COVID-19 Vaccine - mRNA
Pfizer BioNTech (Comirnaty) - Ultra Frozen Vaccine
Pediatric Formulation 5 Years to 11 Years of Age
Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.207**
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	COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty) Ultra Frozen Vaccine **Pediatric Formulation 5 Years to 11 Years of Age** 
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 5 years to 11 years of age.** **Notes:** • Vaccine formulation to administer is based on age at presentation, regardless of vaccine/formulation received for first dose. • Children who received a first dose of the adult formulation of Pfizer or Moderna COVID-19 vaccine at age 11 years will complete their second dose with the pediatric Pfizer formulation if still 11 years of age when presenting for second dose. • Children who received their first dose of pediatric Pfizer vaccine at 11 years of age and are now 12 years of age when presenting for second dose, will receive the adult formulation of Pfizer for their second dose.
Preferred Use	N/A
Dose	**0.2 mL (10 mcg)**
Route	IM
Schedule	**Primary series 2 doses** • Dose 1: day 0 • Dose 2: at least 8 weeks after dose 1 Optimal spacing between dose 1 and dose 2 is at least 8 weeks. • Currently, there is no direct evidence to establish an optimal interval between doses in pediatric populations. However, evidence on COVID-19 mRNA vaccines in adolescents and adults shows that a longer interval between the first and second dose leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer. • Emerging Canadian safety surveillance data suggest a longer interval may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine. **Notes:** • A shortened interval between dose 1 and dose 2 (no less than 21 days) as per product monograph may be considered in certain situations: Individuals with certain immunocompromising conditions who are likely to have less robust immune responses after one dose, individuals at increased risk for infection based on local transmission and the degree of individual risk of exposure, or required for travel.

	• Currently, no data on a maximum interval between doses is available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series. • Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization based on the individual's treatment. • Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible for two doses of COVID-19 vaccine beginning 6 months post-transplant. Consultation with their HSCT physician is not necessary as long as the initial clearance letter has been received to proceed with inactivated vaccines.

Contraindications/ Precautions	**Contraindications:**
	• Persons under 5 years of age.
	• Known severe hypersensitivity to any component of the vaccine.
	  ○ Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
	  ▪ Polyethylene glycol (PEG). This potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
	  ▪ Tromethamine (trometamol or Tris) – This potential allergen may be found in contrast media, oral and parenteral medications.
	• Anaphylaxis 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.
	• Immunization of children with a previous history of multisystem inflammatory syndrome in children (MIS-C) should be postponed until clinical recovery has been achieved or until it has been 90 days or greater since diagnosis, whichever is longer.
	• Refer to Immunocompromised and Auto-Immune Disorders section for specific information on these populations.

Myocarditis	• Cases of myocarditis and/or pericarditis have been reported following immunization with an mRNA COVID-19 vaccine in individuals 12 years of age and older who received the 30 mcg formulation of the Pfizer-BioNTech COVID-19 vaccine or 100 mcg formulation of the Moderna COVID-19 vaccine. However, the risk is considered rare. • Based on cases reported, available information indicates cases of myocarditis and pericarditis occur more commonly after the second dose, more often in adolescents and young adults, more often in males and more frequently following Moderna (SpikeVax) COVID-19 vaccine. Typically, onset of symptoms begins within a week after the receipt of an mRNA COVID-19 vaccine. Available short-term follow-up data suggest that the majority of cases are mild and individuals tend to respond well to conservative therapy and recover quickly, but information on long-term sequelae is lacking. • Currently, the risk of myocarditis in children following immunization with the 10 mcg dose of Pfizer-BioNTech vaccine is unknown. Safety surveillance data from individuals aged 12 and older does not suggest the risk of myocarditis following mRNA COVID-19 immunization would be greater in children aged 5 to 11 years of age compared to older populations. Additionally, the impact of a reduced vaccine dose (10 mcg vs 30 mcg) is also unknown. The clinical trials for children 5 to 11 years of age did not identify any cases of myocarditis following immunization; however, uncommon, rare or very rare

	adverse events that occurs at the frequency less often than 1 in 1,000 would not be detected with that trial size.
	• It is unknown if individuals with a history of previous myocarditis are at higher risk of vaccine associated myocarditis.
	  ○ Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis that is unrelated to COVID-19 mRNA vaccines if they are no longer followed clinically for cardiac issues.
	  ○ If there are questions or concerns about prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.
	• Individuals who experienced myocarditis and/or pericarditis after receiving a first dose of mRNA COVID-19 vaccine should discuss decisions around the second dose with their clinician.
	  ○ In general, they are advised to defer receiving a second dose until more data is available as per NACI's recommendation.
	• Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.

Immunocompromised and Auto-Immune Disorders	• At this time, there is very limited data on the use of Pfizer-BioNTech COVID-19 mRNA vaccine 10 mcg formulation in immunocompromised individuals and those with auto-immune disorders.
	• Individuals who are immunocompromised and those with auto-immune disorders who are receiving immunosuppressive therapy may have a diminished immune response.
	• 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 an informed consent is given by the parents/guardians after a discussion on benefits and potential risks.
	  ○ It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions, especially regarding the timing of immunization based on the individual's treatment.
	  ○ However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.
	  ▪ Response for immunizers if individual has not consulted with their primary health care provider: "There is limited data on the use of this vaccine in immunocompromised individuals or those with auto-immune disorders. Emerging data has not detected any safety issues. We recommend you speak to your physician regarding the timing of immunization based on your treatment or if you have questions about the immunization, but it is not required to receive the vaccine."
	Exceptions:
	  ▪ SOT client require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine.
	  ▪ HSCT clients do not require consultation as long as the initial clearance letter has been received to proceed with inactivated vaccine.

Other Considerations	• Individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be provided COVID-19 vaccine as soon as their isolation period is over. • 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. They

	should isolate, seek testing and get immunized as soon as their isolation period is over. ○ Individuals within facilities who are isolated due to COVID-19-like symptoms can be provided COVID-19 vaccine as long as they are well enough to be immunized. • It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals. It is still unknown what antibody level correlates with protection against COVID-19, and serology testing in many labs may also not detect antibodies developed as a response to vaccine. Serology testing should not be used as evidence to inform whether vaccine doses have been effective.
Possible Reactions	**Common:** • Pain, redness, and swelling at the injection site • Fever, chills • Fatigue • Headache, myalgia, arthralgia • Vomiting, diarrhea • Skin and subcutaneous tissue disorders (including skin rash, dermatitis, eczema, urticarial) **Uncommon:** • Lymphadenopathy • Nausea • Malaise • Decreased appetite **Rare:** • Allergic reactions • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.
Composition	• ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (PEG) • 1,2-distearoyl-sn-glycero-3-phosphocholine • cholesterol • tromethamine • tromethamine hydrochloride • sodium chloride • 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
Administration with Other Products	• COVID-19 vaccines should not routinely be administered on the same day with other live or inactivated vaccines to children 5 to 11 years of age due to the need to monitor for adverse events following COVID-19 immunization. • In the absence of evidence, it is recommended but not required to wait for a period of at least 14 days before and after the administration of COVID-19 vaccine and the administration of another vaccine if it does not create a barrier to receipt of vaccines.

This is to allow for accurate attribution of adverse events following immunization and inform risk estimates of any adverse event that may be associated with the COVID-19 vaccine.

- Clients should not be turned away if presenting for administration of more than one vaccine on the same day or if they are within the 14 day period between the COVID-19 vaccine and another vaccine.
  - Routine school immunizations can be administered regardless of spacing from COVID-19 vaccine.
- Based on evidence including real world experience from the use of COVID-19 vaccine in adolescents and adults, administering the pediatric COVID-19 vaccine on the same day or within 14 days of any other live or inactivated vaccine is not expected to have an impact on the safety or effectiveness of the vaccine.
- If a COVID-19 vaccine is administered on the same day as another vaccine or within 14 days of another vaccine, neither dose should be repeated.
- Currently there is no data on the impact of the COVID-19 mRNA vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.
  - If tuberculin skin testing or an IGRA test is required for baseline screening, it should be administered and read before administration of any COVID-19 vaccine immunization or delayed for at least 28 days after a dose of COVID-19 vaccine.
  - Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed.
  - If tuberculin skin testing is required for other reasons (e.g., contact tracing, immigrants, query LTBI), testing should not be delayed, as these are theoretical considerations. However, re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.
- COVID-19 vaccines should be delayed for at least 90 days after the receipt of SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment of COVID-19 infection. This applies to people who received these therapies before receiving any COVID-19 vaccine dose and between doses.
  - Timing of administration and potential interference between COVID-19 vaccine and monoclonal products or convalescent plasma as part of COVID-19 treatment are currently unknown and administering these products close together may result in less effectiveness of the COVID-19 vaccine.
  - A deferral for at least 90 days is based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon within the 90 days after initial infection.
  - This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses.
  - COVID-19 vaccine doses inadvertently received within 90 days after receipt of passive antibody therapy do not need to be repeated.
- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for the treatment of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis.
- mRNA COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

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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 -90°C to -60°C storage for up to 6 months from the date of manufacture.
	  ○ Date on packaging is date of manufacture. Expiry date is 6 months from date of manufacture.
	• Prior to dilution, thawed vials can be stored:
	  ○ in the refrigerator at +2°C to +8°C for up to 10 weeks or
	  ○ at room temperature (up to +25°C) for no more than 12 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 12 hours.
	• Diluent is **single** use. Once the 1.3 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.
	• 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.
	Notes:
	• At +2°C to +8°C, it will take a carton of 10 vials up to 4 hours to thaw from ultra-frozen.
	• At room temperature, it will take a carton of 10 vials approximately 30 minutes to thaw from ultra-frozen.	

Packaging	**Vaccine:** • 10 doses per vial • 100 doses per carton **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.	

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 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.
	  ○ Thaw for 4 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 1.3 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 1.3 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.	

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	5. Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 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 **12 hours** after dilution. **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	COVPB5y-11ymRNA	
Antigen Code	COVID-19-11	
Licensed Use	• 5 years to 11 years of age	

Program Notes

- 2021 November 19: Licensed for use in Canada
- 2021 November 26: Implemented in Alberta, clarified administration of COVID-19 vaccine with other vaccines
- 2021 December 21: Updated wording with respect to shortened intervals

Related Resources

- Alberta Health Services Website (2021). COVID-19 Vaccine Information
- Preparation of Pfizer-BioNTech COVID-19 Vaccine for Ages 5 to 11 Years
- See Pfizer-BioNTech COVID-19 Vaccine resources www.CVDvaccine.ca for additional information

References

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