Alberta Health Services	**COVID-19 Vaccine - mRNA Pfizer - Ultra Frozen Vaccine Biological Page**

Section 7:	**Biological Product Information**		**Standard #: 07.203**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
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Vaccine Name	**COVID-19 Vaccine - mRNA Pfizer Ultra Frozen Vaccine**
Manufacturer	Pfizer-BioNTech
Biological Classification	• mRNA (new technology) – nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) • Formulated in lipid nanoparticles (LNPs)
Indications for Provincially Funded Vaccine	**Persons 16 years of age and older.** • This vaccine is being offered in a staged approach, please follow operational guidelines to assess eligibility
Preferred Use	N/A
Dose	**0.3 mL**
Route	IM

Schedule	2 doses
	• Dose 1 – day 0
	• Dose 2 – day 21 to 28
	
	Notes:
	• Minimum spacing between doses is 19 days.
	• Recommended spacing between doses is 21 to 28 days.
	• The interval between dose 1 & dose 2 may be extended up to 42 days for all populations except residents of long-term care (LTC) and designated supportive living (DSL) sites. See section below for rationale/evidence.
	  ○ Residents of LTC and DSL sites should receive the second dose 21 to 28 days following the first dose.
	  ○ All others should receive the second dose 21 to 42 days following the first dose. Second dose appointments will be routinely booked for 35 to 42 days following the first dose.
	• Currently, no data on a maximum interval between doses or on medium or long-term efficacy of COVID-19 vaccines are available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series.

Rationale/Evidence for Extending the Interval Between Dose 1 and Dose 2	• Data from clinical trials show a high vaccine efficacy after the initial dose of the Pfizer vaccine. Estimated efficacy 92.3% (95% CI: 69 to 98%) against symptomatic COVID-19 disease 14 days after the first dose and before dose two. • Disease modelling has suggested that there is increased effectiveness in reducing the number of COVID-19 cases and achieving overall benefit by administering one dose to more people quickly when there is limited vaccine supply and widespread community transmission, compared to the strategy of saving early doses to ensure delivery of second dose according to manufacturers' recommendations. • Some participants in the clinical trials for Pfizer-BioNTech vaccine received their second dose up to 42 days or 6 weeks after their first. • In studies on vaccines for other infections, a longer time between the first and second dose can make the overall immune response to the vaccine better, while a shorter time between them can lower the overall response.

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	• The initial immune response in elderly people may be less and the waning may be at a greater rate. Since residents of LTC and DSL are at high risk of severe disease outcomes and outbreaks, at this time, administration of the second dose to those in LTC and DSL is to continue as per product monograph spacing. While these populations were not included in the clinical trials, the studies did include participants up to age 89 years and 42.3% of participants who received the Pfizer-BioNTech vaccine were over age 55. • The rate of waning protection without the administration of the second dose in unknown, therefore a second dose continues to be recommended.
Contraindications/ Precautions	**Contraindications:** • Persons under 16 years of age. • Known hypersensitivity to any component of the vaccine. ○ One non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions is polyethylene glycol (PEG). This potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, skin products and some food and drinks. • Anaphylactic or other allergic reactions to a previous dose of COVID-19 mRNA vaccine. **Precautions:** • Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine. • 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. • Administration should be postponed in individuals suffering from acute severe febrile illness. • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products are currently unknown. Medical consultation with primary care physician is advised. • Refer to Immunocompromised and Auto-Immune Disorders, Pregnancy and Lactation sections for specific information on these populations.

Immunocompromised and Auto-Immune Disorders	• At this time, there is an absence of evidence on the use of COVID-19 vaccine in immunocompromised individuals and those with auto-immune disorders. These groups were not included in large enough numbers in the initial trials to provide solid information.
	• COVID-19 vaccine may be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder if a risk assessment with their primary health care provider or medical specialist determines that the benefits outweigh the potential risks. Risks would include that:
	  ○ Immunocompromised persons may have a diminished immune response to the vaccine and
	  ○ There is a theoretical concern that mRNA vaccine may elicit an inflammatory response and possibly exacerbate existing autoimmune diseases. However, current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk.
	• However, with the exception of SOT and HSCT clients, the individual may also be immunized without consulting their primary health care provider or medical specialist following their acknowledgment of the risks mentioned above and the absence of evidence on the use of COVID-19 vaccine in these populations.
	  ○ Response for immunizers if individual has not consulted with their primary health care provider: “The vaccine studies have not tested whether this vaccine is safe or effective for you. We recommend that you do not receive the immunization until you have discussed the potential risks and benefits with your doctor. However, it is your choice whether to proceed without consulting your doctor.”
	• Additional resources:
	  ○ COVID-19 Scientific Advisory Group Rapid Evidence Report

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	○ Advisory Committee on Immunization Practices (ACIP) interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines
Pregnancy	• The safety and efficacy of Pfizer-BioNTech COVID-19 Vaccine in pregnant women has not yet been established. • At this time, there is an absence of evidence on the use of COVID-19 vaccine in pregnant individuals. These groups were not included in large enough numbers in the initial trials to provide solid information. • COVID-19 vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or obstetrician determines that the benefits outweigh the potential risks for woman and fetus. ○ However, the individual may also be immunized without consulting their primary health care provider or obstetrician following their acknowledgment of the absence of evidence on the use of COVID-19 vaccine in this population. ○ Response for immunizers if individual has not consulted with their primary health care provider: "The vaccine studies have not tested whether this vaccine is safe or effective for you. We recommend that you do not receive the immunization until you have discussed the potential risks and benefits with your doctor. However, it is your choice whether to proceed without consulting your doctor." Additional resources: ○ Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy. • It would 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.
Lactation	• It is unknown whether Pfizer-BioNTech COVID-19 Vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded. • At this time, there is an absence of evidence on the use of COVID-19 vaccine in breast feeding individuals. These groups were not included in large enough numbers in the initial trials to provide solid information. • COVID-19 vaccine may be offered to individuals in the eligible group who are breastfeeding if a risk assessment with their primary health care provider or medical specialist determines that the benefits outweigh the potential risks for the mother and infant. ○ However, the individual may also be immunized without consulting their primary health care provider or medical specialist following their acknowledgment of the absence of evidence on the use of COVID-19 vaccine in this population. ○ Response for immunizers if individual has not consulted with their primary health care provider: "The vaccine studies have not tested whether this vaccine is safe or effective for you. We recommend that you do not receive the immunization until you have discussed the potential risks and benefits with your doctor. However, it is your choice whether to proceed without consulting your doctor."
Other Considerations	• Individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be provided COVID-19 vaccine. • Individuals presenting for immunization do not need to be tested for previous COVID-19 infection. • Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. ○ However, individuals with COVID-19-like symptoms should not go to an immunization/venue in order to minimize the risk of COVID-19 transmission and their immunization should be deferred. ○ For residents of LTC/DSL who are isolated due to COVID-19-like symptoms, immunization should be deferred until the test result is back and negative and the person is otherwise eligible based on the acuity of their symptoms (i.e., no acute severe febrile illness).
Possible Reactions	**Common:** • Pain, redness, and swelling at the injection site • Fever, chills

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	• Fatigue • Headache, myalgia, arthralgia • Vomiting, diarrhea **Uncommon:** • Lymphadenopathy **Rare:** • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.
Composition	Each 0.3 mL dose contains: <u>Lipids nanoparticles (these help the mRNA enter the cell):</u> • ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide <u>Other Lipids: (provide structural integrity of the nanoparticles)</u> • 1,2-distearoyl-sn-glycero-3-phosphocholine • cholesterol <u>Salts: (help maintain the vaccine pH)</u> • bibasic sodium phosphate dihydrate • monobasic potassium phosphate • potassium chloride • sodium chloride <u>Other:</u> • sucrose (protects the nanoparticles when frozen) • water for injection No adjuvants or preservatives
Blood/Blood Products	Contains no human blood/blood products.
Bovine/Porcine Products	Contains no bovine/porcine products.
Latex	Does not contain latex.
Interchangeability	• Currently, no data exists on the interchangeability of COVID-19 vaccines. • The vaccine series should be completed with the same COVID-19 vaccine product.
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	• Can be stored in a freezer between -80°C to -60°C storage for up to 6 months.

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	• 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:
	  o in the refrigerator at +2°C to +8°C for up to 5 days
	  o at room temperature 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 o 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.

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.
	
	<u>Thaw vaccine before use:</u>
	
	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).
	  o Thaw for 30 minutes at room temperature.
	  o Thaw for 3 hours in the refrigerator; and allow the vial to come to room temperature before dilution.
	
	<u>Dilute before use:</u>
	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.
	  o 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.
	  o 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.

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	Note: Pre-loading vaccine into syringes is not supported. The immunizing health practitioner must draw up the vaccine dose at the time of administration.
Vaccine Code	COVPBmRNA
Antigen Code	COVID-19-1
Licensed for	Individuals 16 years of age and older

Notes:

- Licensed for use in Canada December 9, 2020

Related Resources

- Alberta Health Services Website (2020). COVID-19 Vaccine Information
- Preparation of Pfizer-BioNTech COVID-19 Vaccine

References

- Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy (2021, January 13). COVID-19 Vaccine-mRNA: Pfizer – Ultra frozen vaccine.
- National Advisory Committee on Immunization. *Canadian immunization guide (Evergreen Edition*). Ottawa, ON: Public Health Agency of Canada. http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php
- National Advisory Committee on Immunization (2020). Recommendations on the use of COVID-19 Vaccine(s).
- Pfizer-BioNTech (December 9, 2020). PFIZER-BIONTECH COVID-19 VACCINE (COVID-19 mRNA Vaccine). *Product monograph.*
- Pfizer Training Materials. December 8, 2020.