Ontario

Ministry of Health

COVID-19 Vaccine Information Sheet

Version 12.0 – September 29, 2021

Highlights of changes

- New guidance on authorized vaccines (page 1)
- Information regarding a preferential recommendation for Pfizer BioNTech in specific age groups (page 4)

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 and Moderna COVID-19 vaccines are the only COVID-19 vaccines authorized by Health Canada for children aged 12 (or turning 12 in 2021) to 17.

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 (Severe Acute Respiratory Syndrome Coronavirus 2 - SARS-CoV-2). COVID-19 was recognized for the first time in December 2019 and has since spread around the world to cause a global 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 (MIS-C)." Like adults, children can experience more serious, longer-lasting symptoms (i.e. Long COVID, post-acute COVID-19 syndrome) that can affect their health and well-being and can transmit the virus to others if they are infected, even if they don't feel sick. In very rare cases, the virus can also cause death in children.

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 COVID-19. In large clinical trials/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. There is a growing evidence to suggest mRNA vaccines provide protection against asymptomatic infection and SARS-CoV-2 transmission. It is important that you receive **all recommended doses** of the vaccines. Longer-term protection against COVID-19 is not achieved until after all recommended doses of vaccine are received. **All of the COVID-19 vaccines authorized for use in Canada are highly effective at preventing severe outcomes including hospitalizations, ICU admission, severe disease and death.**

When is a third dose recommended?

The COVID-19 vaccines provide strong protection against illness and severe outcomes, and at this time third doses of vaccine are not recommended for the general population.

Certain populations that are moderately to severely immunocompromised may demonstrate a suboptimal immune response to a two-dose COVID-19 vaccine series due to underlying health conditions. There is also some evidence to indicate that the vulnerable elderly in high-risk congregate settings develop less of an initial immune response and exhibit more rapid waning of antibody. In these populations, a third dose of an mRNA COVID-19 vaccine is recommended as described in the COVID-19 Vaccine Third Dose Recommendations. Individuals that received AstraZeneca/COVISHIELD COVID-19 vaccine for their first and second doses are recommended to receive an mRNA COVID-19 vaccine for their third dose unless contraindicated. Individuals who are unable to receive an mRNA vaccine due to contraindications may be offered a viral vector vaccine. Informed consent for an additional dose of viral vector vaccine should include discussion of potential risks with a health care provider.

It should be noted that there is limited evidence on the use of third doses of mRNA COVID-19 vaccines and the recommendation is based on expert opinion of the potential benefits for specific populations.

Who can receive these vaccines and which vaccine will be given?

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.
    - As of August 18th, 2021 individuals turning 12 in 2021 (born in 2009) are eligible to receive the Pfizer-BioNTech COVID-19 vaccine. This age group expansion for Pfizer-BioNTech was decided based on expert opinion and after close review of the experiences from other jurisdictions who have immunized this age cohort and have not seen safety concerns associated with this practice.

  - Following a thorough review of the current global and Canadian experience and provincial vaccine safety surveillance data, Ontario will continue using the **Pfizer-BioNTech** vaccine for youth individuals ages 12-17 (including those turning 12 in 2021). This preferential recommendation stems from the fact that there is more experience to date with this vaccine in this age group, and there is the possibility of a lower rate of myocarditis and/or pericarditis with Pfizer-BioNTech in this age group.

- The Moderna COVID-19 vaccine is currently authorized for individuals 12 years of age and older.
  - Based on advice from Ontario's Vaccine Clinical Advisory Group, the Ministry of Health is also issuing a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 12-24 (including those turning 12 in 2021).** This recommendation stems from an observed increase in the number of reports in Ontario of pericarditis/myocarditis following vaccination with Moderna relative to Pfizer-BioNTech in the 18-24 year old age group, particularly among males. Further information on trends in myocarditis/pericarditis following mRNA vaccines in Ontario are summarized in an enhanced epidemiologic summary from Public Health Ontario.
- The AstraZeneca COVID-19 vaccine and COVISHIELD COVID-19 vaccine are 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. First doses should only be given in extenuating circumstances (i.e. on the recommendation of an allergist/immunologist where a confirmed allergy exists to components of the mRNA vaccines).
- NACI recommends that while either an AstraZeneca/COVISHIELD COVID-19 vaccine or an mRNA COVID-19 vaccine product may be offered for the second dose in a vaccine series started with an AstraZeneca/COVISHIELD COVID-19 vaccine, an mRNA COVID-19 product is preferred as a second dose, due to emerging evidence, including the possibility of better immune response, and the safety of heterologous schedules. Regardless of which product is offered, a complete two-dose series is important for protection; the previous dose should be counted, and the series need not be restarted. See COVID-19 Vaccine Information for Individuals who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine for more information.

- NACI recommends that, if readily available (defined by NACI as easily available at the time of vaccination without delay or vaccine wastage), the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a two-dose vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered as the second dose in the vaccine series. The previous dose should be counted, and the series need not be restarted.

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.

If you have previously experienced episodes of capillary leak syndrome **you cannot get** the AstraZeneca/COVISHIELD COVID-19 vaccine.

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

Before receiving the vaccine, tell 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 (listed below), or any other vaccine.
- You were diagnosed with myocarditis or pericarditis following a previous dose of a COVID-19 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 another vaccine within 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 you 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.

What are the ingredients in the vaccines?

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

COVID-19 vaccines **do not** contain eggs, gelatin (pork), gluten, latex, preservatives, antibiotics, adjuvants 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 (trometamol or Tris)**. However, these ingredients 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. 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 injectable medications.

Who should delay receiving their COVID-19 vaccine?

- 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.
- As a precautionary measure, individuals who were diagnosed with myocarditis/pericarditis after a previous dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) should wait to receive their second dose until more information is available. The National Advisory Committee on Immunization

(NACI), Public Health Ontario (PHO) and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available.

How is the vaccine administered?

The COVID-19 vaccine is given as a needle in the upper arm (into the deltoid muscle).

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. 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, tiredness, headache, muscle pain, joint pain, chills, and mild fever. Studies evaluating people who were provided a Pfizer-BioNTech COVID-19 vaccine as a second dose after receiving a first dose of AstraZeneca COVID-19 vaccine, reported more frequent 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 a subsequent dose of COVID-19 vaccine, **tell the health care provider administering the subsequent dose if you had any side effects after a previous 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 thromboses (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 between 1 per 26,000 and 1 per 100,000 persons vaccinated with a first dose of an AstraZeneca/COVISHIELD COVID-19 vaccine. The rate of VITT in Canada after a first dose has been estimated to be approximately 1 per 55,000

doses given. At this time international data suggests that after the second dose, the risk of VITT is estimated to be 1 for every 600,000 doses given. These estimates may change as more people around the world receive a second dose and we learn more.

There have been Canadian and international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. Cases have occurred more frequently in males than in females, most frequently in adolescents and young adults and more commonly after the second dose of vaccine. The global experience to date has indicated that the majority of reported cases have responded well to conservative therapy (rest, treatment with non-steroidal anti-inflammatory drugs (NSAIDS)) and tend to recover quickly. Symptoms have typically been reported to start within one week after vaccination**.** Myocarditis/pericarditis following COVID-19 mRNA vaccines remains a rare AEFI (defined by the Canadian Immunization Guide as occurring at frequency of 0.01% to less than 0.1%), even among the age groups with the highest observed rates of this event, and COVID-19 vaccines continue to be recommended to prevent COVID-19 disease, which also includes a risk of myocarditis. Further information on trends in myocarditis/pericarditis following mRNA vaccines in Ontario are summarized in an enhanced epidemiologic summary from Public Health Ontario.

The National Advisory Committee on Immunization (NACI) continues to strongly recommend that a complete series with an mRNA COVID-19 vaccines be offered to all eligible individuals in Canada, including those 12 years of age and older. mRNA vaccines continue to be recommended internationally. As a precautionary measure, NACI is recommending that individuals who experienced myocarditis/pericarditis after a first dose of an mRNA COVID-19 vaccine should wait to receive a second dose until more information is available. The National Advisory Committee on Immunization, Public Health Ontario and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available.This situation is being monitored closely in Canada and internationally.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe consequences for all age groups.

In the context of adequate Pfizer-BioNTech COVID-19 vaccine supply, the preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 12-24 (including those turning 12 in 2021) is anticipated to reduce the rare number of events of myocarditis/pericarditis in Ontario. Evidence on this topic

continues to evolve and this recommendation may be amended as more information becomes available. Vaccines are safe, effective and continue to be the best way to protect young adults, their families and our community from COVID-19.

Very rare cases of capillary leak syndrome (CLS), a condition that causes fluid leakage from small blood vessels (capillaries), have been reported following vaccination with AstraZeneca/COVISHIELD COVID-19 vaccine. Symptoms are often associated with feeling faint (due to low blood pressure). Individuals with a history of capillary leak syndrome should not receive the AstraZeneca/COVISHIELD COVID-19 vaccine.

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, throat or mouth
- trouble breathing
- serious drowsiness
- high fever (over 40˚C or 104˚F)
- 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 within 42 days (most often occur between 4 and 28 days) after receiving the vaccine **please seek immediate medical attention**:

- shortness of breath
- chest pain
- limb swelling, redness, pallor, coldness or pain
- persistent back or abdominal pain
- unusual bleeding, skin bruising (other than at the site of vaccination) or petechiae (red or purple spots or blood blisters under the skin)
- persistent or worsening headaches
- blurred vision or double vision
- confusion or seizures
- difficulty speaking or moving a part of the body

If you have received the Pfizer-BioNTech or Moderna vaccine and you develop any of the following symptoms after receiving the vaccine, **please seek medical attention**:

- chest pain
- shortness of breath
- palpitations (pounding or racing heart) or feeling of a rapid or abnormal heart rhythm

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

When should I return for my next dose?

Be sure to return for your next (second or subsequent – if recommended) dose as instructed by the vaccination clinic or the health care provider who provided you with your first dose. Bring your immunization record when you come for your subsequent dose. **It is very important that you receive all doses in order to have optimal protection.**

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.