

Ministry of Health

COVID-19 Administration of Pfizer-BioNTech COVID-19 Vaccine

Version 1 – December 12, 2020 (amended December 13, 2020)

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.

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.

What is COVID-19?

COVID-19 is a novel coronavirus disease 2019 that is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Anyone can be infected with SARS-CoV-2 (COVID-19). However, some populations are at increased risk of exposure to the virus (e.g., due to living or work settings), and some populations are at increased risk of severe disease and death due to biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., low socioeconomic status, belonging to a racialized population) factors.

Additional information about the Pfizer-BioNTech COVID-19 Vaccine can be found in the [product monograph](#).

General Clinic Precautions

All staff working in the clinic must take appropriate infection prevention and control measures, including donning appropriate personal protective equipment (PPE) when interacting with clients as they move through the immunization clinic and when responding to any adverse events following immunization.

The Vaccine

Pfizer-BioNTech COVID-19 Vaccine	
Type of vaccine	COVID-19 mRNA
Date of authorization in Canada	December 9, 2020
Authorized ages for use	16 years of age and older
Dose	30 mcg of mRNA per 0.3 mL (after dilution- see product monograph for choice of diluent and dilution instructions)
Schedule	2 doses, a minimum of 19 days apart (recommended interval 21-28 days apart)
Booster doses	No evidence for the need for an additional booster after the 2-shot series
Route of administration	Intramuscular (IM) into the deltoid muscle
Nature of the antigen	Prefusion spike protein
Adjuvant (if present)	None

Storage requirements	
Frozen vials prior to use	Must be stored at ultra-low temperatures (-80°C to -60°C) and protected from light, in the original packaging until ready to use. Refer to the re-icing guidelines packaged with the vaccine for instructions regarding the use of the manufacturer's original thermal container for temporary storage
Vials prior to dilution	May be thawed and stored at +2°C to +8°C for up to 120 hours (5 days) or at room temperature (up to +25°C) for no more than 2 hours. During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions. Do not refreeze thawed vials.
Vials after dilution	Must be stored between +2°C to +25°C and used within 6 hours from the time of dilution. During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions.
Formats available	Multi-dose vial (5 doses) preservative free
Usage limit post-dilution	6 hours from time of dilution at +2°C to +25°C
Drug Interactions	No interaction studies have been performed.

Who Should Not Receive the Vaccine

Vaccine should not be administered to:

The Pfizer-BioNTech COVID-19 vaccine is contraindicated in:

- Individuals with a **history of anaphylaxis** after previous administration of the vaccine.

- Persons with **proven immediate or anaphylactic hypersensitivity** to any allergic to any of the component of the vaccine or its container, including polyethylene glycol.
- **Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19.**
- **Acutely ill individuals:** As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illness, it would be prudent to wait for all symptoms of acute illness to completely resolve.
- Individuals who have received another vaccine (not a COVID-19 vaccine) in the past 14 days.
- **Women who are or who may become pregnant until further evidence is available:** There is limited data from the use of the Pfizer-BioNTech COVID-19 vaccine in pregnant women as they were excluded from the clinical trials.
- **Breastfeeding women until further evidence is available:** It is unknown whether the Pfizer-BioNTech COVID-19 vaccine is excreted in human milk. A risk to the newborn or infant cannot be excluded. This population was not included in the clinical trials.
- **Individuals who are immunosuppressed** due to disease or treatment or those with an autoimmune disorder until further evidence is available, as they were excluded from the clinical trials.
- **Individuals under the age of 16:** The safety and efficacy in children under 16 years of age have not yet been established. The manufacturer plans to conduct clinical trials in children.

More data may be available in the near future on the use of the vaccine in immunosuppressed individuals, pregnant and breastfeeding women and in children.

Considerations for other patient groups

Precautions should be taken for:

- Patients who have a bleeding problem, bruise easily or use a blood-thinning medicine

The Pfizer-BioNTech COVID-19 vaccine **may not be** recommended:

- In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, investigation is indicated which may lead to immunization in a controlled setting. Consultation with an allergist is advised.

- Individuals with previous allergic reaction or breathing problems from the Pfizer-BioNTech COVID-19 vaccine
- Individuals who have experienced a serious allergic reaction, including anaphylaxis, to another vaccine, drug or food, should talk to their health professional before receiving the vaccine

The medical needs of these patients, including whether or not the administration of a vaccine is appropriate for a patient, are best determined between the patient and their healthcare provider.

Side effects

The Pfizer-BioNTech COVID-19 vaccine, like other medicines and vaccines can cause side effects, although not everyone gets them. The most common side effects of receiving the Pfizer-BioNTech COVID-19 vaccine are mild and include injection site pain, swelling or redness.

Other side effects that have been reported include headache, fatigue, muscle pain, chills, joint pain, fever and enlarged lymph nodes. Most of these side effects experienced were mild to moderate and on average did not last longer than three days. Please see the [product monograph](#) for a complete list of reported side effects/ adverse reactions.

Very common side effects	May affect more than 1 in 10 people	<ul style="list-style-type: none"> • Pain at injection site (84.1%*) • Fatigue (62.9%*) • Headache (55.1%*) • Muscle pain (38.3%*) 	<ul style="list-style-type: none"> • Chills (31.9%*) • Joint pain (23.6%*) • Fever (14.2%*) 	*subset (n=8183)
Uncommon side effects	May affect up to 1 in 100 people	Enlarged lymph nodes (0.008%**)		**subset (n=7960)

Adverse Events Following Immunization

What information should be provided to individuals related to potential adverse events following immunization (AEFIs) with the Pfizer-BioNTech COVID-19 vaccine?

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients or their parents/guardians are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine, particularly any of the following:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- Other serious reactions

Health care providers (e.g., physicians, nurses and pharmacists) are required by law (i.e., *Health Protection and Promotion Act*, s. 38) to report AEFIs. Reports should be made using the [Ontario AEFI Reporting Form](#) and sent to the local [public health unit](#).

The Ontario Ministry of Health in collaboration with Public Health Ontario monitors reports of adverse events after immunization. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

The Brighton Collaboration has developed a list of [Adverse Events of Special Interests](#).

Point-of-care Guidance

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of this vaccine.
- The vaccine is administered through an intramuscular injection into the upper arm (deltoid muscle).
- In order to be fully effective in preventing SARS-CoV2 infection, the vaccine must be administered twice: a single dose of the vaccine is administered followed by a second single dose 21 days later.
 - A minimum of 19 days between the first and second dose with a recommended interval 21-28 days.
 - If administration of the second dose of the vaccine is delayed, it should be administered as soon as possible.
- In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series as delays between doses do not result in a

reduction in final antibody concentrations for most multi-dose products. However, maximum protection may not be attained until the complete vaccine series has been administered.

- The vaccine series must be completed with the same COVID-19 vaccine product.
- Do not mix the Pfizer-BioNTech COVID-19 vaccine with other vaccines/products in the same syringe.
- Pfizer-BioNTech COVID-19 vaccine should not be given simultaneously with other live or inactivated vaccines.

Vaccine Preparation:

Additional information on vaccine preparation can be found in the [product monograph](#).

- The Pfizer-BioNTech COVID-19 vaccine multiple dose vial contains a frozen suspension that does not contain preservative and **must be thawed and diluted prior to administration**.
- Vials may be thawed in the refrigerator (+2°C to +8°C) for up to 5 days, or at room temperature (up to +25°C) and used within 6 hours.
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles. Before dilution, the vial must be inverted gently 10 times to mix the vaccine. **Do not shake**. The contents of the vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP.
- After dilution, the vial contains 5 doses of **0.3 mL**. The vial containing the Pfizer-BioNTech COVID-19 vaccine should be gently inverted 10 times to mix. **Do not shake**.
- After dilution, the vaccine will be an off-white suspension. Inspect vial to confirm there are no particulates and no discolouration is observed.
- The time and date of dilution must be recorded on the vial label and the vial must be stored between +2° C to +25° C. Any unused vaccine must be discarded 6 hours after dilution.
- Strict adherence to aseptic techniques must be followed.

Vaccine Administration:

- It is important the proper sized syringes (to ensure the correct volume is accurately drawn up) and safety engineered needles are used when administering the vaccine

- Visually inspect each dose in the dosing syringe prior to administration. The diluted vaccine will be an off-white suspension.
- During the visual inspection:
 - Verify the final dosing volume of **0.3 mL**, and
 - Confirm there are no particulates and that no discolouration is observed.
- **If the visual inspection fails, do not administer the vaccine.**
- Administer Pfizer-BioNTech COVID-19 Vaccine intramuscularly in the deltoid muscle.
- Do not inject the vaccine intravascularly, subcutaneously or intradermally.

All clients should be reminded to continue to practice recommended public health measures for prevention and control of COVID-19 infection and transmission regardless of receipt of COVID-19 vaccine.

Storage, Stability and Disposal

Frozen Vials Prior to Use

- Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials (after dilution each vial contains 5 doses of 0.3 mL) arrive in thermal containers with dry ice.
 - To ensure all appropriate safeguards are in place, refer to the Dry Ice Safety Data Sheet and the Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Reference Guide provided.
- Appropriate PPE must be worn when handling the vaccines.
- Once received, remove the vial cartons immediately from the thermal container and store in the freezer between -80°C to -60°C).
- Vials must be kept frozen between -80°C to -60°C and protected from light, in the original cartons, until ready to use.
- If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently refilled to the top of the container with dry ice.
 - Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage.
 - The thermal container maintains a temperature range of -90°C to -60°C. Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Prior to Dilution

- Prior to dilution, multiple dose vials of Pfizer-BioNTech COVID-19 Vaccine may be thawed and stored in the refrigerator between +2°C to +8°C.
 - A carton of 25 vials or 195 vials may take up to 2 or 3 hours to thaw in the refrigerator, respectively, whereas a fewer number of vials will thaw in less time.
 - Vials may be stored in the refrigerator for up to 5 days (120 hours).
- Frozen vials may also be thawed at room temperature up to +25°C.
 - Prior to dilution, the multiple dose vial may be stored at room temperature for no more than 2 hours.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Thawed vials can be handled in room light conditions. **Do not refreeze thawed vials.**

Vials After Dilution

- After dilution, multiple dose vials of Pfizer-BioNTech COVID-19 Vaccine must be stored between +2°C to +25°C and **used within 6 hours from the time of dilution.**
- Any vaccine remaining in vials must be discarded after 6 hours.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- After dilution, the vaccine vials can be handled in room light conditions.
- **Do not freeze. If the vaccine is frozen, it must be discarded.**