

Ministry of Health

Janssen COVID-19 Vaccine Information Sheet

Version 1.0 – December 2, 2021

Every effort should be made to immunize with an mRNA vaccine. The Janssen vaccine should only be used when an mRNA vaccine is declined and after informed consent.

This document provides basic information only and is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

Please read this information sheet carefully and make sure all your questions have been answered by a health care provider before you get the vaccine.

How does the Janssen COVID-19 vaccine work?

- The vaccine teaches your immune system to recognize and fight against the COVID-19 virus, which helps to prevent illness if you come into contact with the virus.
- The Janssen vaccine is a viral vector vaccine which is a type of vaccine that takes another virus, called an adenovirus that is weakened so it cannot grow; it teaches your body how to fight against the COVID-19 virus.
- You cannot get COVID-19 from the vaccine.
- The vaccine generally requires a single dose given as a needle in the upper arm.
- If you have moderate to severe problems with your immune system, it is recommended that you receive mRNA COVID-19 vaccine. If you receive a dose of Janssen vaccine, it is recommended that you receive an mRNA COVID-19 vaccine at least two months (56 days) later.
 - Exact timing should be decided with your treating provider to optimize your immune response from the vaccine series and minimize delays in management of their underlying condition.

- [Ontario recommends](#) that a booster dose of an mRNA COVID-19 vaccine should be given at least 6 months after the Janssen vaccine.
 - If you have an allergy to an mRNA vaccine, speak with your treating provider about appropriate next steps for a booster dose.
- Clinical trials showed that beginning 2 weeks after the single dose, the Janssen COVID-19 **vaccine lowered the chance of getting sick from COVID-19 by 67% and of getting seriously ill by 77%**. This protection is somewhat lower than with an mRNA COVID-19 vaccine (Pfizer-BioNTech, Moderna). Because of lower protection and some safety concerns, mRNA vaccines are recommended by the National Advisory Committee on Immunization (NACI).
- A single dose of mRNA vaccine is still preferred over a single dose of the Janssen vaccine. A second dose of mRNA is recommended for most people as it offers higher protection than Janssen.
- Discuss your vaccine choices with a health care provider.

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

- The Janssen vaccine is authorized for use in people who are 18 years of age and older.
- The Janssen vaccine should not be used in individuals younger than 18.
- Individuals with the following conditions should not receive the Janssen COVID-19 vaccine:
 - A history of blood clots with low platelets (i.e., major venous and/or arterial thrombosis with thrombocytopenia) following any vaccine
 - If you had blood clots with low platelets after a previous viral vector vaccine (AstraZeneca or Janssen), you should not receive the Janssen COVID-19 vaccine. Consult with your health care provider.
 - Thrombosis with thrombocytopenia syndrome (TTS) or vaccine-induced immune thrombotic thrombocytopenia (VITT) following the AstraZeneca COVID-19 vaccine
 - A history of capillary leak syndrome (CLS)
 - A history of cerebral venous sinus thrombosis (CVST) with thrombocytopenia
 - A history of heparin-induced thrombocytopenia (HIT)

- Actively receiving monoclonal antibody therapy OR convalescent plasma therapy for the treatment or prevention of COVID-19
 - Vaccine should not be administered while actively receiving therapy
- Individuals with severe allergic reaction (including anaphylaxis) to a component/ingredient of the Janssen vaccine should discuss their vaccine choices with a health care provider before receiving the Janssen COVID-19 vaccine.
- Individuals who have experienced serious adverse event following COVID-19 immunization should discuss their vaccine choices with a health care provider before receiving the Janssen COVID-19 vaccine.

What are the ingredients in the vaccines?

- The vaccine contains lipids (fats), salts, sugars and buffers. COVID-19 vaccines **do not** contain eggs, gelatin (pork), gluten, latex, preservatives, antibiotics, adjuvants or aluminum.
- Talk to a health care provider first before getting the vaccine if you have allergies to the following vaccine ingredients: polyethylene glycol (PEG), polysorbate 80 and/or tromethamine (trometamol or Tris).
- Serious allergic reactions (anaphylaxis) to the vaccine are very rare and can be treated. Get medical help if you have trouble breathing or develop hives or swelling in the face and throat after being vaccinated.

Before receiving the vaccine, tell the health care provider at the clinic who is providing the vaccine if:

- You are currently feeling sick or have [signs and symptoms of COVID-19](#)
 - You should wait until your symptoms go away before getting vaccinated. If you have been told to self-isolate because of COVID-19 you should not attend a vaccine clinic and should wait until your isolation period is over to get the vaccine.
- You have allergies or had an allergic reaction to a previous COVID-19 vaccine dose, another vaccine, and/or any of the vaccine's components or ingredients.

- You are or could be pregnant or are breastfeeding. You can still get your vaccine if you are pregnant or are breastfeeding.
 - Evidence is now available from real world use of mRNA COVID-19 vaccines, which has not indicated any safety concerns for pregnant and breastfeeding populations. There is less evidence regarding the safety of the Janssen vaccine including pregnant women and breastfeeding women. An mRNA COVID-19 vaccine is recommended by the National Advisory Committee on Immunization (NACI) since they have been shown to be more effective than viral vector vaccines and generally safer, with less side effects.
- You are immunosuppressed due to disease or treatment or have been diagnosed with an autoimmune condition.
- You have ever fainted or became dizzy after getting a vaccine or medical procedure or you have a fear of needles.
- You have a bleeding disorder or are taking medication that could affect blood clotting.
- You have a history of a problem with low platelets (a type of cell in the blood that helps with clotting)
 - Rarely, low platelets can occur after receiving the Janssen vaccine. If you already have a history of low platelets, you should consider receiving an mRNA COVID-19 vaccine. If you have a history of low platelets and choose to get the Janssen vaccine you should watch for easy bruising or excess bleeding that is unexplained. Your health care provider may monitor your blood platelet count after receiving the Janssen vaccine.
- You have a history of blood clots
 - Rarely, blood clots have occurred after receiving the Janssen vaccine. Discuss your risks with your health care provider.

What are the normal side effects to expect after receiving the vaccine?

Some mild side effects may occur after getting the COVID-19 vaccine, such as pain and swelling where the vaccine was given, tiredness, muscle or joint soreness, headache or mild fever. These side effects are normal signs that the body is building protection. Serious side effects after receiving the vaccine are extremely rare.

Some very rare reactions that have been found to occur from taking a viral vector vaccine are:

- **Vaccine-induced immune thrombotic thrombocytopenia (VITT)**, also called thrombosis with thrombocytopenia syndrome (TTS)
 - VITT is a serious condition involving thrombosis (blood clots) and thrombocytopenia (low platelets; platelets are a part of the blood used for clotting). VITT can cause blood clots to develop in the brain, abdomen, legs and other parts of the body. VITT symptoms can occur within 4 weeks, and sometimes up to 6 weeks, after vaccination.
 - VITT has been reported to occur in about 1 in 300,000 people who receive a Janssen vaccine. VITT can result in death.
 - Because of the risk of VITT, mRNA vaccines are preferred.
- **Capillary leak syndrome (CLS)**
 - Capillary leak syndrome is a serious and sometimes fatal condition that causes fluid to leak from small blood vessels causing rapid swelling of the arms and legs, sudden weight gain, and low blood pressures resulting in feeling faint.
 - Those who have previously had capillary leak syndrome appear to be at increased risk following vaccination with a viral vector vaccine, such as Janssen.
- **Guillain-Barré syndrome (GBS)**
 - GBS is a potentially serious neurologic disorder that results in numbness and weakness in the arms, legs, face, chest or other muscles, causing paralysis in severe cases. It can occur within several weeks after vaccination with the Janssen vaccine.
 - Most people fully recover from GBS but some have remaining symptoms and fatal cases can occur.
- **Immune thrombocytopenia (ITP)**
 - ITP results in low platelets (a part of the blood used for clotting) that can cause easy or excessive bruising or bleeding. It can occur within 4 weeks of vaccination and cases can be fatal.
 - Some of the cases of ITP after vaccination have occurred in people with a previous problem of low platelets.

- **Venous thromboembolism (VTE)**
 - VTE causes blood clots in the deep veins such as in the legs, arms or groin that can travel to the lungs causing serious illness. Symptoms include shortness of breath and chest pain.
 - Some people are more prone to VTE. Discuss your risks with your health care provider.

If I am feeling unwell after my vaccine, when should I call a health care provider?

If you experience a high fever (over 40°C or 104°F), or side effects that are worrying you or do not seem to be going away after a few days, contact your health care provider or seek medical attention. Go to the nearest **emergency department or call 911** if you have hives, swelling of the face, throat or mouth, altered levels of consciousness/serious drowsiness, trouble breathing, seizures/convulsions, “pins and needles”/numbness, or other serious symptoms (listed below).

- **Seek medical care immediately** if you develop these symptoms following immunization which could be associated with **vaccine-induced immune thrombosis with thrombocytopenia (VITT, TTS)**:
 - New severe headaches, worsening or persistent headaches; blurred vision, confusion or seizures
 - Shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
 - Unusual skin bruising or pinpoint round spots under the skin beyond the site of vaccination
- **Seek medical care immediately** if you develop these symptoms following immunization which could be associated with **capillary leak syndrome (CLS)**:
 - Rapid swelling of the arms and legs
 - Sudden weight gain
 - Feeling faint or lightheaded
- **Seek medical care immediately** if you develop these symptoms following immunization that could be associated with **Guillain-Barré syndrome (GBS)**:
 - Numbness, weakness or inability to move the muscles in the arms, legs, face, chest or other muscles

- **Seek medical care immediately** if you develop these symptoms following immunization that could be associated with **immune thrombocytopenia (ITP)**:
 - Unexplained and/or excessive bleeding or bruising
 - Small purplish pinpoint spots under the skin
- **Seek medical care immediately** if you develop these symptoms following immunization that could be associated with **venous thromboembolism (VTE)**:
 - Leg or arm pain and/or swelling, warmth, redness
 - Shortness of breath
 - Chest pain

If I have questions, who should I ask?

If you have any questions, please speak with a health care provider or the person providing the vaccine. You can also contact your [local public health unit](#) to ask questions or to report an adverse reaction following vaccination.