

INFORMATION

Janssen (Johnson & Johnson) COVID-19 Vaccine May 20, 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). COVID-19 was recognized for the first time in December 2019 and has since 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](#) 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.
- Unvaccinated people are at much higher risk of COVID-19 infection and serious illness, including hospitalization and death, compared to vaccinated people.
- [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 body to produce protection (such as antibodies) to help keep us from becoming sick if we are exposed to the COVID-19 virus.
- The vaccine, which is a viral vector vaccine, uses a fairly new method that involves taking another virus called an adenovirus, weakening it so it cannot grow, and inserting instructions for part of the COVID-19 virus to help our body make protection against the COVID-19 virus.
- Clinical trials show that 4 weeks after getting immunized, the Janssen COVID-19 vaccine lowered the chance of being moderately ill from COVID-19 by 66.1%, compared to not being immunized.

Who can receive Janssen COVID-19 vaccine at this time?

- Adults 18 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 any symptoms that could be due to COVID-19, you should not go out to get vaccinated because you could spread the infection to others. Talk with your health care provider, or call 811, about your symptoms and getting a COVID-19 test. Your health care provider will advise you when you are able to receive the vaccine.
- have an allergy to any of the vaccine ingredients or other adenovirus vaccines
- had a severe or unusual side effect after this vaccine or one like it
- have received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19

- had a major venous or arterial thrombosis with thrombocytopenia syndrome (TTS) after getting any viral vector COVID-19 vaccine
- have a history of cerebral venous sinus thrombosis (CVST) with thrombocytopenia
- have a history of heparin-induced thrombocytopenia (HIT)
- have had thrombotic anti-phospholipid antibody syndrome (APS)
- have a history of capillary leak syndrome
- are pregnant (should only receive an mRNA COVID-19 vaccine, unless there are contraindications)
- If you belong to one of the following groups you MUST consult your health care provider prior to receiving:
 - » All stem cell transplant recipients.
- If you belong to one of the following groups, it is preferred you contact your health care provider prior to receiving the vaccine:
 - » are receiving treatment with immunosuppressive medications to determine the optimal time to receive the COVID-19 vaccine
 - » have 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 and is only one dose.
- Some high-risk individuals may be eligible for additional/booster doses.
- Health Canada approved COVID-19 vaccines can be given at the same time as other non-COVID-19 vaccines; no intervals are needed before or after COVID-19 vaccine administration.

What are common reactions to this vaccine?

- Side effects can develop up to 3 days after receiving this 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.
- Common Janssen side effects include:

pain, redness or swelling where the needle was given		
pain in arms and hands, legs and feet	nausea	fever, chills
tiredness, low energy	headache	low energy
feeling generally unwell	dizziness	muscle aches
general body or muscle weakness	rash	joint pain

- Tinnitus (ringing or other noises in one or both of your ears) has been reported after receiving Janssen COVID-19 vaccine.

- Janssen COVID-19 vaccine can very rarely cause serious blood clots and low levels of blood platelets (thrombosis with thrombocytopenia syndrome or TTS), in some cases with bleeding, following immunization. This includes severe cases presenting in unusual sites such as the brain and abdomen. The reaction typically occurs within 3 weeks of immunization, but may occur up to 6 weeks after vaccination. Up to 15% of TTS cases have been fatal following immunization. Current evidence supports that Janssen COVID-19 vaccine can cause TTS.
- There have been very rare reports of capillary leak syndrome following immunization with viral vector vaccines. This syndrome is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries) resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood, and low levels of albumin (an important protein in blood).
- There have been very rare reports of an autoimmune condition called immune thrombocytopenia (ITP) following immunization with viral vector vaccines that causes bleeding, bruising, shortness of breath, chest pain, leg pain and swelling and small purple spots beyond the injection site. It can occur within 4 weeks of vaccination and can be fatal.
- There have been very rare reports of blood clots in the vein (venous thromboembolism or VTE) following immunization with this vaccine that causes unexplained shortness of breath, chest pain, stomach pain that lasts for a while, leg pain or tenderness of the thigh or calf, swelling in the legs, skin that feels warm to the touch and reddish skin discoloration or red streaks. Some people are more prone to VTE.
- Very rare events of demyelinating disorders, such as Guillain-Barré syndrome (GBS) and transverse myelitis (TM) (inflammation of the spinal cord) have been reported following vaccination with Janssen COVID-19 vaccine. Most people fully recover but some have remaining symptoms and fatal cases can occur. For TM, seek immediate medical attention if you develop weakness, sensory symptoms or problems with bladder or bowel function.
- Health Canada and the Public Health Agency of Canada (PHAC) are actively monitoring reports of myocarditis (inflammation of the heart) and/or pericarditis (inflammation of the outer lining of the heart) following immunization with a COVID-19 vaccine in Canada. There have been a small number of cases reported in Canada (mostly following mRNA vaccination), and it is not yet known if there is any relationship between these events and the vaccines.
- 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 your 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 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 healthcare 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 911 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. Inform your health care provider of any concerning side effects after receiving the vaccine.
- 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 return for my next vaccine dose?

- Janssen COVID-19 vaccine is a 1-dose series.
- You should return to receive a first booster dose 2 months later.
- It is recommended that eligible individuals return for a second booster dose 4 months after the first booster dose.
- mRNA is the preferred vaccine for booster doses for those who received Janssen. However, Janssen vaccine can be provided if the other COVID-19 vaccines are contraindicated or if a client states their preference for Janssen after receiving all information to provide informed consent.

What does Janssen vaccine contain?

SARS-CoV-2 particles*, adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein in a stabilized conformation. 2-hydroxypropyl- β -cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injection.

*Produced in the PER.C6® TetR Cell Line and by recombinant DNA technology

