from foods or drinks. 2. Tromethamine (trometamol or Tris) may very rarely cause allergic reactions and is found in some medications injected to do tests (contrast media) as well as other medications taken by mouth or injection, and some creams and lotions. Note that this is not a complete list. | |

**How is the vaccine administered?**

The vaccine is given using a needle, usually in the muscle in the upper arm or, less commonly, in the thigh. The thigh is the recommended site for children 6 months to less than 1 year of age.

If you are not previously vaccinated, the number of doses you will receive will depend on your age, and if you have problems with your immune system. If you started the vaccine series with an earlier vaccine but did not complete the series, you should complete it with the XBB.1.5 vaccine. Tables 2 and 3 of the [*Updated guidance on the use of COVID-19 vaccines in individuals who have not previously been vaccinated against COVID-19*](https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-updated-guidance-covid-19-vaccines-individuals-not-previously-vaccinated.html) provide information on the number and timing of doses recommended.

If you have been previously vaccinated with a primary series, a dose of XBB.1.5 COVID-19 vaccine is recommended 6 months following previous COVID-19 vaccination or SARS-CoV-2 infection (whichever is later). Shorter intervals (i.e., 3 months to less than 6 months) following previous vaccination or infection have also not been shown to pose a safety risk.

**What are the risks of the vaccine?**

* Side effects can develop in the few days after receiving vaccines. Although most side effects are not serious, they may make you feel unwell for a few days; they will go away on their own. **Some common and expected side effects** include one or more of the following:
  + pain, redness or swelling where the needle was given
  + tiredness
  + headache
  + muscle pain
  + joint pain
  + chills
  + fever
  + diarrhea, nausea or vomiting
  + swollen glands in the underarm
* **Rarely allergic reactions** can occur after receiving a vaccine. Symptoms of an allergic reaction include:
  + difficulty breathing
  + hives (bumps on the skin that are often very itchy), or
  + swelling of the face, tongue or throat

The clinic staff are prepared to manage an allergic reaction should it occur. Seek immediate medical care if you develop any of these symptoms.

* **Inflammation of the heart or the lining of the outside of the heart** (myocarditis or pericarditis) have rarely been reported after mRNA vaccines. Most cases are mild and symptoms resolve quickly after seeking medical care.
  + The risks of myocarditis or pericarditis from mRNA vaccines are higher:
    - after the second dose
    - within a week of vaccination
    - in adolescents and young adults (less than 30 years of age)
    - in males than females
    - after Moderna Spikevax compared to after Pfizer-BioNTech Comirnaty in adolescents and young adults, based on information from previous vaccines used in the primary series
  + Myocarditis or pericarditis after COVID-19 vaccination in children is uncommon.
  + Seek medical attention immediately if you develop any of the following:
    - chest pain
    - shortness of breath
    - fast or irregular heartbeat
* Bell’s palsy (weakened or inability to move the muscles of the face) has rarely been reported after mRNA vaccines. Seek medical attention if you experience facial weakness or drooping or other symptoms involving the face.
* Other side effects such as unusual sensations (such as numbness or tingling), dizziness or skin rashes have also been reported.
* It is important to note that **you cannot get COVID-19 infection from the vaccine**.

**What should you do before coming to the clinic?**

* Make sure that you wear a short-sleeve shirt or top with sleeves that are easy to roll up.
* To prevent feeling faint while being vaccinated, make sure not to skip a meal before coming to the clinic.
* A mask should be worn. A medical mask or N95 or KN95 respirator are preferred.
* Bring any identification required by the clinic, such as your health card.
* Bring your immunization record with you.

**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. Inform a health care provider right away if you feel unwell while waiting. You should not leave the clinic for at least 15 to 30 minutes after receiving a vaccine, based on the recommendation of the health care provider, and should not leave if you are feeling unwell.
* **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 the face, tongue or throat, or difficulty breathing. Inform your health care provider or local public health department of any concerning side effects after receiving the vaccine.
* Seek medical care right away if you develop symptoms that could be **myocarditis or pericarditis** such as chest pain, shortness of breath or a fast or irregular heartbeat.
* **Continue to follow the recommendations of local public health officials** to prevent the spread of COVID-19.
* If possible, **wait at least two weeks after vaccination or completing a COVID-19 vaccination series before starting drugs that suppress the immune system**,as recommended by your health care provider.
* **Keep your immunization record** in a safe place.

**When should the next dose of COVID-19 vaccine be given?**

* For the primary series for children 6 months to under 5 years of age who are NOT immunocompromised, the National Advisory Committee on Immunization (NACI) recommends 8 weeks between the 2 doses of Moderna Spikevax or 3 doses of Pfizer-BioNTech Comirnaty.
* For the primary series for children 6 months to under 5 years of age who ARE moderately to severely immunocompromised, NACI recommends 4 to 8 weeks between the 3 doses of Moderna Spikevax (or 4 doses of Pfizer-BioNTech Comirnaty, although this is not the preferred product).
* For the primary series for those 5 years of age and older who are not immunocompromised, only 1 dose of XBB.1.5 vaccine is recommended, while 2 doses 4 to 8 weeks apart are recommended for those who are moderately to severely immunocompromised.
* A different schedule may be advised if you started a primary series with an earlier COVID-19 vaccine and are completing it with 1 or more XBB.1.5 vaccines. Consult with a health care provider.
* At this time, individuals whose primary series included the XBB.1.5 COVID-19 vaccine do not require further doses once the primary series is complete. As well, individuals who were previously vaccinated and then received an XBB.1.5 vaccine do not require any further doses at this time.
* After a SARS-CoV-2 infection, NACI suggests waiting 8 weeks to start or complete the primary series (or 4 to 8 weeks for people who are moderately to severely immunocompromised) and 6 months after the infection to receive a subsequent dose for those who were previously vaccinated. Shorter intervals may also be used based on recommendations from your health care provider.
* It is very important to stay up to date with all recommended COVID-19 vaccines. Your health care provider or local public health department can provide advice about vaccine recommendations if you have questions.

Bring your immunization record with you when you come for the next dose.

If you have any questions, please speak with the person providing the vaccine or contact: *Insert contact information*