Ministry of Health

COVID-19 About Vaccines

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This guidance provides basic information only. It is not intended to take the place of medical advice, diagnosis or treatment, legal advice or legal requirements.

- 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.

COVID-19 Vaccines: Overview

Representing a turning point in our fight against COVID-19, Health Canada has authorized the Pfizer-BioNTech mRNA vaccine. More vaccines will likely be authorized in the near future.

What you should know:

- Health Canada only approves a vaccine if it is supported by very robust scientific data and evidence.
- After approval, Health Canada and the Public Health Agency of Canada continue to monitor the ongoing safety and effectiveness of all approved vaccines.
- Canadians will have easy access to detailed information on the vaccine and the evidence behind the vaccine approval process through the Government of Canada's website.
- The benefits of vaccination greatly outweigh the risks, and many more illnesses and deaths would occur without vaccines. Vaccines prevent illness and disease and save lives and livelihoods. Mass vaccination will protect people's lives and help Canada recover from the COVID-19 pandemic.

After more than a decade of research and development on mRNA vaccines, this vaccine is the first mRNA vaccine approved for use in humans. To date, mRNA has been successfully used in cancer treatments, and research into its value for vaccinations has been ongoing for over ten years.

How does vaccination work?

mRNA vaccines	Use genetic instructions in molecules called mRNA to generate a coronavirus protein that initiates the body's natural production of antibodies and cellular immune response. mRNA vaccines are not live vaccines and cannot cause infection in the host. mRNA vaccines also cannot alter a person's DNA.
Viral vector vaccines	Use a genetically engineered virus that cannot cause disease but can produce coronavirus proteins to generate an immune response in the body.
Protein-based vaccines	Use harmless fragments of proteins or protein shells that mimic a coronavirus to generate an immune response in the body.
Inactivated or weakened virus vaccines	Use an inactivated or weakened form of the virus so it does not cause disease but does still generates an immune response in the body.

The Pfizer-BioNTech mRNA vaccine

The Pfizer-BioNTech mRNA vaccine is highly efficacious in the short-term against laboratory-confirmed symptomatic COVID-19 disease; trials are ongoing. The Pfizer-BioNTech mRNA vaccine is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2.

Clinical trial details

Participants	Of the clinical trial participants: ● Over 40,000 doses were administered. ● 42.3% of participants were aged 55 and older. ● 17% of participants were of diverse racial and ethnic backgrounds. ● 46.2 % of participants had pre-existing stable medical conditions (disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrolment) such as asthma, obesity, chronic lung disease, diabetes and high blood pressure. ● Participants with known stable infection were included, including those with HIV, hepatitis B, and hepatitis C virus.
Time followed	● At the time of the final primary efficacy analysis, participants had been followed for symptomatic COVID-19 disease for a median of 2 months, corresponding to 2,214 person-years for the Pfizer-BioNTech COVID-19 vaccine and 2,222 person-years in the placebo group. ● Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19 disease.
Protection	● Based on the results of the clinical trials, the best protection is not achieved until 7 days after the second dose, but it remains unknown how long the protection will last.
Efficacy	● Highest efficacy and immune response were observed after the second dose. ● Limited data on protection provided for only one dose. ● Efficacy was consistent across age groups for two-doses. ● Adverse events were generally milder and occurred less often in those 56 years of age and older. ● No difference in efficacy was observed between men and women or across different age groups, races or ethnicities. However, the size of groups for some comparisons were small.

Side effects

Like all vaccines, Pfizer-BioNTech COVID-19 Vaccine can cause side effects. Those observed during the clinical trials were commonly reported side effects of vaccines and do not pose a health risk.

- The most frequent adverse reactions were mild or moderate and resolved within a few days after vaccination.
- No major safety concerns were reported in the data submitted to Health Canada.

Very common side effects (may affect more than 1 in 10 people)	**Uncommon side effects** (may affect up to 1 in 100 people)
• Pain at injection site (84.1%*) • Fatigue (62.9%*) • Headache (55.1%*) • Muscle pain (38.3%*) • Chills (38.3%*) • Joint pain (38.3%*) • Fever (38.3%*) *subset (n=8183)	• Enlarged lymph nodes (0.008%*) *subset (n=7960)

FAQ's

Can recipients contract the coronavirus from this vaccine?	**No.** This is not a live vaccine and does not contain the virus; therefore, the vaccine cannot give recipients infection or disease (COVID-19).
Will this vaccine alter the recipient's DNA?	**No.** This 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 the harmless genetic instructions.

Do recipients of the vaccine still need to follow public health guidance (masking and distancing) after receiving the vaccine?	**Yes.** There is insufficient evidence at this time on the effectiveness of COVID-19 vaccines in preventing asymptomatic infection and reducing transmission of SARS-CoV-2.
If the patient gets mild side effects, should they receive the second shot?	**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 efficacy achieved after the second dose.