COVID-19 Vaccine – mRNA
Pfizer – Ultra frozen Vaccine
Implementation Date: December 16, 2020

This policy is evergreen and will be updated as new information becomes available.

Please consult the Product Monograph\(^1\) for further information about the vaccine.

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### Precautions
- Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their healthcare provider before receiving the vaccine.\(^2,4\)
- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.\(^1\)
- Administration should be postponed in individuals suffering from acute severe febrile illness.\(^1,2\)
- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.
- COVID-19 vaccine should not be offered to populations who are immunosuppressed due to disease or treatment or those with an autoimmune disorder until further evidence is available as there is a lack of evidence on efficacy and safety in this group.
  - However, a complete series of COVID-19 vaccine may be offered in consultation with the individual's physician to individuals in the eligible group in this population if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population.\(^2\)

### Possible reactions
**Very Common (≥1/10)**
- injection-site pain, fatigue, chills, fever, headache, arthralgia, myalgia

**Common (≤1/100 to <1/10)**
- redness or swelling at injection site, vomiting, diarrhea

**Uncommon (≥1/1000 to <1/100)**
- lymphadenopathy

### Pregnancy
- The safety and efficacy of Pfizer-BioNTech COVID-19 Vaccine in pregnant women have not yet been established.\(^1\)
- Vaccine should not be offered to individuals who are pregnant until after completion of pregnancy.\(^2\)
- However, a complete series of COVID-19 vaccine may be offered in consultation with the individual's physician to pregnant individuals in the eligible group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population.\(^2\)

### Lactation
- It is unknown whether Pfizer-BioNTech COVID-19 Vaccine is excreted in human milk. A risk to the newborn/infants cannot be excluded.\(^2\)
- COVID-19 vaccine should not be offered to individuals who are breastfeeding.
- However, a complete series of COVID-19 vaccine may be offered in consultation with an individual's physician to individuals in the eligible group who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population.\(^2\)

### Interchangeability
- Currently, no data exists on the interchangeability of COVID-19 vaccines.\(^2\)
- The vaccine series should be completed with the same COVID-19 vaccine product.\(^2\)
| Administration with Other Products | In the absence of evidence, COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines due to the potential for immune interference and the need to be able to monitor for potential symptoms of COVID-19 and COVID-19 vaccine adverse events without potential confounding from adverse events following other vaccines.  
If a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.  
In the absence of evidence, it would be prudent to wait for a period of at least 28 days between the administration of the complete two-dose schedule of COVID-19 vaccine and the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis).  
In the absence of evidence, it would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine.  |
| Appearance | Frozen - white to off-white solution.  
Thawed – may contain white to off-white opaque particles.  
Thawed and reconstituted – off-white solution with no visible particulates.  |
| Storage and Handling | Can be stored in a freezer between -80°C to -60°C storage for up to 6 months.  
If an ultra-low temperature freezer is not available, the thermal container in which the vaccine arrives may be used as temporary storage up to 30 days when consistently refilled to the top of the container with dry ice.  
Prior to dilution, thawed vials can be stored:  
- in the refrigerator at 2°C to 8°C for up to 5 days, or  
- at room temperature (up to 25°C) for no more than 2 hours.  
Do not refreeze.  
After thawing and mixing with 0.9% sodium chloride diluent, the vaccine can be stored at 2°C to 25°C for up to 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.  |
| Packaging | **Vaccine**  
5 doses per vial  
975 doses per package  
- Tray is 229 mm long, 229 mm wide, 40 mm high  
Cannot be re-packaged  
**Diluent**  
Diluent is provided in 10 mL plastic vials (latex-free, preservative-free).  
Packaged in cartons of 25 vials and can be stored at room temperature.  
Diluent is single use. Once the 1.8 mL required is drawn from the diluent vial and added to the antigen vial, the diluent vial MUST be discarded. It cannot be used to dilute multiple vials of vaccine.  |
| Non-medicinal Ingredients | Lipid nanoparticles (these help the mRNA enter the cell):  
- ALC-0315 = (4-hydroxybutyl) azanediyl)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)
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- cholesterol

### Salts: (help maintain the vaccine pH)
- bibasic sodium phosphate dihydrate
- monobasic potassium phosphate
- potassium chloride
- sodium chloride

### Other:
- sucrose (protects the nanoparticles when frozen)
- water for injection

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### Preparation/Reconstitution

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.

**Thaw vaccine before use:**

The frozen vial contains 0.45 mL and will need to be thawed before dilution.

- Vials may be thawed in the refrigerator (2°C to 8°C) or at room temperature (up to 25°C).
  - Thaw for 30 minutes at room temperature. (Vials at room temperature must be diluted within 2 hours.)
  - Thaw for 3 hours in the refrigerator; and allow the vial to come to room temperature before dilution.

**Dilute before use:**

1. Before dilution, invert gently 10 times to mix. Do not shake.
2. Dilution with sterile 0.9% Sodium Chloride Injection is required. (Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.)
3. Cleanse the vial stopper with a single-use antiseptic swab.
4. Add 1.8 mL of 0.9% Sodium Chloride Injection, into the Pfizer-BioNTech COVID-19 Vaccine vial using a needle 21-gauge or narrower.
   - Diluent is single use. Once the 1.8 mL required is drawn from the diluent vial and added to the antigen vial, the diluent vial MUST be discarded. It **cannot** be used to dilute multiple vials of vaccine.
5. Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
   - This is to prevent any vaccine loss through spraying out due to higher pressure.
6. Gently invert the vial again 10 times to mix. Do not shake.
7. Inspect the vial to confirm there are no particulates and no discoloration is observed.
8. Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
9. Store between +2°C to +25°C.
10. Discard any unused vaccine **6 hours** after dilution.

**Notes:** Pre-loading vaccine into syringes is not supported. The immunizing health practitioner must draw up the vaccine dose at the time of administration.

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**Program Notes**

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See [www.CVDvaccine.ca](http://www.CVDvaccine.ca) for additional information.
References


3 Pfizer Training Resources. 2020 December 8,