Ministry of Health

# COVID-19 Vaccine Information Sheet

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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.

To date, the following COVID-19 vaccines have been authorized for use in Canada by Health Canada: Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca COVID-19 vaccine, COVISHIELD COVID-19 vaccine, and Janssen COVID-19 vaccine. Currently, the Pfizer-BioNTech vaccine is the only COVID-19 vaccine authorized by Health Canada for children aged 12 and up.

All vaccines for COVID-19 authorized for use in Canada have been evaluated by Health Canada, using rigorous standards.  Health Canada will continue to monitor all vaccines to make sure they are safe and effective.

**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.**

## What is COVID-19?

COVID-19 is an infection 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. 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.

Children who get infected with COVID-19 typically experience mild symptoms. However, some children can get very sick requiring hospitalization. Children can also get a serious medical condition called "Multisystem Inflammatory Syndrome in Children." Others can experience more serious, longer-lasting symptoms that can affect their health and well-being. In very rare cases, the virus can also cause death in children.  Like adults, children also can transmit the virus to others if they are infected, even if they don't feel sick.

# How do the vaccines protect against COVID-19?

All vaccines work by presenting our body with something that looks like the infection so that our immune system can learn how to produce its own natural protection. This natural protection then helps to prevent future illness if you come into contact with the COVID-19 virus in the future. **You cannot get COVID-19 from the vaccine.**

More detailed information on how COVID-19 vaccines provide protection can be found on [Public Health Ontario's (PHO) COVID-19 Vaccines](#) webpage and [What You Need to Know About mRNA Vaccines](#) and [What You Need to Know About Viral Vector Vaccines](#).

**All  COVID-19 vaccines authorized for use in Canada are effective at protecting against symptomatic, lab-confirmed disease.**  In large studies where people were given the vaccines, all of the vaccines worked very well to prevent people from becoming sick with symptomatic,  lab-confirmed COVID-19.  Vaccine efficacy 14 days after dose one and before dose two is estimated to be over 90% for Pfizer-BioNTech and Moderna and over 70% for AstraZeneca and COVISHIELD.  Vaccine efficacy after dose two at the recommended interval is estimated to be over 90% for Pfizer-BioNTech and Moderna and over 80% for AstraZeneca and COVISHIELD. It is important that you receive both doses of the vaccines, Pfizer-BioNTech, Moderna, AstraZeneca or COVISHIELD since they are two dose vaccine series. Long-term protection against COVID-19 is not achieved until after the second dose of vaccine is received for two dose vaccines.  **All of the COVID-19 vaccines authorized for use in Canada are highly effective at preventing hospitalizations.**

The Pfizer-BioNTech vaccine has been demonstrated to be highly effective at protecting against COVID-19 for individuals 12 and over. The Pfizer-BioNTech clinical trial studied 2,260 youth aged 12 to 15 years old in the United States. In the trial, there were 18 cases of COVID-19 in the group that did not get the vaccine (the "placebo" group) compared to zero cases in the vaccinated group. Based on these results, the vaccine was calculated to be 100% effective in the trial.

# Who can receive these vaccines?

A complete vaccine series should be offered to individuals without contraindications to the vaccine and in currently identified priority groups.

- The Pfizer-BioNTech COVID-19 vaccine is currently authorized for individuals 12 years of age and older.
- The Moderna COVID-19 vaccine is currently authorized for individuals 18 years of age and older.
- The AstraZeneca COVID-19 vaccine and COVISHIELD is currently authorized for individuals 18 years of age and older.  At this time, Ontario has paused the rollout and administration of first doses of AstraZeneca/COVISHIELD COVID-19 vaccines.  At present, this vaccine is being offered to individuals 40 years of age and older for second doses only.

To find out if you are eligible to receive the vaccine at this time based on prioritization please refer to Ontario's COVID-19 vaccination plan.

You will be counselled on the benefits and risks of the vaccine you are recieving prior to receiving the vaccine.

If you have experienced major venous and/or arterial thrombosis (blood clot) with thrombocytopenia (low platelets) following vaccination with any vaccine **you cannot get** the AstraZeneca/ COVISHIELD COVID-19 vaccine.

If you have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia or have experienced heparin-induced thrombocytopenia (HIT) **you cannot get** the AstraZeneca, COVISHIELD COVID-19 vaccine.

## Before receiving the vaccine, inform the health care provider at the clinic who is providing you with the vaccine if:

- You are currently feeling unwell or have signs and symptoms of COVID-19.
- You have had a previous allergic reaction to a COVID-19 vaccine or any ingredients in the COVID-19 vaccines, or any other vaccine.
- You have any allergies or allergic conditions.
- You are or could be pregnant or are breastfeeding.  You can still get your vaccine if you are pregnant or are breastfeeding.
- You are immunosuppressed due to disease or treatment or have been diagnosed with an autoimmune condition.

- You have fainted or became dizzy after receiving a previous vaccine or medical procedure or you have a fear of needles. The healthcare provider may offer supports to assist you, for example, recommending that you receive the vaccine lying down to prevent fainting.
- You have a bleeding disorder or are taking medication that could affect blood clotting. This information will help the healthcare provider prevent bleeding or bruising from the needle at the time of vaccination.
- You have received any other vaccine (not COVID-19 vaccine) in the past 14 days.

The Vaccination Recommendations for Special Populations guidance document provides additional information for people who are breastfeeding or pregnant, have allergies, autoimmune conditions, or are immunocompromised due to disease or treatment.  The Vaccination in Pregnancy and Breastfeeding Decision-Making Support Tool can help make an informed decision about COVID-19 vaccination during pregnancy and breastfeeding.  If you have questions about whether the vaccine is right for you based on your medical condition, talk to your health care provider.

# Who should delay receiving these vaccines?

- Individuals who have received another vaccine (not a COVID-19 vaccine) in the previous 14 days.
- Individuals with symptoms of an acute illness (e.g., runny nose, sore throat, cough, fever, chills, diarrhea, nausea/vomiting); these individuals should wait until symptoms have completely resolved in order to avoid attributing any complications resulting from the illness to vaccine-related side effects.
- Individuals with symptoms of COVID-19 (e.g., loss of taste or smell, shortness of breath, etc.) To minimize the risk of COVID-19 transmission, if these individuals arrive at an immunization venue, they will be instructed to follow current local public health measures including self-isolation, and be encouraged to get tested.
- Symptomatic and asymptomatic individuals who have been advised to self-isolate due to suspected or confirmed COVID-19 infection or due to close contact with a COVID-19 case should not attend a vaccine clinic and should wait to get their vaccine until their isolation period is over.

# How is the vaccine administered?

The COVID-19 vaccine is given as a needle in the upper arm (into the deltoid muscle).  The province is following current recommendations from the National Advisory Committee on Immunication (NACI) to extend the time interval of the second dose of COVID-19 vaccine for the Pfizer-BioNTech and Moderna up to 16 weeks after the first dose and AstraZeneca/COVISHIELD vaccines at or greater than 12 weeks.

- Individuals who received a first dose of AstraZeneca/COVISHIELD and who do not wish to receive AstraZeneca/COVISHIELD for a second dose will be provided the option to receive an mRNA vaccine product for their second dose.
- Individuals who received a first dose of the Moderna or Pfizer mRNA vaccines may receive either Moderna or Pfizer for their second dose.  Both the Moderna and Pfizer vaccines are very similar and NACI advises mRNA vaccines are safe to be used together in a vaccine schedule.

## What are the ingredients in the vaccines?

| Ingredients | | Pfizer-BioNTech | Moderna | AstraZeneca/ and COVISHIELD |
|---|---|---|---|---|
| Medical | | • mRNA | • mRNA | • Non-replicating viral vector (ChAd) |
| Non-medical | Lipids | • ALC-0315<br>• ALC-0159 – a polyethylene glycol (PEG)<br>• 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)<br>• Cholesterol | • 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)<br>• Cholesterol<br>• PEG2000 DMG SM-102 | • Disodium edetate dihydrate (EDTA)<br>• Ethanol<br>• L-Histidine<br>• L-Histidine hydrochloride monohydrate<br>• Polysorbate 80 |
| | Salts | • Dibasic sodium phosphate dihydrate<br>• Monobasic potassium phosphate<br>• Potassium chloride<br>• Sodium chloride | • Acetic acid<br>• Sodium acetate trihydrate<br>• Tromethamine<br>• Tromethamine hydrochloride | • Magnesium chloride hexahydrate<br>• Sodium chloride |
| | Sugar | • Sucrose<br>• Water for injection | • Sucrose<br>• Water for injection | • Sucrose<br>• Water for injection |

COVID-19 vaccines do not contain eggs, gelatin (pork), gluten, latex, preservatives, antibiotics or aluminum.

It is important to review this list carefully as some people may be allergic to these ingredients, including **polyethylene glycol (PEG), polysorbate 80** and/or **tromethamine**. However, these rarely cause allergic reactions. Polyethylene glycol (PEG) is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, dermal fillers, cosmetics, skin creams, toothpaste, contact lenses and contact lens solution. Polyethylene glycol can also be found in food or drinks, but is not known to cause allergic reactions from food or drinks. Polysorbate 80 is found in medical preparations (such as vitamin oils, tablets, and anticancer agents) and cosmetics. Tromethamine (trometamol or Tris) is a component in contrast media, oral and parenteral medications.

## What are the side effects of the vaccine?

COVID-19 vaccines, like all vaccines, may cause side effects in both adults and children, although not everyone experiences them and those who do experience them, mostly report mild side effects within the first 1-2 days after vaccination. The most commonly reported side effects after receiving a COVID-19 vaccine are localized reactions including pain, swelling, and colour changes in the skin (e.g. red, purple) at the injection site, and tiredness, headache, muscle pain, joint pain, chills, and mild fever. Studies evaluating people who were provided a second dose of Pfizer after a first dose of AstraZeneca COVID 19 vaccine reported increased frequency of short term mild side effects.

Ongoing studies on these COVID-19 vaccines indicate serious side effects found to-date are **extremely rare.** People who have received the vaccine in these studies continue to be monitored for any longer-term side effects.

Clinic staff are prepared to manage a severe allergic reaction should it occur. When receiving your second dose of COVID-19 vaccine, **tell the health care provider administering the second dose if you had any side effects after the first dose.**

Very rarely, the AstraZeneca and COVISHIELD COVID-19 vaccines have been associated with a rare form of blood clot after vaccination. Doctors are calling this Vaccine-Induced Immune Thrombotic [Thrombocytopenia](#) (VITT). These blood clots have two important features: they typically occur 4 to 28 days after vaccination, and they are associated with low platelets (tiny blood cells that help form blood clots to stop bleeding). VITT seems to be rare. The rate of VITT is estimated to be approximately 1 per 26,000 and 1 per 127,000 persons vaccinated with AstraZeneca and/or COVISHIELD COVID-19 vaccine.

There have been international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the sac in which the heart sits inside of the chest) following vaccination with COVID-19 mRNA vaccines. Cases have been mild, happening more commonly after the second dose of vaccine and more often in male adolescents and young adults. Symptoms have been reported to start a few days after vaccination.  At this time, the Public Health Agency of Canada (PHAC) and Health Canada are not seeing higher rates of these conditions than would normally be expected due to other causes in the general population. No clear causal association has been established between myocarditis/pericarditis and mRNA vaccines. mRNA COVID-19 vaccines continue to be recommended in Canada and other countries where mRNA vaccines are being used.  This situation is being monitored closely in Canada and internationally.

# When should I call my health care provider?

If you experience 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 any of the following adverse reactions develop within three days of receiving the vaccine:

- hives
- swelling of the face or mouth
- trouble breathing
- serious drowsiness
- high fever (over 40°C)
- convulsions or seizures
- other serious symptoms (e.g., "pins and needles" or numbness)

If you have received the AstraZeneca/COVISHIELD  vaccine and you develop any of the following symptoms after receiving the vaccine **please seek immediate medical attention**:

- shortness of breath
- chest pain
- leg swelling or pain
- persistent abdominal pain

- skin bruising (other than at the site of vaccination) or petechiae (red or purple spots or blood blisters under the skin)
- sudden onset of severe headaches or persistent or worsening headaches
- blurred vision, double vision or dizziness
- confusion or seziures
- difficulty speaking or moving a part of the body

You can also contact your local public health unit to ask questions or to report an adverse reaction.

# When should I return for my second dose?

If this is your first dose of a two dose vaccine, be sure to return for your second dose as instructed by the vaccination clinic or the health care provider who provided you with your first dose.  It is important that you receive two doses of the vaccine as protection against COVID-19 is not optimal until after the second dose of vaccine is received.  Bring your immunization record when you come for your second dose. **It is very important that you receive the second dose even if you experienced side effects the first time**.

# Who should I contact with any questions?

If you have any questions, please speak with your health care provider or the person providing the vaccine.