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

<table>
<thead>
<tr>
<th>Section 7:</th>
<th>Biological Product Information</th>
<th>Standard #: 07.207</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created by:</td>
<td>Provincial Immunization Program</td>
<td></td>
</tr>
<tr>
<td>Approved by:</td>
<td>Provincial Immunization Program</td>
<td></td>
</tr>
<tr>
<td>Approval Date:</td>
<td>November 23, 2021</td>
<td>Revised: June 30, 2023</td>
</tr>
</tbody>
</table>

Note: Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.

**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 their first dose of pediatric Pfizer-BioNTech Original (non-bivalent) 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-BioNTech COVID-19 Original (non-bivalent) vaccine for their second dose.

**Preferred Use**  
N/A

**Dose**  
0.2 mL (10 mcg)

**Route**  
IM in the deltoid or vastus lateralis muscle

**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 Original (non-bivalent) vaccines in adolescents and adults shows that extending the interval between the first and second dose by several weeks 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 an extended interval between the first and second dose may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine.
- Due to the lower risk of myocarditis with the Pfizer-BioNTech COVID-19 vaccine compared to Moderna COVID-19 vaccine, National Advisory Committee on Immunization (NACI) preferentially recommends Pfizer-BioNTech COVID-19 original (non-bivalent) vaccine for individuals 5 to 11 years of age to start and/or complete their primary series.
COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)  
Original (Non-Bivalent) Ultra Frozen Vaccine

Pediatric Formulation 5 Years to 11 Years of Age

Note: Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.

Notes:
- A shortened interval between dose 1 and dose 2 of 21 days as per product monograph may be considered in certain situations: required for travel, work requirement, increased risk for infection based on local transmission and the degree of individual risk of exposure.
- Minimum spacing between dose 1 and dose 2 is 19 days and is required for a dose to be considered valid.
- 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.

Schedule for Individuals with Certain Immunocompromising Conditions

Primary series 3 doses
- Dose 1: day 0
- Dose 2: 28 days after dose 1
- Dose 3: 8 weeks after dose 2

It is recommended that the interval between dose 1 and dose 2 be 28 days and the interval between dose 2 and dose 3 be 8 weeks.
- The interval between dose 2 and 3 is recommended to be 8 weeks because emerging evidence from the general population indicates that a longer interval will likely result in a better immune response and 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 may be considered for those with increased risk of 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 who are immunocompromised; studies have shown that a third dose of an mRNA vaccine leads to increased immune response in some adults who are immunocompromised. An 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 for a third dose:
  - 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.
  - Individuals receiving chimeric antigen receptor (CAR) T-cell therapy.
  - Individuals on:
### COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)

**Original (Non-Bivalent) Ultra Frozen Vaccine**

**Pediatric Formulation 5 Years to 11 Years of Age**

**Note:** Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.

<table>
<thead>
<tr>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight &gt; 10 kg, for ≥ 14 days), or</td>
</tr>
<tr>
<td>▪ alkylating agents, or</td>
</tr>
<tr>
<td>▪ anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or</td>
</tr>
<tr>
<td>▪ antimetabolites (e.g., methotrexate, azathioprine, mycophenolate), or</td>
</tr>
<tr>
<td>▪ tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or</td>
</tr>
<tr>
<td>▪ other agents that are significantly immunosuppressive at clinicians’ discretion</td>
</tr>
<tr>
<td>o HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS).</td>
</tr>
<tr>
<td>o Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).</td>
</tr>
</tbody>
</table>

**Notes:**

- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above could be offered the 3 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 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 without a prior history of HSCT 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 HSCT recipients whose post-HSCT vaccine series were interrupted by CAR T-cell therapy, see the following HSCT guidance:
  - o #08.304 Standard for Immunization of Transplant Candidates and Recipients
  - o Immunization of Child HSCT Transplant Recipients
### COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)  
Original (Non-Bivalent) Ultra Frozen Vaccine  

**Pediatric Formulation 5 Years to 11 Years of Age**  
*Note: Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.*

<table>
<thead>
<tr>
<th>Interval Between Previous COVID-19 Infection and COVID-19 Immunization</th>
<th>For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.</th>
</tr>
</thead>
</table>
| **Notes:**  
- 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.  
- 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 infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days). |

<table>
<thead>
<tr>
<th>Infection prior to initiation or completion of a primary COVID-19 immunization series</th>
<th>Individuals <strong>without</strong> certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C)</th>
<th>8 weeks after a positive test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals <strong>with</strong> certain immunocompromising conditions (as listed above) AND no history of MIS-C</td>
<td>4 to 8 weeks after a positive test</td>
<td></td>
</tr>
<tr>
<td>History of MIS-C (regardless of immunocompromised status)</td>
<td>Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer</td>
<td></td>
</tr>
</tbody>
</table>

| 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 may not be an absolute contraindication. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.  
**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. |

Alberta Health Services  
Immunization Program Standards Manual  
Provincial Population & Public Health  
Standard #07.207  
June 30, 2023  
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## Myocarditis

- 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 occur at the frequency less often than 1 in 1,000 would not be detected with that trial size.
- Preliminary real world safety data available to date are reassuring. As of December 19, 2021, the U.S. has administered about 8.7 million doses of pediatric Pfizer-BioNTech COVID-19 vaccine to individuals aged 5 to 11 years (21-day interval between doses). Overall, 12 confirmed cases of myocarditis have been reported to the Vaccine Adverse Event Reporting System (VAERS).
- From the safety surveillance data from the U.S:
  - The cases of myocarditis among the 5 to 11 year old population appear to have similar characteristics to those reported in older age groups; onset usually within a week after immunization, more often after the second dose, more often in males than females, and the majority of individuals tend to recover quickly.
  - The risk of myocarditis/pericarditis may be lower in children aged 5 to 11 years of age following pediatric Pfizer-BioNTech COVID-19 vaccine compared to adolescents and young adults who receive a 30 mcg formulation of the Pfizer-BioNTech COVID-19 vaccine.
  - Among children 5 to 11 years of age, the reported rate of myocarditis in males after dose 2 is around 4.3 cases per million doses administered.
- More information will assist in further assessment of the risk of myocarditis/pericarditis among individuals aged 5 to 11 years of age. At this time, the risk of myocarditis/pericarditis after the second dose when using an extended interval of at least 8 weeks among children ages 5 to 11 years of age and the safety of a third dose of COVID-19 vaccine in individuals aged 5 to 11 years of age are unknown.
- 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.
- Individuals who experienced myocarditis 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.
- 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.
**COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)**

**Original (Non-Bivalent) Ultra Frozen Vaccine**

Pediatric Formulation 5 Years to 11 Years of Age

Note: Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.

- 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 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 vaccine.

### Other Considerations

- 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.
  - 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 and 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
### COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)

**Original (Non-Bivalent) Ultra Frozen Vaccine**

#### Pediatric Formulation
5 Years to 11 Years of Age

**Note:** Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.

<table>
<thead>
<tr>
<th>Side Effects</th>
</tr>
</thead>
</table>
| • Skin and subcutaneous tissue disorders (including skin rash, dermatitis, eczema, urticarial)  
  • Lymphadenopathy |
| **Uncommon:** |
| • 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

<table>
<thead>
<tr>
<th>Component</th>
</tr>
</thead>
</table>
| • ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diy)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 may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines) to individuals 6 months of age and older.  
  
  This is based on vaccine principles, better knowledge of the safety of COVID-19 mRNA vaccines in children 6 months of age and older, and the need to improve uptake of routine vaccines which has been negatively impacted by the COVID-19 pandemic.  
  
  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, repeat tuberculin skin testing or IGRA (at least 4 weeks after a dose of COVID-19 vaccine) of individuals with negative results for whom there is high suspicion of latent tuberculosis may be considered 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
COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty) Original (Non-Bivalent) Ultra Frozen Vaccine

Pediatric Formulation 5 Years to 11 Years of Age

Note: Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.

<table>
<thead>
<tr>
<th>Pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses.</th>
</tr>
</thead>
<tbody>
<tr>
<td>o 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.</td>
</tr>
<tr>
<td>o 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.</td>
</tr>
<tr>
<td>o There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.</td>
</tr>
<tr>
<td>o Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who received the monoclonal antibodies or convalescent plasma for their infection.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen – white to off-white solution</td>
</tr>
<tr>
<td>Thawed – may contain white to off-white opaque particles</td>
</tr>
<tr>
<td>Thawed and reconstituted – off white solution with no visible particulates</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be stored in a freezer between -90°C to -60°C storage for up to 18 months from the date of manufacture.</td>
</tr>
<tr>
<td>o Date on packaging is date of manufacture. Expiry date is 18 months from date of manufacture.</td>
</tr>
<tr>
<td>o Prior to dilution, thawed vials can be stored:</td>
</tr>
<tr>
<td>o in the refrigerator at +2°C to +8°C for up to 10 weeks or</td>
</tr>
<tr>
<td>o at room temperature (up to +25°C) for no more than 12 hours</td>
</tr>
<tr>
<td>Do not refreeze.</td>
</tr>
<tr>
<td>o 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.</td>
</tr>
<tr>
<td>o 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.</td>
</tr>
<tr>
<td>o During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.</td>
</tr>
<tr>
<td>o After dilution, the vaccine vials can be handled in room light conditions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>o At +2°C to +8°C, it will take a carton of 10 vials up to 4 hours to thaw from ultra-frozen.</td>
</tr>
<tr>
<td>o At room temperature, it will take a carton of 10 vials approximately 30 minutes to thaw from ultra-frozen.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine:</td>
</tr>
<tr>
<td>10 doses per vial</td>
</tr>
<tr>
<td>100 doses per carton</td>
</tr>
<tr>
<td>Diluent:</td>
</tr>
<tr>
<td>Diluent is provided in 10 mL plastic vials (latex-free, preservative-free).</td>
</tr>
<tr>
<td>Packaged in cartons of 25 vials and can be stored at room temperature.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preparation/Reconstitution</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

| Thaw vaccine before use: |
### COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)
#### Original (Non-Bivalent) Ultra Frozen Vaccine

<table>
<thead>
<tr>
<th>Pediatric Formulation 5 Years to 11 Years of Age</th>
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<tr>
<td><strong>Note:</strong> Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.</td>
</tr>
</tbody>
</table>

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.

**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 1.3 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.
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.

<table>
<thead>
<tr>
<th>Vaccine Code</th>
<th>COVPB5y-11ymRNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigen Code</td>
<td>COVID-19-11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Licensed Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary series: 5 years to 11 years of age</td>
</tr>
<tr>
<td>First booster: 5 years to 11 years of age at least 6 months after completion of a primary series</td>
</tr>
</tbody>
</table>

**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.
- 2022 February 14: Updated to incorporate NACI recommendations for children 5-11 years of age with certain immunocompromising conditions to receive a three dose primary series.
- 2022 March 2: Updated to incorporate NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization.
- 2022 April 11: Included link to “COVID-19 Immunization for Individuals with Allergies and Other Health Conditions”.
- 2022 June 1: Updated to include recommendation for immunization post CAR-T cell therapy and extended storage time in an ultra-frozen state.
- 2022 June 11: Updated to lift restrictions on co-administration with other vaccines and removed reference to rescinded orders 02-2022 and 04-2022.
COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)
Original (Non-Bivalent) Ultra Frozen Vaccine

**Pediatric Formulation 5 Years to 11 Years of Age**

**Note:** Both Pfizer-BioNTech Original (Non-Bivalent) and bivalent COVID-19 vaccines for 5-11 years of age have orange caps and orange labels. To avoid medication errors, pay close attention to vial and carton label.

- 2023 January 5: Updated booster dose indications.
- 2023 March 1: Removed booster dose recommendations as no longer offering product as a booster. Removed off-license section.
- 2023 April 21: Removed references to Moderna Spikevax Original for primary series as vaccine is no longer available in Alberta. for this age group.
- 2023 June 30: Storage updated to indicate product can be stored for up to 18 months prior to being thawed.

**Related Resources**
- Preparation of Pfizer-BioNTech COVID-19 Vaccine for Ages 5 to 11 Years.
- See Pfizer-BioNTech COVID-19 Vaccine resources [www.CVDvaccine.ca](http://www.CVDvaccine.ca) for additional information.

**References**