# What you need to know about getting the COVID-19 vaccine



#### What is the COVID-19 vaccine?

- A COVID-19 vaccine can protect you from getting the virus that causes COVID-19.<sup>1</sup> This is critically important because COVID-19 can cause severe sickness or death.<sup>2</sup>
- Health Canada has approved two COVID-19 vaccines for use in Canada, the Pfizer-BioNTech vaccine and the Moderna vaccine.<sup>3,4</sup>





#### How do the vaccines work?



Your body's cells read the mRNA like a recipe and produce a spike protein which mimics the COVID-19 virus. Your immune system recognizes that the protein doesn't belong there and builds T-cells and antibodies, which are designed to fight the real virus.





If your body encounters the COVID-19 virus in the future, your T-cells and antibodies are now prepared to fight off the virus before you can get sick



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#### What are the differences between the two vaccines?

The two vaccines currently available in Canada are similar in many ways. See the table below for a side by side comparison:

Vaccine	Pfizer-BioNTech	Moderna
What type of vaccine is it?	mRNA vaccine	mRNA vaccine
When was it approved?	December 9, 2020	December 23, 2020
How it is given?	Injection into the shoulder muscle	Injection into the shoulder muscle
How much is given?	Two doses of 0.3mL	Two doses of 0.5mL
When is the second dose given?	21 days after first dose (The second dose may be safely delayed up to 42 days after the first dose if necessary) <sup>5</sup>	28 days after first dose (The second dose may be safely delayed up to 42 days after the first dose if necessary) <sup>5</sup>
How long after my vaccine will it take to be protected against COVID-19?	7-days after the second dose	14-days after the second dose
How effective is the vaccine once it is protecting you against COVID-19?	95% effective	94% effective
How is it stored?	In freezers between -60 to -80 degrees Celsius (these temperatures make it hard to transport!)	In freezers of -20 degrees Celsius
Ingredient List *The Pfizer-BioNTech and Moderna vaccines do not contain preservatives, latex or eggs. <sup>6,7</sup>	<ul> <li>mRNA</li> <li>Lipids</li> <li>((4-hydroxybutyl)azanediyl) bis(hexane-6,1-diyl)bis(2- hexyldecanoate)</li> <li>2-[(polyethylene glycol (PEG))- 2000]-N,N-ditetradecylacetamide</li> <li>1,2-distearoyl-sn-glycero-3- phosphocholine (DSPC)</li> <li>Cholesterol</li> <li>Salts:</li> <li>Dibasic sodium phosphate dihydrate</li> <li>Monobasic potassium phosphate</li> <li>Potassium chloride</li> <li>Sodium chloride</li> <li>Sucrose</li> </ul>	<ul> <li>mRNA</li> <li>Lipids</li> <li>1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)</li> <li>SM-102</li> <li>Polyethylene glycol (PEG) 2000 DMG</li> <li>Cholesterol</li> <li>Acids:</li> <li>Acetic acid</li> <li>Acid Stabilizers:</li> <li>Tromethamine</li> <li>Tromethamine hydrochloride</li> <li>Salts:</li> <li>Sodium acetate</li> <li>Sucrose</li> </ul>

Both vaccines are highly effective in protecting against COVID-19

#### Which vaccine will I receive?

 Given that the Moderna vaccine is easier to transport, the vaccine you receive will largely depend on where you live and work.<sup>8</sup>

#### How safe are the vaccines?

 Serious side effects in vaccines are very rare. Health Canada reviewed the data on both the Pfizer-BioNTech and Moderna COVID-19 vaccines and found no major life-threatening safety concerns.<sup>3,4</sup>

#### How were the vaccines studied?

- Both vaccines were studied in large, international clinical trials of 30,000-44,000 adults using randomization.<sup>9,10</sup> Randomization is similar to flipping a coin to see who gets to receive the vaccine or placebo (a placebo does not contain any active ingredients that could affect health).
  - These types of studies are considered the "gold standard" of health research, and produce the highest quality evidence.<sup>11</sup>
- Participants were assigned to receive two doses of either the vaccine or placebo by injection into the shoulder muscle. Participants were monitored to see if they developed symptomatic COVID-19 or side effects.<sup>910</sup>
- The studies found the vaccines to be 94-95% effective after two doses. Protective effects were achieved within 1-2 weeks of receiving the vaccines.<sup>9,10</sup> Our knowledge of COVID-19 vaccine effectiveness is based on people receiving the full two doses of the vaccine. We do not have specific information on how effective only one dose is (estimates of 30-68% for the Pfizer-BioNTech vaccine), but we know that receiving two doses is much more effective to protect you over time.<sup>12,13</sup>



#### What are the normal side effects to expect after receiving the vaccine?

- Side effects can occur with many vaccines including the flu vaccine and others. Common side effects experienced during the clinical trials for both the Pfizer-BioNTech and Moderna vaccines included:
  - Pain, redness, or swelling at the injection site
  - Fever
  - Headache
  - Muscle soreness
- Most of these side effects were mild to moderate and experienced after the second dose of the vaccine, with fewer than 0.1% (1 out of 1000 people) experiencing these side effects to a degree where it affected their ability to do daily activities.<sup>9,10</sup>
- If you are concerned about taking time off to deal with side effects related to the administration of the COVID-19 vaccine, discuss these concerns with your employer.

Side effects within 7 days of second vaccine dose	Pfizer-BioNTech <sup>14</sup>	Moderna <sup>15</sup>	
Local side effects (at the vaccine injection site)			
Pain	73%	88%	
Redness	7%	9%	
Swelling	7%	12%	
Swelling or tenderness in the armpit (same side as vaccine administration)	Data on this side effect was not collected in the trial	14%	
Systemic side effects (whole body)			
Fever	14%	16%	
Headache	46%	59%	
Fatigue	56%	65%	
Muscle pain	34%	58%	
Joint pain	21%	43%	
Nausea/vomiting	1%	19%	
Diarrhea	10%	Data on this side effect was not collected in the trial	
Chills	30%	44%	

• As more Canadians receive the vaccine, adverse events are continuously updated and reported here: <u>https://health-infobase.canada.ca/covid-19/vaccine-safety/#summary</u>

#### Who should NOT get the vaccine?

- There are **only two reasons** why you should not receive a COVID-19 vaccine:
- If you are below the age of 16 years old (for the Pfizer-BioNTech vaccine) or 18 years old (for the Moderna vaccine).
  - The vaccines have only been tested and approved for people 16 years or older for the Pfizer-BioNTech vaccine, or 18 years or older for the Moderna vaccine.<sup>3</sup> Vaccines for people under the age of 16 years are currently being tested.
- If you have previously had a severe or immediate allergic reaction to polyethylene glycol (PEG) or polysorbate, you should not get a mRNA COVID-19 vaccine
  - A severe allergic reaction means an allergic (anaphylactic) reaction requiring a dose of epinephrine (or use of an EpiPen). An immediate allergic reaction means a reaction within 4 hours of getting vaccinated, including symptoms such as hives, swelling, or wheezing (respiratory distress).<sup>5</sup>
- If you have a bleeding disorder so severe that you cannot receive intramuscular injections (e.g., hemophilia).

# What if I have had severe allergic reactions to other substances?

- You may be more likely to have a reaction to the vaccine; however, the chances of having an allergic reaction are quite low (11.1 cases of anaphylaxis per million doses of the Pfizer-BioNTech COVID-19 vaccine<sup>16</sup>; 2.5 cases of anaphylaxis per million doses of the Moderna vaccine). If you are concerned, you are encouraged to discuss your risk with your care provider.
- All vaccination clinics have trained individuals present and a process in place to monitor you after you receive your vaccine and respond to allergic reactions in case they do occur.

# Can I get the vaccine if I am pregnant or breastfeeding?

- Pregnant or breastfeeding individuals were not included in the vaccine trials, therefore there is very little data on the effect of COVID-19 vaccines in these groups. Despite this lack of data, based on the how mRNA vaccines work, experts believe that they are unlikely to pose a specific risk for people who are pregnant or breastfeeding,<sup>17</sup> and:
  - If you are pregnant: You may still receive the vaccine, but it is recommended that you discuss this choice and engage in informed decision making with your healthcare provider if you have any concerns.<sup>18</sup>
  - If you are breastfeeding: The vaccine is likely safe for you and it is possible that the antibodies to COVID-19 that your body develops will impart protection to your infant.<sup>18</sup>
  - If you are trying to get pregnant: There is currently no evidence to guide the time interval between completion of the COVID-19 vaccines series and conception. In the face of scientific uncertainty, it may be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of an mRNA COVID-19 vaccine. An mRNA COVID-19 vaccine may be administered any time after pregnancy.<sup>19</sup>

#### Can I get the vaccine if I am immunocompromised or have an underlying health condition?

- If you are immunocompromised or have underlying health conditions, you may still receive the vaccine, but should engage in informed decision making with your healthcare provider.
- While people who are immunocompromised were included in vaccine clinical trials, we do not have enough safety evidence on this group to make strong recommendations.<sup>9,10</sup> It is likely that people who are immunocompromised may not get as much protection from the vaccine as people who are healthy. However, there is likely enough protection even in those who are immunocompromised that the vaccine is still worth taking.<sup>20</sup>

Taking the COVID-19 vaccine is a personal choice. If you are concerned about taking the vaccine due to any underlying health conditions or medications that you are currently taking, talk with your doctor before receiving the COVID-19 vaccine

You may also reach out to the Toronto Public Health Hotline or Health Canada COVID-19 Information Line for additional information at:

Toronto Public Health Hotline: Telephone: 416-338-7600 TTY: 416-392-0658 Email: <u>PublicHealth@toronto.ca</u>

Translation is available in multiple languages.

Health Canada COVID-19 Information Line: Telephone: 1-833-784- 4397 Email: phac.covid19.aspc@canada.ca

#### When and how do I get my vaccine?

- The vaccine will be free and available to all Canadians, through demonstration of your health (OHIP) card or a government-issued photo ID (provincial health card, status card, driver's license, etc.)<sup>21</sup>
- Because there will be limited quantities at first, populations at the greatest risk of experiencing serious complications as a result of the virus and/or of acquiring and transmitting the virus are being prioritized.
- Residents, essential care partners and staff in congregate living settings for seniors (long-term care homes, retirement homes etc.) will be among the first to have access to the vaccine, in addition to adults 70 years of age and older, healthcare workers with direct patient contact, and adults living in Indigenous communities.<sup>22,23</sup>

# Will I still have to wear a mask and socially distance after I get the vaccine?

Yes, wearing a mask and practicing physical distancing are still important even after receiving the vaccine. We do not know yet whether people who are vaccinated can still carry the virus and be contagious to others. It will be important to continue implementing recommended public health measures such as universal masking, physical distancing, and self-isolation after travel.<sup>9,10</sup> A small percentage of individuals who receive the vaccine may still contract COVID-19.<sup>24</sup>



## Will I need to keep taking the vaccine every year?

 As with any new vaccination program, the duration of the immunity that will be provided by the vaccine is not yet known. Scientists will be monitoring individuals' immune responses post-vaccine over the coming years to better understand how long immunity will last.<sup>25</sup>

# If I miss the second dose of the vaccine, do I have to start the whole process over again?

 Currently approved evidence suggests that the second dose of the Pfizer-BioNTech and Moderna vaccines can be delayed up to 42 days from the 1st dose with no notable impact on efficacy. As long as the second dose is within a few weeks of when it is scheduled, you will not need to begin the whole process over again.<sup>5</sup>

# What do I do if I get COVID-19 after my first dose of the vaccine?

- The vaccines do not start working well until about 2 weeks after you get your first dose, and does not reach its full level of protection until about 1-2 weeks after your second dose.<sup>9,10</sup>
- It is possible that you could get infected with COVID-19 between your first and second dose of the vaccine. You may have been exposed to COVID-19 prior to receiving your vaccination, or soon after your vaccination when your body did not yet have time to build immunity. You will be able to receive your second dose of the vaccine as soon as you have recovered and consult with your healthcare provider. It is okay to get the second dose up to 42 days after the first dose if needed for both Pfizer-BioNTech and Moderna.<sup>5</sup>

#### Can I get my first dose of one vaccine brand, and my second dose with another brand?

No data exist on whether the COVID-19 vaccines can be interchanged,<sup>19</sup> but it is recommended that the same manufacturer's products be used for all doses in a vaccine series.<sup>26</sup>

#### What are the implications of Pfizer-BioNTech's shipment delays in Canada?

- On January 15, 2021, the Canadian government announced Pfizer-BioNTech vaccine deliveries to Canada would be reduced by half for a four week period starting January 25<sup>th</sup>, 2021.<sup>27</sup>
- The Ministry of Health announced directives, in consultation with National Advisory Committee on Immunization (NACI) guidelines, on vaccine delivery to ensure that the highest risk individuals –specifically residents in LTCH- will get their second dose on schedule.
- Studies have shown that the COVID-19 vaccines are effective with timelines up to 42 days between dose 1 and dose 2.<sup>27</sup>
- The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) recommendations are supportive of extending dosing during shortages.<sup>28,29</sup> Analysis of vaccine effectiveness in the Pfizer-BioNTech clinical trial included participants who received their second dose within 19 to 42 days after their first dose.<sup>9</sup>
- There is good evidence that the currently approved vaccines are 90% effective 2 weeks after receiving the first dose of the vaccine.<sup>19</sup> As with other multi-dose vaccines, the short-term protection is provided by the first dose, and the second dose provides long-term protection. The duration between doses should not affect the long-term protection as long as it is given after minimum duration. The minimum duration between doses is 21 days for the Pfizer-BioNTech vaccine and 28 days for the Moderna vaccine.<sup>19</sup>

# What do I need to know about the new variants?

- All viruses develop mutations over time. When a specific group of mutations occur that cause the virus to behave differently than the original virus, this mutated virus is what we call a variant. Variants of the COVID-19 virus are expected to occur.<sup>30</sup>
- While there are many variants of the COVID-19 virus circulating around the world,<sup>30</sup> there are 3 variants that seem to spread more easily and quickly than other variants, which may lead to more cases of COVID-19.<sup>31</sup> These variants are:
  - Variant B.1.1.7 → First detected in the United Kingdom in September 2020.
  - Variant 1.351 → First detected in South Africa in October 2020.
  - Variant P.1 → First detected in Brazil in December 2020
- Currently, there is no evidence that these variants cause more severe illness or increased risk of death.<sup>31</sup>
- The BioNTech and Moderna vaccines may still be equally effective against variant B1.1.7.<sup>32,33</sup> The Moderna vaccine may be slightly less effective against variant 1.351, but still offers some protective effects including decreasing the risk of severe infection.<sup>33</sup> There are no data yet available on vaccine effectiveness against variant P.1, although this variant may be more challenging to protect against due to the nature of its mutations that may affect its ability to be recognized by antibodies.<sup>34</sup>
- Scientists are actively monitoring the effect of vaccines against these new variants.<sup>35</sup>

### Vaccine rumours... Are they true?



#### **Q:** Can the mRNA vaccine alter my DNA?

- A: No. There are three reasons why we can be confident that mRNA vaccines will not alter our DNA:
  - Location mRNA is active in the cytoplasm of a cell, whereas DNA is in the cell's nucleus. Therefore the vaccine mRNA and your DNA never in the same place in the cell.
  - 2) Process mRNA is not DNA. So, if a person's DNA was going to be altered, the RNA would have to be made into DNA. This would require a special protein which the vaccine does not contain
  - Stability mRNA is not very stable and can only stay alive in human cells for a few hours.<sup>3,24</sup>



- **Q:** I heard that messenger RNA (mRNA) vaccine technology "has never been tested or approved before." How do we know this vaccine is not dangerous?
- A: mRNA vaccine technology has been in development for many years. These vaccines have been tested on tens of thousands of people around the world and underwent rigorous safety approval processes before they were recommended for widespread use. The Pfizer-BioNTech and Moderna COVID-19 vaccines are the first mRNA vaccines to be approved by Health Canada, but this technology has been studied in humans for the last several years.<sup>5</sup>
- **Q:** There are claims that the coronavirus pandemic is a cover for a plan to implant trackable microchips. Is this true?
- **A**: No. There is no vaccine "microchip." The vaccine has no ability to track people or gather any personal information.<sup>36</sup>

### **Q:** Can I get COVID-19 from receiving the vaccine?

A: No. These vaccines do not contain any infectious materials (this means there is no live virus) in them; you cannot get COVID-19 from the vaccine.<sup>1</sup>





### **Q:** Can the vaccine impact fertility, pregnancy and breastfeeding in women?

A: No. There is no scientific basis for the claim that the COVID-19 vaccines impact fertility. Both the Pfizer-BioNTech and Moderna vaccines were not tested on pregnant or breastfeeding individuals. In Canada, pregnant and breastfeeding individuals can still receive the vaccine if they choose, but should do so in consultation with their healthcare provider after weighing their personal risks of exposure.

### **Q:** Can the vaccine cause erectile dysfunction in men?

**A:** No. There is no evidence to support the claim that the COVID vaccines can cause erectile dysfunction (ED) in men. On the contrary, there has been some evidence linking the COVID-19 disease itself to increased suffering from ED.<sup>37</sup>

### **Q:** Will the COVID-19 vaccine cause long-term autoimmune issues?

A: There is no evidence to suggest that mRNA vaccines cause new autoimmune disease or worsen existing autoimmune diseases. People with autoimmune diseases are encouraged to consult with their healthcare providers about whether the vaccine is right for them after weighing their personal risks of exposure.<sup>38</sup>

# **Q:** Will the COVID-19 vaccine cause neurological issues, for example, facial weakness or paralysis (also known as Bell's Palsy)?

A: In the Pfizer-BioNTech vaccine trial, four people out of 43,449 participants in the trial (less than 0.01%) developed a temporary weakness or paralysis of facial muscles. Although these four participants all received the vaccine, the frequency at which this occurred is similar to what we see in the general population. Therefore, there is no evidence it was linked to the vaccine.<sup>39</sup>

## **Q:** Is the vaccine permitted and recommended for those practicing different religions?

- A: Many North American faith-based communities recommend or permit vaccination. Among these are The Canadian Muslim Covid-19 Task Force (CMTF), The Orthodox Union and Rabbinical Council of America, the United States Conference of Catholic Bishops, and the Hindu American Foundation.<sup>40-43</sup>
  - Taking the COVID-19 vaccine is a personal choice. If you are concerned about your faith-based or cultural group's guidance on vaccination, consult relevant leadership within your community or seek additional information before choosing to be vaccinated.

#### **Q:** These vaccines underwent a "Fast Track" Process for approval in Canada– what does that mean for the safety of the vaccine?

- A: Key decision makers in healthcare have spent decades planning for how the vaccine regulatory process could be made more efficient and cost-effective if there was an emergency need
  - On September 16, 2020, Canada's Minister of Health signed the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
  - This order allows for temporary measures to expedite the authorization for importing, selling, and advertising COVID-19-related drugs without compromising patient safety.<sup>44</sup>
  - Health Canada and the Minister of Health authorized both the Pfizer-BioNTech and Moderna vaccines under the Interim Order. Among other measures under the interim order, some of the measures which expedited the approval of the vaccine involved:.
    - Rolling review of data Allowed health regulators to analyze vaccine data on a rolling basis as it became available

- Foreign Approval Allowed special consideration to be given to the review of drugs that have already been approved in another country
- Pre-positioning Allowed for import of promising COVID-19 drugs for placement in Canadian facilities prior to their authorization in Canada

This has not led to "cutting corners" in the creation of these vaccines; but rather an extreme focus and added attention to detail in these processes.<sup>44</sup>

Both vaccines successfully underwent **all phases** of clinical trials:



### **Q:** If I already had COVID-19 and recovered, should I still get the vaccine?

A: Yes. Even if you previously had COVID-19, it is recommended that you get vaccinated. Recovering from COVID-19 is not a substitute for vaccination; there have been numerous reported cases of COVID-19 re-infection.<sup>45</sup> Although scientists are still trying to understand how long immunity from the vaccine will last, current evidence suggests that the vaccine will provide better and longer immunity than your body's natural antibodies would.<sup>46</sup>

## **Q:** Am I immune to COVID-19 if I have type O blood?

A: There is some evidence to suggest that people with type O blood may experience somewhat less severe COVID-19 symptoms,<sup>47,48</sup> but more evidence is needed. This definitely does not mean that you will not get infected. If you have type O blood, you should still take all precautions to protect yourself from COVID-19, including taking the COVID-19 vaccine if you are eligible.

#### Q: Do COVID-19 vaccines contain fetal tissue?

- A: No. Neither the Pfizer-BioNTech nor Moderna COVID-19 vaccines contain fetal tissue. Early explorative research into mRNA vaccine technology were tested on fetal cell cultures, but fetal tissue was not used in the design, development or production of the COVID-19 vaccines.<sup>49</sup>
- **Q:** Is the COVID-19 vaccine similar to the flu shot in that it will not guarantee that we will not get it.?
- **A:** The COVID-19 vaccines are over 94% effective at preventing COVID-19, whereas the flu shot only prevents up to 50% of the flu.<sup>50</sup>

If you have any concerns about taking the COVID-19 vaccine, discuss these with your doctor or healthcare practitioner. You may also reach out to the Toronto Public Health Hotline for additional information at:

Telephone: 416-338-7600 TTY: 416-392-0658 Email: <u>PublicHealth@toronto.ca</u>

Translation is available in multiple languages.

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