

Ministry of Health

# Information Sheet

## Pfizer-BioNTech and Moderna COVID-19 Vaccines

Version 2.0 – December 30, 2020 (amended January 7, 2021)

### Highlights of changes

- Updated to include information on Moderna vaccine (throughout)
- Updated information for breastfeeding women (page 4)
- Reference and hyperlink to [Vaccination Recommendations for Special Populations](#) guidance document (throughout)

Ministry of Health

# Information Sheet

## Pfizer-BioNTech and Moderna COVID-19 Vaccines

Version 2.0 – December 30, 2020 (amended January 7, 2021)

This information sheet provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment. For more information about the Pfizer-BioNTech COVID-19 vaccine, please refer to the [Pfizer-BioNTech Product Monograph](#) authorized by Health Canada. For more information about the Moderna COVID-19 vaccine, please refer to the [Moderna Product Monograph](#), authorized by Health Canada. Additional information on the use of COVID-19 vaccines is available in [statements and publications by the National Advisory Committee on Immunization \(NACI\)](#).

Please read this information sheet carefully and ensure all your questions have been answered by a healthcare provider before receiving the vaccine. The Pfizer-BioNTech and Moderna COVID-19 vaccines have been evaluated and authorized for use in Canada by Health Canada, using rigorous standards. Health Canada will continue to monitor to ensure it is safe and effective.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) [COVID-19 website](#) regularly for updates to this document, list of symptoms, other guidance documents, Directives and other information.

## 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.
- [Of people diagnosed with COVID-19 in Canada](#), about 1 in 13 require hospitalization and about 3 out of every 100 people diagnosed with COVID-19 die. Even people with mild symptoms may feel unwell for a long time after a COVID-19 infection.

## How do the Pfizer-BioNTech and Moderna COVID-19 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 natural protection. This natural protection then helps to keep us from becoming sick if we come into contact with the real virus in the future.

Both vaccines use a method called messenger RNA (mRNA). The mRNA is like a code that tells the cells in your body how to make a piece of the outer lining of the virus, for a short time. This piece of the virus cannot hurt you, but it is enough for your immune system to learn how to recognize and be ready to fight off the virus. More information on mRNA vaccines can be found on [Public Health Ontario's \(PHO\) COVID-19 Vaccines](#) webpage. In large studies where people were given 2 doses of either vaccine, the vaccine was shown to work very well at preventing people from becoming sick with COVID-19. The immunized group of people were about 95% less likely to become sick with COVID-19 compared to the group that did not receive the vaccine. **You cannot get COVID-19 from the vaccine.**

## Who can receive this vaccine and who cannot?

A complete vaccine series should be offered to individuals without contraindications to the vaccine.

- The Pfizer-BioNTech vaccine: 2 doses given 21 days apart to individuals who are 16 years of age and older.
- The Moderna vaccine: 2 doses given 28 days apart to individuals who are 18 years of age and older.

If you have any [symptoms that could be due to COVID-19](#), you should not receive the vaccine at this time. You should also wait 14 days after receiving any other vaccine before receiving the COVID-19 vaccine.

Talk with your healthcare provider or where available, call Telehealth Ontario (1-866-797-0000) about your symptoms and getting a COVID-19 test. Your healthcare provider will advise you when you are able to receive the vaccine.

See below for more details regarding who should not get this vaccine.

## Who should not receive the vaccine?

The Pfizer-BioNTech and Moderna COVID-19 vaccines are contraindicated in:

- Individuals who have ever had a severe allergic reaction (i.e. anaphylaxis) to a previous dose of an mRNA vaccine or to any of its components (including polyethylene glycol (PEG) and/or polysorbate, see below) or its container, should not get either mRNA COVID-19 vaccine. Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19. To minimize the risk of COVID-19 transmission, symptomatic individuals who arrive at an immunization clinic/venue, should be instructed to follow current local public health measures, and be encouraged to get tested.
- Individuals who have received another vaccine (not a COVID-19 vaccine) in the past 14 days.
- Vaccine should not be offered to individuals who are not in the authorized age group.

## Considerations for other patient groups:

- Guidance for special populations, including for example breastfeeding or pregnant individuals, individuals with allergies, individuals with autoimmune conditions, or individuals who are immunocompromised due to disease or treatment, is available in the [Vaccination Recommendations for Special Populations](#) guidance document

## Precautions during vaccination should be taken with:

- Patients who have a bleeding problem, bruise easily or use a blood-thinning medicine should receive the vaccine. Individuals receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized through the intramuscular route as recommended, without discontinuation of their anticoagulation therapy.
  - There is some evidence to suggest that intramuscular administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes
- Individuals with a history of severe allergic reactions (i.e. anaphylaxis) not related to vaccines or injectable medications—such as allergies to food, pet, venom, environmental, or latex, etc. should be offered the COVID-19 vaccines.
  - An extended period of observation post-vaccination of 30 minutes is recommended for these groups
  - For more detailed recommendations on people with allergies, please consult the [Vaccination Recommendations for Special Populations](#) guidance document

## What are the non-medicinal ingredients in the vaccine?

Non-medical ingredients in the Pfizer-BioNTech COVID-19 vaccine include:

- ALC-0315 = (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- dibasic sodium phosphate dihydrate
- monobasic potassium phosphate
- potassium chloride
- sodium chloride

- sucrose
- water for injection

Non-medical ingredients in the Moderna COVID-19 vaccine include:

- 1, 2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- Acetic acid
- Cholesterol
- Lipid SM-102
- PEG2000 DMG 1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol
- Sodium acetate
- Sucrose
- Tromethamine
- tromethamine hydrochloride
- water for injection

It is important to review this list carefully as some people may be allergic to these ingredients, including **polyethylene glycol**. Polyethylene glycol can rarely cause allergic reactions and is found in some products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, 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 foods or drinks. Due to potential cross-reactive hypersensitivity with the vaccine ingredient polyethylene glycol, those with a suspected hypersensitivity or who have had an immediate allergic reaction to **polysorbate** should speak to their health care provider before vaccination.

### **How is the vaccine administered?**

The vaccine is given as a needle in the upper arm (into the deltoid muscle) and will require two doses of the same vaccine product given:

- 21 days apart for the Pfizer-BioNTech vaccine
- 28 days apart for the Moderna vaccine

## What are the side effects of the vaccine?

Ongoing studies on the Pfizer-BioNTech and Moderna vaccine indicate **no serious side effects found to-date**. People who have received the vaccine in these studies continue to be monitored for any longer-term side effects.

As with other vaccines, **some people can develop mild side effects in the days following immunization that are generally not serious** and go away on their own. In the study, side effects included one or more of the following symptoms: pain where the needle was given, redness and swelling, tiredness, headache, muscle pain, joint pain, chills, mild fever, and/or swollen glands (less frequently). These types of side effects are expected and simply indicate the vaccine is working to produce protection. These side effects are more likely to occur after your second dose.

As with any medicines and vaccines, allergic reactions are rare but 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. Clinic staff are prepared to manage an allergic reaction should it occur. If you are concerned about any reactions you experience after receiving the vaccine, contact your healthcare provider. You can also contact your [local public health unit](#) to ask questions or to report an adverse reaction.

## Can you get COVID-19 from the vaccine?

You cannot get COVID-19 infection from the vaccine. The vaccines are not live vaccines and do not cause the disease they are designed to prevent.

## What measures have been put in place to safely provide immunizations during COVID-19?

Healthcare 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 or receive the vaccine.
- 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

- 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 before coming to the clinic?**

- Wear a short-sleeve shirt or shirt with sleeves that are easy to roll up.
- Have something to eat before coming to the clinic to prevent feeling faint while being vaccinated.
- Wear your mask.
- Bring any identification required by the clinic, such as your health card.
- Bring your immunization record with you to record this vaccine with other vaccines that you have received.

### **Before receiving the vaccine, tell the healthcare provider if:**

- You are currently feeling unwell or have signs and symptoms of COVID-19
- You are currently breastfeeding.
- You are or could be pregnant.
- You have fainted after receiving past vaccines or medical procedures. Your healthcare provider may recommend 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.
- You have had a previous allergic reaction to any vaccine or any non-medical ingredients of the COVID-19 vaccine.
- You have experienced an immediate or serious allergic reaction, including anaphylaxis, to another vaccine or injectable therapy. You should talk to your healthcare provider before you receive the vaccine.
- You have experienced a serious allergic reaction, including anaphylaxis, to food, pet, venom, environmental, or latex
- You are immunosuppressed due to disease or treatment or have been diagnosed with an autoimmune disorder.
- When receiving your second dose of COVID-19 vaccine, tell the healthcare provider if you had any side effects after the first dose.



- You have received any other vaccine (not a COVID-19 vaccine) in the past 14 days. You will be asked to wait 14 days from the time you received the other vaccine.

### **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. You may be asked by the healthcare 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 minutes after receiving your vaccine.

### **When should I seek medical attention?**

Serious side effects after receiving the vaccine are rare. However, should you develop any of the following adverse reactions within three days of receiving the vaccine, seek medical attention right away or call 911 if you are severely unwell:

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

### **Do I need to continue to follow public health measures now that I have received the vaccine?**

Continue to follow the advice of public health officials to prevent COVID-19, such as wearing a mask, and maintaining a physical distance of 2 metres from people outside of your household.

### **When can I receive other vaccines?**

- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines.

- Do not receive any other vaccines until at least 28 days after you receive the second dose of the COVID-19 vaccine, unless required for post-exposure prophylaxis.
- You should wait 14 days after receiving another vaccine before receiving the COVID-19 vaccine.

### **When should I return for my second dose?**

If this is your first dose of the COVID-19 vaccine, be sure to return for your second dose. If you are receiving the Pfizer-BioNTech COVID-19 Vaccine, you should return for your second dose in 21 days. If you are receiving the Moderna COVID-19 Vaccine, you should return for your second dose in 28 days.

**You should book an appointment to receive the next dose right away.** It is important that you receive 2 doses of the vaccine. Protection against COVID-19 is not complete 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 mild side effects the first time.**

### **Who should I contact with any questions?**

If you have any questions, please speak with the person providing the vaccine or a designated contact.

**Ministry for Seniors  
and Accessibility**

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January 7, 2021

**MEMORANDUM TO:** Retirement Homes in Toronto Public Health Unit, Peel Public Health Unit, Region of York Public Health Services and Windsor-Essex County Health Unit

**FROM:** Denise Allyson Cole  
Deputy Minister  
Ministry for Seniors and Accessibility

**SUBJECT:** **Moderna COVID-19 Vaccine Administration in Retirement Homes**

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Representing another turning point in our fight against COVID-19, the Moderna COVID-19 Vaccine will soon be available to residents, staff and essential caregivers in retirement homes in the above-noted regions. Regions continue to prioritize homes for immunization based on risk. As such, you may be invited by your local Public Health Unit or regional representatives to have all residents and remaining staff vaccinated over the next month.

The Moderna COVID-19 vaccination program will target residents, staff, essential caregivers and support workers who have regular interaction with residents and will be administered on-site in the homes. While staff and essential caregivers will be offered the Moderna vaccine as part of in-home clinics, you are encouraged to continue registering staff for hospital clinics to maximize all available vaccines' speed and impact.

Successful implementation of the vaccination program will be dependent on the readiness of homes. Your local Public Health Unit will contact you to partner and with specific details to support effective execution. For further support, the Ministry for Seniors and Accessibility, the Ministry of Health and the Ministry of Long-Term Care have developed an assessment checklist (Attachment 1) to provide guidance and help you plan and prepare.

As a part of that planning, the following steps should also be taken:

- **Consent Forms:** A critical component of the vaccination program is obtaining consent from residents or, if applicable, their Substitute Decision Makers. Consent

must be secured for vaccinations to be given. As such, it is essential that retirement home operators start as soon as possible in securing completed consent forms from those wishing to be vaccinated. It is also important to record who declined vaccination. For your use, I have attached the COVID-19 Vaccine Screening and Consent Form (Attachment 2).

- **IT Readiness:** In partnership with your local Public Health Unit, ensure there are IT protocols in place that define and confirm staff roles and responsibilities in data collection and reporting. As well, ensure staff are appropriately trained in their assigned roles within the on-site vaccination clinics. If staff are identified for IT responsibility by your local Public Health Unit, complete the COVax Users Template for Retirement Homes (Attachment 3).
- **Identification of Participants for Vaccination:** Work with staff, essential caregivers, residents, their substitute decision makers and family members to identify participants for immunization and complete the Vaccine Participants Template for Retirement Homes (Attachment 4) for all participants. This template will be required for upload into the IT system to track vaccinations during on-site clinics.
- **Communications Protocol:** To prioritize residents' safety and health, media events on-site at retirement homes should not be planned. Establish communication plans for media protocols and escalation protocols, as well as other contingency planning, as needed, with your local Public Health Unit.

I want to thank you for your continued commitment and partnership in keeping our most vulnerable Ontarians safe during the COVID-19 pandemic.

Sincerely,

***Original signed by***

Denise Allyson Cole

c: Jacqueline Cureton, Assistant Deputy Minister, Ministry for Seniors and Accessibility  
Dr. David Williams, Chief Medical Officer of Health  
Dr. Barbara Yaffe, Associate Chief Medical Officer of Health  
Dr. Eileen deVilla, Medical Officer of Health, City of Toronto  
Dr. Wajid Ahmed, Medical Officer of Health, Windsor-Essex County Health Unit  
Dr. Lawrence Loh, Medical Officer of Health, Region of Peel  
Dr. Karim Kurji, Medical Officer of Health, York Region  
Jay O'Neill, Chief Executive Officer and Registrar, Retirement Homes Regulatory Authority  
Cathy Hecimovich, Chief Executive Officer, Ontario Retirement Communities Association  
Lisa Levin, Chief Executive Officer, AdvantAge Ontario

Attachment 1: Initial COVID-19 Immunization Readiness Checklist to Support Preparations for Moderna Pilots in Long-Term Care and Retirement Homes

Attachment 2: COVID-19 Vaccine Screening and Consent Form

Attachment 3: COVax Users Template for Retirement Homes

Attachment 4: Vaccine Participants Template for Retirement Homes