

Vaccines Approved in Canada

Two vaccines for COVID-19 have been approved by Health Canada: the Pfizer-BioNTech vaccine and the Moderna vaccine.

- Both are classified as mRNA vaccines.
- Health Canada approved these vaccines as safe, effective and reliable.



Why should people choose to get the vaccine?

- Safe and reliable vaccines can help protect you and your family from COVID-19. They are an important tool to help stop the spread of the virus and allow individuals, families and workers to safely resume normal life.
- When a large percentage of the population becomes immune to COVID-19, the spread of the virus will slow down or stop. This is known as herd immunity.
- Vaccinated individuals can still be infected, but the vaccine greatly reduces the risk of infection and of the infection progressing to a more severe form of disease

Who can get the vaccine?

People who have no contraindications to the vaccine and are:

- Pfizer-BioNTech: age 16 or older
- Moderna: age 18 or older



Who is not recommended to receive the vaccine?

- Currently feeling unwell or have signs and symptoms of COVID-19
 - Anyone who has symptoms should be tested for COVID-19. Once well, then can be vaccinated.
- Children not in the authorized age group*

*Children will be included in future clinical trials and may become eligible for the vaccine once concluded

What considerations are there for special populations to receive the vaccine?

Some groups of people are considered 'special populations' when it comes to COVID-19 vaccination. These populations were not included in Phase 3 clinical trials for current COVID-19 vaccines, or require special consideration. These groups are:

- Breastfeeding women
- Women who are or could be pregnant
- Allergies to the vaccine or its components
- Other serious or anaphylactic allergies
- Autoimmune conditions and Immunocompromised persons

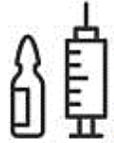
People who are part of a special population are advised to speak with their primary health care provider and discuss the risks vs the benefits of vaccination. The Ministry of Health provided guidance this week that special populations can still be vaccinated if they provide written documentation from their health care provider.

Can I receive the vaccine if I previously tested positive for COVID-19?

Yes. Only those with active illness are excluded from vaccination until they are well and have completed their isolation period.

How is the vaccine administered?

The vaccine is injected into the deltoid muscle (upper shoulder). Two doses are required, spaced 21-28 days (Pfizer-BioNTech) or 28 days (Moderna) apart.



What happens after receiving the vaccine?

Everyone – vaccinated or not – must continue to follow all public health guidance (ie. hand hygiene, masking, physical distancing). Clinical trials have not yet shown that the vaccine reduces transmission from an asymptomatic carrier of COVID-19 to a non-immunized person.

If I have mild side effects from the first dose, should I get the second dose?

Yes. Mild side effects are common for all vaccines and typically resolve in a few days. It is important to receive both doses. Protection offered by the first dose is lower than the protection achieved after the second dose.

How long does it take until the vaccine is effective?

- Pfizer-BioNTech vaccine: maximum protection is achieved 7 days after the second dose.
- Moderna vaccine: maximum protection is achieved 14 days after the second dose.



Are the vaccines safe?

- Ontarians can be confident. Standards of safety, efficacy and quality have not been compromised to expedite the approval of COVID-19 vaccines.
- Health Canada oversight of COVID-19 vaccines continues beyond when vaccines are approved. Monitoring of vaccine safety and effectiveness will continue now and into the future.

How were COVID-19 vaccines developed so quickly, when it usually takes years?

The development of COVID-19 vaccines has progressed quickly for many reasons, including:

- Reduced time delays in the vaccine approval process
 - Health Canada uses a “rolling review” to receive and collect clinical trial and safety data instead of only receiving the information all at once at completion of the clinical trials
 - This “rolling review” allows for scientists and independent reviewers to analyze the data as soon as it is produced creating a faster process
 - Final approval of vaccines only occurs once all data is received
- International collaboration among scientists
- Increased dedicated funding to vaccine researchers and manufacturers
- Quick recruitment of participants for clinical trials
- Rapid set-up of clinical trials to demonstrate effectiveness of the vaccine



How is vaccine safety monitored?

Local, provincial and federal authorities as well as vaccine manufacturers and health care providers all share responsibility and work together to monitor vaccine safety.



- Health care providers report side effects from vaccines to their local public health unit
- Public Health Ontario leads surveillance of adverse events following immunization (AEFI)
- Health Canada monitors safety and effectiveness of vaccines and can require further safety measures and information from the vaccine manufacturer
- Public Health Agency of Canada manages the Canadian AEFI System which monitors post-market vaccine safety
- Manufacturers monitor the safety of their products by continuing clinical trials and continuing follow-up with trial participants. Should concerns arise, they are legally obligated to report this information to Health Canada
 - For example, Pfizer-BioNTech are following participants for at least 2 years following the second vaccine dose

What is an Adverse Event Following Immunization (AEFI)?

An AEFI is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the use of a vaccine.

- The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.
- An event is considered serious if it: results in death, is life-threatening, requires hospitalization, results in persistent or significant disability/incapacity, or results in a congenital anomaly/birth defect.

What AEFIs have occurred with the COVID-19 vaccine in Ontario?

Public Health Ontario publishes regular reports on AEFIs for COVID-19 vaccines:

<https://www.publichealthontario.ca/en/diseases-and-conditions/infectious-diseases/respiratory-diseases/novel-coronavirus/vaccines>

From Dec 13, 2020 to January 9, 2021

- Out of 113, 246 doses of COVID-19 vaccine, there were only 21 AEFI reports in Ontario (0.02% or 18.5 per 100,000 doses administered)
 - 21 AEFI reports were non-serious (100% of total reports)
 - Most commonly reported adverse event was allergic skin reaction (9 reports)

Will the vaccine alter my DNA?

No. The vaccine does not affect, interact or alter DNA in any way. Our DNA resides in the nucleus of our cells and the mRNA does not travel into the nucleus. Therefore, there is no risk of altering DNA. It uses the body's natural defense response which breaks down and gets rid of the mRNA after it is finished using it.



Information Sheet COVID-19 Vaccine FAQs

Want detailed vaccine product information?

Pfizer-BioNTech COVID-19 Vaccine Product Monograph

<https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>

Moderna COVID-19 Vaccine Product Monograph

<https://covid-vaccine.canada.ca/info/pdf/moderna-covid-19-vaccine-pm1.pdf>

More questions about vaccines?

Public Health Agency of Canada: *Moderna COVID-19 Vaccine: What you should know*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html>

Public Health Agency of Canada: *Pfizer-BioNTech COVID-19 Vaccine: What you should know*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html>