COVID-19 Vaccine – mRNA
Pfizer Monovalent (Comirnaty) – Ultra Frozen Vaccine
Children 6 Months to 4 Years of Age Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.219**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
Approval Date:	November 14, 2022	**Revised:**	

	COVID-19 Vaccine – mRNA Pfizer Monovalent (Comirnaty) Ultra Frozen Vaccine **Children 6 Months to 4 Years of Age** 
Manufacturer	Pfizer BioNTech
Biological Classification	• Nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 (original strain) and non-medicinal ingredients • Formulated in lipid nanoparticles (LNPs)
Indications for Provincially Funded Vaccine	**Children 6 months to 4 years of age** • Vaccine type/dosage is based on age at presentation. Children who received one or two doses of Pfizer Comirnaty (3 mcg) and turn 5 years old prior to completing the primary series are recommended to receive the age-appropriate dose(s) of Pfizer Comirnaty (10 mcg) to complete the three dose primary series. • The same mRNA COVID-19 vaccine product should be offered for the complete primary vaccine series. If two different products are administered (i.e., mixed schedule), please refer to Management of COVID-19 vaccine administration errors and deviations
Schedule **See below Schedule for Individuals with Certain Immunocompromising Conditions**	**<u>Primary series 3 doses</u>** • Dose 1: day 0 • Dose 2: at least 8 weeks after dose 1 • Dose 3: at least 8 weeks after dose 2 **Note:** • Recommended spacing between doses is at least 8 weeks. • Currently, there is no direct evidence to establish an optimal interval between doses in the 6 months to 4 years of age population. However, evidence on COVID-19 mRNA vaccines in adolescents and adults shows that extending the interval between the first and second dose in their primary series by several weeks leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer. • Minimum spacing between doses is 21 days and is required for a dose to be considered valid. • A shorter than recommended interval between doses (no less than 21 days) may be considered in certain situations: required for travel, increased risk of infection based on local transmission or the degree of individual risk of exposure. • 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. • While there is no preferential recommendation between Moderna and Pfizer for children 6 months to 4 years of age without eligible immunocompromising conditions, when advising the parent/guardian of a child, immunizers should review the number of doses, the timeline required to complete a primary series and the risk associated with incomplete protection during this timeline.

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	○ The total length of time it takes to complete a three-dose Pfizer primary series at the recommended intervals is 16 weeks, compared to a two-dose Moderna primary series that takes 8 weeks to complete.
Schedule for Individuals with Certain Immunocompromising Conditions	**<u>Primary series 4 doses</u>** • Dose 1: day 0 • Dose 2: 28 days after dose 1 • Dose 3: 8 weeks after dose 2 • Dose 4: 8 weeks after dose 3 **Note:** • A primary series of three doses of the Moderna monovalent vaccine (6m-5yr) is preferentially recommended over the four dose primary series of the Pfizer monovalent vaccine (6m-4yr) for children with eligible immunocompromising conditions. ○ The total length of time it takes to complete a four-dose Pfizer primary series at the recommended intervals is 20 weeks, compared to a three-dose Moderna primary series that takes 12 weeks to complete. ○ When advising the parent/guardian of a child, immunizers should review the number of doses, the timeline required to complete a primary series and the risk associated with incomplete protection during this timeline. This is particularly important if the parent/guardian of a child with eligible immunocompromising conditions requests a Pfizer primary series. • The interval between dose 2 and dose 3 and the interval between dose 3 and 4 is recommended to be 8 weeks because emerging evidence from the older general population indicates that a longer interval will likely result in a better immune response and longer duration of protection. • However, there is heterogeneity among those who are moderately to severely immunocompromised, and risks from COVID-19, as well as the likelihood of a reduced response to vaccines, will vary depending on the immunocompromising condition. Thus, a shortened interval no less than 28 days between dose 2 and 3 and between dose 3 and 4 may be considered for those with increased risk for exposure and greater severity of immunodeficiency, based on their clinician's recommendation. • There are currently no data on the safety, immunogenicity, or efficacy of an additional dose of a COVID-19 vaccine in children 6 months to 4 years of age who are immunocompromised; studies have shown that an additional dose of an mRNA vaccine leads to increased immune response in some adults who are immunocompromised. The additional dose provides another opportunity for those who are immunocompromised to develop a better immune response and in turn better protection against COVID-19. • Specific immunocompromising conditions that make an individual eligible: ○ solid organ transplant recipients - pre-transplant and post-transplant ○ hematopoietic stem cell transplants recipients - pre-transplant and post-transplant while in immunosuppressed state (post-HSCT individuals are generally considered to be immunocompetent after 3 years as long as they are not on immunosuppressive drugs) ○ individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention). ○ Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.

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	○ Individuals receiving chimeric antigen receptor (CAR) T-cell therapy. ○ individuals on: ▪ long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), or ▪ alkylating agents, or ▪ anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or ▪ antimetabolites (e.g. methotrexate, azathioprine, mycophenolate), or ▪ tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or ▪ other agents that are significantly immunosuppressive at clinicians' discretion ○ HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS). ○ individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome). **Note:** • Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered the 4 dose primary 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 (initiation and interval) based on the individual's treatment and unique circumstances. • Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible to restart their COVID-19 vaccine series beginning at least 3 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. • CAR T-cell therapy recipients (who are not HSCT recipients) who received COVID-19 vaccine pre-CAR T-cell therapy are eligible to restart their COVID-19 vaccine series beginning at least 3 months post CAR T-cell therapy. Consultation with their physician is not necessary as long as a clearance letter has been received to proceed with inactivated vaccines. • For individuals who receive both HSCT and CAR T-cell therapy, see the HSCT guidance: ○ Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients ○ Child HSCT Recipients
Interval between previous COVID-19 infection and COVID-19 immunization	For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization. **Note:** • These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request.

<table>
<tr><td></td><td colspan="3">COVID-19 Vaccine – mRNA Pfizer Monovalent (Comirnaty)
Ultra Frozen Vaccine</td><td>  </td></tr>
<tr><td></td><td colspan="4">Children 6 Months to 4 Years of Age</td></tr>
<tr><td></td><td colspan="4">• For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer considered infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days).</td></tr>
<tr><td></td><td rowspan="3">Infection prior to initiation or completion of a primary COVID-19 immunization series</td><td>Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C),</td><td colspan="2">8 weeks after symptom onset or positive test (if asymptomatic).</td></tr>
<tr><td>Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C,</td><td colspan="2">4 to 8 weeks after symptom onset or positive test (if asymptomatic).</td></tr>
<tr><td>History of MIS-C (regardless of immunocompromised status),</td><td colspan="2">Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.</td></tr>
<tr><td>Preferred Use</td><td colspan="4">N/A</td></tr>
<tr><td>Dose</td><td colspan="4">0.2 mL (3 mcg)</td></tr>
<tr><td>Route</td><td colspan="4">Intramuscular injection in the vastus laterlis or deltoid muscle</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="4">Contraindications:
• Persons under 6 months 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
o Polyethylene glycol (PEG). The 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.
o Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
• Anaphylaxis to a previous dose of Pfizer (6m-4yr) 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 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.</td></tr>
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	COVID-19 Vaccine – mRNA Pfizer Monovalent (Comirnaty) Ultra Frozen Vaccine 
	Children 6 Months to 4 Years of Age
Possible Reactions	**Common or very common:** • Pain, tenderness, erythema, and swelling at the injection site • Fever, chills • Fatigue, drowsiness • Headache • Myalgia, arthralgia • Irritability • Loss of appetite • Vomiting, diarrhea • Rash **Uncommon:** • Lymphadenopathy **Rare:** • Allergic reactions • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.

Myocarditis/ Pericarditis	• The clinical trials for children 6 months to 4 years of age did not identify any cases of myocarditis following immunization with a Pfizer vaccine; however, rare, or very rare adverse events that would not be detected with that trial size.
	• At this time, the risk of myocarditis/pericarditis after receiving Pfizer (6m-4yr) vaccine when using extended intervals is unknown. More information is needed.
	• Canadian and international post-market safety surveillance data for other mRNA COVID-19 vaccines in older populations have reported the rare risk of myocarditis and/or pericarditis with mRNA vaccines, which varies by sex, age, interval between doses, vaccine dose, and vaccine product. Current data suggests the risk of myocarditis and/or pericarditis in children 5 to 11 years of age is lower than that of adolescents or young adults.
	• Available information on myocarditis and/or pericarditis following mRNA vaccines (from individuals twelve years of age and older) indicates that cases of myocarditis and pericarditis:
	  ○ occur more commonly after the second dose;
	  ○ more often in adolescents and young adults (12 to 29 years of age);
	  ○ more often in males;
	  ○ more frequently following Moderna COVID-19 vaccines than Pfizer COVID-19 vaccine;
	  ○ typically have onset of symptoms within a week after the receipt of an mRNA COVID-19 vaccine; and
	  ○ the majority of cases were mild, individuals recovered quickly and the investigation into long-term outcomes is ongoing.
	• It is unknown if individuals with a history of previous myocarditis and/or pericarditis are at higher risk of vaccine associated myocarditis and/or pericarditis.
	  ○ Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis 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 the child's clinician be consulted. However, consultation with a clinician is not required to receive COVID-19 vaccines. • In general, individuals who experienced myocarditis (with or without pericarditis) within 6 weeks after receiving a first dose of mRNA COVID-19 vaccine, are advised to defer receiving a second dose until more data is available as per NACI's recommendation. If there is a preference not to wait, decisions around the second dose should be discussed with the child's clinician. • Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can receive the next dose of vaccine when they are symptom free and at least 90 days have passed since previous immunization. • 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 no data on the use of Pfizer (6m-4yr) vaccine in immunocompromised children 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. Exceptions: ▪ SOT clients 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 vaccines.
Other Considerations	• Individuals presenting for immunization do not need to be tested for previous COVID-19 infection. • It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in immunocompromised 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. • Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. • Individuals with COVID-19-like symptoms should not go to an immunization venue in order to minimize the risk of COVID-19 transmission.

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Composition	Each 0.2 mL dose contains: <u>Lipid 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 • sodium chloride • sucrose • tromethamine • tromethamine hydrochloride <u>Other</u> • 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	• Pfizer (6m-4yr) vaccine should not routinely be administered on the same day with other live or inactivated vaccines to children 6 months to 4 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. If the parents/guardians want to proceed after the importance of having a 14 day spacing has been emphasized, COVID-19 immunization can occur on the same day or within 14 days of administration of another 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. ○ In the absence of data, and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test.

	○ 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. • Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses. • A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type ○ Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown. ○ There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients. ○ Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection. • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for 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 not specific to COVID-19 treatment has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.
Appearance	• Thawed - Prior to dilution, the thawed suspension may contain opaque amorphous particles. • Thawed - After dilution, the vaccine will be a white to off-white suspension. Inspect vials to confirm there are no particulates and no discolouration is observed.
Storage	• Can be stored in a freezer between -90°C to -60°C storage for up to 12 months from the date of manufacture. ○ Date on packaging is date of manufacture. Expiry date is 12 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 2.2 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.

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	Children 6 Months to 4 Years of Age
	Notes: • At +2°C to +8°C, it will take a carton of 10 vials up to 2 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 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 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 2 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 2.2 mL of 0.9% Sodium Chloride Injection, into the Pfizer COVID-19 Vaccine vial using a needle 21-gauge or narrower.
	  ○ Diluent is **single** use. Once the 2.2 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 2.2 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 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	COVPB6m-4ymRNA
Antigen Code	COVID-19-14
Licensed for	Primary series: 6 months to 4 years of age
Program Notes: • 2022 September 9: Licensed for use in Canada. • 2022 November 14: Implemented in Alberta.	

Related Resources:

- Alberta Health Services Website (2022). COVID-19 mRNA Vaccine Information Sheet.
- Preparation of Pfizer-BioNTech COVID-19 Vaccine for Ages 6 months to 4 Years.
- See Pfizer-BioNTech COVID-19 Vaccine resources www.CVDvaccine.ca for additional information

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8. National Advisory Committee on Immunization. (2022 March 17). Recommendations on the use of Moderna SpikeVax COVID-19 vaccine in children 6-11 years of age. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/statement-recommendations-use-moderna-spikevax-covid-19-vaccine.pdf
9. Pfizer-BioNTech (updated 2022 September 16). COVID-19 mRNA vaccine, Suspension for Intramuscular Injection. *Product Monograph.* https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf