

COVID-19 VACCINE

Questions & answers for health-care practitioners

What vaccines are available and how do they work?

The first COVID-19 vaccines available in Alberta are the Pfizer and Moderna vaccines. Both are mRNA vaccines.

An mRNA vaccine is a new type of vaccine that prepares the body to defend and protect itself against infectious diseases – in this case, COVID-19. The mRNA vaccine teaches your body's cells to make a viral protein that triggers the immune response. When a person is given the vaccine, their body's cells will read the instructions from the mRNA and produce the harmless "spike protein" which is the same protein that is normally found on the surface of the COVID-19 virus, but not found in our bodies. The person's immune system will then treat this spike protein as foreign and produce defenses to fight against it. These defenses are then ready to protect the person against the real COVID-19 virus.

Can this vaccine affect my DNA?

The vaccine does not affect, interact with or alter your DNA in any way. The mRNA in the vaccine is broken down quickly by normal cellular processes after the harmless genetic instructions have been used to make the spike protein. In a cell, DNA is in the nucleolus, and the mRNA works outside of the nucleolus in the cytoplasm. It is not possible for the mRNA to enter the nucleolus, as this process would require many enzymes that the cell or vaccine does not have.

Can I get COVID-19 from the vaccine?

The mRNA vaccine does not contain any virus in it. It has only genetic instructions on how the cell can make one single coronavirus protein (the spike protein). It takes several different coronavirus proteins and other genetic materials to make a coronavirus. Therefore, this vaccine cannot make the virus and then lead to disease. The mRNA does not become a permanent part of your body, as it is naturally broken down after use.

How effective is the vaccine?

The initial vaccines Pfizer and Moderna COVID-19 vaccines available for use in Canada have been demonstrated to be over 90% effective in preventing COVID-19 disease in clinical trials.

'Vaccine efficacy' is the term used to describe the percentage reduction of disease in a vaccinated group of people compared to an unvaccinated group in clinical trials where the study conditions are controlled. It does not describe whether an immunized person can still transmit the virus.

'Vaccine effectiveness' is the term used to describe how the vaccine works in the real world where conditions cannot be controlled, such as previous exposure to the virus, the immune status of the individual, and if people receive both doses that are required. Vaccine effectiveness will continue to be evaluated as the COVID-19 immunization program is rolled out.

Will the vaccine still work if the virus mutates?

Mutations in the COVID-19 virus over time are expected. At this time, the virus has mutated a bit, but so far, analysis of these small changes does not affect how well the vaccine works. However, we are watching this closely.

How do we know the vaccine is safe when it was developed so quickly?

The production and approval of COVID-19 vaccines was not rushed. Instead, it was prioritized. Around the world, financial supports, open and transparent sharing of information amongst researchers, and adjustments in regulatory processes led to the relatively fast development of successful COVID-19 vaccines.

Usually Health Canada reviews vaccine submissions after all study results are available; this can take up to a year. An interim order approved by the federal Minister of Health provided the flexibility to expedite the review and authorization of vaccines. This allowed manufacturers to submit study data to Health Canada as it became available, shortening the time needed for the review process.

Review of the data from the clinical trials and of the manufacturing processes allows Health Canada to confirm that there are no significant safety concerns and that the vaccine will protect against disease. The review also assesses whether the benefits of the vaccine outweigh the risks, and whether the vaccine is manufactured to high quality standards. In order to support the independent review process for COVID-19 vaccines, Health Canada, dedicated more resources to the review process than usual and global partnerships have expedited the process.

What are the expected side effects from the vaccine?

Common short-term side effects of the COVID-19 vaccine include:

- Pain at the injection site lasting one to two days
- Fatigue, headache, muscle pain, chills, fever, and joint pain lasting approximately one day

These short-term mild or moderate side effects are very common to many vaccines and may affect more than 10 per cent of people. Some side effects, including fever, are more frequent after the second dose.

It is important to note that the common short-term side effects are not necessarily bad. Your immune system is functioning and building the necessary protections for you against this virus.

Over-the-counter pain or fever medication may be considered for the management of short-term side effects if they occur after immunization.

No serious safety concerns have been identified in clinical trials.

What do I do if I experience the expected reactions that are similar to the symptoms of COVID-19 that require isolation?

Individuals who receive the COVID-19 vaccine may experience some side effects. These reactions are most often mild, develop within 24 hours, and could last 24 to 48 hours. Many of the reactions that occur are similar to the symptoms of COVID-19 infection such as:

- fever and/or chills,
- feeling tired,
- headache or body aches,
- nausea

Individuals should monitor themselves for these symptoms. Individuals who develop the above symptoms should stay home. If the symptoms develop within 24 hours of receiving the COVID-19 vaccine and resolve within 48 hours after starting, the individual can return to normal activities, unless they have been instructed to quarantine or isolate for other reasons by Alberta Health Services.

If symptoms persist longer than 48 hours and are not related to a pre-existing illness or health

condition, individuals must continue to stay home and contact Health Link at 811 or complete the online COVID-19 online self-assessment tool for testing.

If testing is not done, adults with fever, cough, runny nose, sore throat or shortness of breath are to remain in isolation at home and stay away from others for 10 days, or until symptoms improve and they have been without a fever for at least 24 hours without the use of fever-reducing medications, whichever is longer. Individuals with any other symptoms on the COVID-19 symptom list should remain home until symptoms resolve.

Will I have to follow public health measures if I get immunized? Will I have to quarantine if I received the vaccine and then am a close contact of someone who was positive for COVID-19?

Yes, continue to follow all public health measures, including quarantining if you are informed that you are a close contact of a COVID-19 case.

Based on recommendations from the National Advisory Committee on Immunization (NACI), Alberta Health advises that all individuals should continue to follow public health measures for prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine at this time. This includes masking when in public, maintaining physical distancing, practicing diligent hand hygiene and staying home when sick, following quarantine requirements if exposed to a case of COVID-19.

The Pfizer BioNTech and Moderna COVID-19 vaccines require two doses, three to six weeks apart. It takes time for your body to build up an immune response after receiving the vaccine.

Currently, there is little evidence on how:

- Effective these vaccines are in everyday life;
- Long these vaccines will offer protection from the virus; or

- Effective the COVID-19 vaccines are in preventing asymptomatic infections and reducing transmission to others.

Health Canada and Alberta Health continue to monitor the emerging evidence on vaccine effectiveness and will provide updates when possible.

Is it recommended to receive the vaccine while pregnant?

The safety and efficacy of Pfizer BioNTech and the Moderna COVID-19 vaccines in pregnant women has not yet been established. Pregnant individuals were not included in large enough numbers in the initial trials of the COVID-19 vaccines to provide solid information.

COVID-19 vaccines may be offered to individuals in the eligible group who are pregnant if a risk assessment with their doctors determines that the benefits outweigh the potential risks for the woman and fetus.

The individual may also be immunized without consulting their doctors following their acknowledgment of the absence of evidence on the use of COVID-19 vaccine in this population.

Is it recommended to receive the vaccine while breastfeeding?

It is unknown whether Pfizer BioNTech and the Moderna COVID-19 vaccines can be present in human milk. A risk to the newborns/infants cannot be determined because there is an absence of evidence on the use of COVID-19 vaccines in breastfeeding individuals. These groups were not included in large enough numbers in the initial trials to provide solid information.

COVID-19 vaccines may be offered to individuals in the eligible group who are breastfeeding if a risk assessment with their doctors determines that the benefits outweigh the potential risks for the mother and infant.

The individual may also be immunized without consulting their doctors following their

acknowledgment of the absence of evidence on the use of COVID-19 vaccine in this population.

Is it recommended to receive the vaccine if I am immunocompromised or have an autoimmune disorder?

At this time, there is an absence of evidence on the use of COVID-19 vaccine in immunocompromised individuals and those with auto-immune disorders. These groups were not included in large enough numbers in the initial trials to provide solid information.

COVID-19 vaccines may be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder if a risk assessment with their doctors determines that the benefits outweigh the potential risks.

Risks include:

- Immunocompromised persons may have a diminished immune response to the vaccine
- There is a theoretical concern that mRNA vaccine may elicit an inflammatory response and possibly exacerbate existing autoimmune diseases. However, current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk.²

However, with the exception of SOT and HSCT clients, the individual may also be immunized without consulting their doctors following their acknowledgment of the risks mentioned above and the absence of evidence on the use of COVID-19 vaccine in these populations.

Additional resources:

- [COVID-19 Scientific Advisory Group Rapid Evidence Report](#).
- [Advisory Committee on Immunization Practices \(ACIP\) interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines](#).

I have recovered from COVID-19, should I still be immunized?

Yes, the COVID-19 vaccine is recommended for those that have had and recovered from COVID-19 infection because it is unknown how long immunity may last after recovering from COVID-19.

What ingredients are in the vaccine?

The two vaccines available for use contain ingredients that help the vaccine work in the body and protect the vaccine while frozen. The vaccines do not contain antibiotics or preservatives.

One non-medicinal ingredient in both the Moderna and Pfizer BioNTech vaccines may cause a hypersensitivity reaction. This ingredient is polyethylene glycol (PEG). This ingredient is also found in cosmetics, cough syrup, skin products and some food and drinks. When you are being immunized or offering immunization, potential allergic reactions will be discussed.

Additional ingredient information:

Pfizer BioNTech	
Lipid nanoparticles (these help the mRNA enter the cell)	<ul style="list-style-type: none">○ ALC-0315 = (4-hydroxybutyl) azanediy]bis(hexane-6,1-diyl)bis(2-hexyldecanoate)○ ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
Other Lipids: (provide structural integrity of the nanoparticles)	<ul style="list-style-type: none">○ 1,2-distearoyl-sn-glycero-3-phosphocholine○ cholesterol
Salts: (these help maintain the PH of the vaccine)	<ul style="list-style-type: none">○ bibasic sodium phosphate dihydrate○ monobasic potassium phosphate○ potassium chloride○ sodium chloride
Other:	<ul style="list-style-type: none">○ sucrose (this protects the nanoparticles when frozen)○ water for injection

Moderna	
Lipid nanoparticles (these help the mRNA enter the cell):	<ul style="list-style-type: none"> ○ PEG2000-DMG LSM-102, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethyleneglycol ○ 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) ○ Cholesterol ○ Lipid SM-102
pH stabilizers (help maintain the PH of the vaccine)	<ul style="list-style-type: none"> ○ acetic acid ○ sodium acetate ○ tromethamine ○ tromethamine hydrochloride
Other:	<ul style="list-style-type: none"> ○ sucrose (protects the nanoparticles when frozen)

Why does the vaccine need to be frozen?

The mRNA vaccine is stored in a frozen or ultra frozen temperatures because mRNA breaks down quickly, even at refrigerator temperatures. To ensure the vaccine will work the best when it is administered, the vaccine is stored frozen for as long as possible. The manufacturers continue to study the stability of the vaccine in various storage conditions and the temperature guidelines for storage may change in the future.

Will there be priority groups that receive the vaccine first?

Alberta Health is expecting a very limited amount of vaccine from the middle of December 2020 to the end of March. As the vaccine is in limited supply and has unique transportation and distribution requirements, Alberta Health is taking a phased approach, targeting key populations in each phase. The precise timeframe for each of Alberta's phases are unknown and immunization activities may need to start and stop based on available supply.

Information about all phases can be found on our website at www.alberta.ca/covid19-vaccine.aspx.

Are international students eligible to receive the vaccine?

Students are not likely to be eligible until Phase 3, when immunizations are rolled out to the general Alberta population. Subject to vaccine availability, it is anticipated that Phase 3 will begin in the fall of 2021. Once a universal COVID-19 immunization program is in place, individuals who are living, working, or going to school in Alberta will be eligible for the COVID-19 vaccine free of charge.

Can my employer require me to be immunized?

Yes, private employers can require employees to be immunized as part of their company policy or as a required precondition of employment.

Some employers have occupational health and safety policies that require some immunizations as a condition of employment to protect themselves and others around them. Employers may ask that employees present their immunization records, to have them on file to determine who is at risk of infection in the event of an outbreak or if an individual is exposed to someone with a communicable disease. It is recommended that employees speak with their employer about their specific occupational health and safety immunization policy.

Will healthcare workers who are not immunized be excluded from work if they do not get immunized or if there is a COVID-19 Outbreak in the workplace?

Immunization is voluntary for all Albertans. There are many reasons a person may not be immunized for COVID-19. For example, individuals may be waiting for their scheduled appointment time to receive the vaccine, may have declined the vaccine, or the vaccine may be contraindicated or there are precautions to consider (e.g., pregnancy, allergy to components of the vaccine).

Although current outbreak management guidelines from Alberta Health Services indicate that health care workers who are not immunized against influenza need to either take influenza antivirals or be excluded from work when there is an outbreak in the facility. Currently, there are no antivirals recommended for COVID-19.

At this time, exclusion of workers who are not immunized against COVID-19 is not required due to the measures already in place to prevent transmission. These measures include active and passive health assessment screening, staying home when sick, continuous masking, hand hygiene, contact and droplet precautions with appropriate Personal Protective Equipment. These measures must be maintained as there is currently limited evidence on the duration of protection of COVID-19 vaccines and the effectiveness of these vaccines in preventing asymptomatic infection and reducing transmission of other strains of the virus.

When can my child receive the vaccine?

The safety and efficacy of the COVID-19 vaccine in children under 16 years of age has not yet been established. Manufacturers will be conducting clinical trials in children, which will help inform recommendations about use in children once more data become available.

Currently, the Pfizer vaccine is licensed for individuals 16 years and older and the Moderna vaccine is licensed for individuals 18 years of age and older. It is too soon to know what ages future vaccine will be licensed for.

When vaccine supply is sufficient, NACI recommends that the Pfizer vaccine may be considered for youth 12 to 15 years of age who are at very high risk of severe outcomes of COVID-19 and are at increased risk of exposure.

The immunization provider must seek informed consent with the individual and the parent or guardian, including information about the lack of evidence on the use of COVID-19 vaccines for children.

How will I know when I am eligible for vaccine and where to access it?

As more vaccine becomes available, the eligibility criteria will be expanded. Information, when available, will be shared here:

<https://www.alberta.ca/covid19-vaccine.aspx>

What will clinics do to protect clients and healthcare workers from COVID-19 during immunization?

All healthcare providers follow [guidelines](#) to protect you and themselves from COVID-19. This includes:

- Screening clients and staff for illness and exposure to COVID-19;
- Setting up the clinic and using an appointment-based system to make sure that everyone can keep physical distance;
- Enhanced environmental cleaning;
- Using personal protective equipment (PPE) such as masks; and
- Requiring hand washing or the use of hand sanitizer when clients arrive.

Is anyone ineligible for COVID-19 immunization? Who should not get the COVID-19 vaccine?

The Pfizer vaccine is licensed for anyone 16 years of age and older and Moderna vaccine is licensed for anyone 18 years of age and older. It will be offered to anyone in these age groups.

Anybody with a current infection of COVID-19 should wait to be immunized until the isolating period is over, meaning 10 days from the start of symptoms or until symptoms have resolved and they have been non-feverish for at least 24 hours without the use of fever-reducing medications, whichever is longer.

Canadians who receive any other vaccine, including their flu shot, should wait at least 14 days before getting immunized against COVID-19.

The following groups should not receive the COVID-19 vaccine:

- people who have had an allergic reaction (anaphylaxis) to a previous dose of the vaccine.
- people who have severe hypersensitivity to any component of the vaccine.

This vaccine should not be offered to the following groups until further evidence is available, unless a consultation with an individual's physician indicates the benefits outweigh the potential risks and the individual is aware of the lack of evidence and has provided informed consent.

- Immunocompromised people (due to disease or treatment) or those with an auto-immune disorder
- Pregnant or breastfeeding women

In these situations, immunization providers are responsible for offering information on the absence of evidence, and seeking informed consent.

NACI recommends additional research and surveillance of COVID-19 immunization, particularly for populations not currently included in clinical trials (e.g., people who are pregnant, breastfeeding, or immunocompromised, and seniors living in congregate care settings).

Will the vaccine prevent getting COVID-19? Will the vaccine just prevent severe illness? Will the vaccine prevent transmission?

Vaccines that have been licensed in Canada are demonstrating a high efficacy in preventing COVID-19 disease. For example, the Pfizer and Moderna vaccines have been demonstrated to be over 90% effective.

The vaccine is used both for preventing the occurrence of COVID-19 disease and diminishing the severity of the disease.

At this time, based on the evidence submitted to Health Canada, it remains unknown how long the protection will last. International jurisdictions, Health Canada and Alberta Health will evaluate the data and promptly update the product information about how long the protection lasts and whether there may be a need for additional doses of the vaccine.

There is currently no evidence (Pfizer vaccine) or insufficient evidence (Moderna vaccine) on the effectiveness of COVID-19 vaccines in preventing asymptomatic infection and reducing transmission.

Everyone must continue following public health measures to prevent the spread of COVID-19, regardless of immunization with COVID-19 vaccines.

How long after getting a vaccine until I am protected against COVID-19? How long does the protection last?

The first two vaccines available show protection starting 12-14 days after the first dose. High efficacy against symptomatic COVID-19 disease is achieved 1-2 weeks after the second dose. At this time, based on the evidence submitted to Health Canada, it remains unknown how long the protection will last. Health Canada and Alberta Health will evaluate the data and promptly update the product information about how long the protection lasts and whether there may be a need for additional doses of the vaccine.

Will I have to pay for the vaccine? If I don't want to wait to be included in the populations being offered the vaccine, can I buy the vaccine privately?

The vaccine will be available to eligible Albertans free of charge. No vaccine is available for purchase at this time.