COVID-19 Vaccine – mRNA Pfizer-BioNTech - Bivalent (Original and Omicron BA.4/BA.5) - Frozen Vaccine (Comirnaty) Biological Page

**Orange Cap and Label**

*Note: Both Pfizer-BioNTech original (non-bivalent) and bivalent 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**
- A dose is recommended for all individuals 5 to 11 years of age who have completed a primary series of COVID-19 vaccine and have not previously received an mRNA original (non-bivalent) COVID-19 booster dose.
  - At this time, healthy children 5 to 11 years of age who already received an mRNA original (non-bivalent) booster dose are considered up to date and an Omicron-containing bivalent booster dose is not indicated.
- However, a booster dose is most important for individuals considered at increased risk of severe COVID-19 disease (including those who are immunocompromised and who received a 3-dose primary series). Therefore, children with underlying medical conditions listed below who previously received an mRNA original (non-bivalent) COVID-19 booster dose may receive an Omicron-containing bivalent booster dose.
  - cerebrovascular disease
  - chronic kidney disease on peritoneal dialysis or hemodialysis
  - chronic liver diseases
  - chronic lung diseases
  - cystic fibrosis
  - diabetes mellitus: type 1 and type 2
  - disabilities (e.g., Down syndrome, learning, intellectual, or developmental disabilities; spinal cord injuries)
  - heart conditions (e.g., cardiomyopathies, coronary artery disease, heart failure, etc.)
  - mental health disorders
  - obesity
  - primary immunodeficiency diseases
  - 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
COVID-19 Vaccine - mRNA Pfizer BioNTech Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine (Comirnaty) Pediatric Formulation 5-11 Years of Age

Individuals 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 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
  - antimitabolites (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
- Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).

Note:
- Documentation of underlying medical conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered the Omicron-containing bivalent mRNA booster.
- Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Individuals are recommended to consult with their physician regarding the timing of immunization based on their individual treatment and unique circumstances, respecting the NACI recommended minimum spacing of at least 6 months since last COVID-19 dose (or infection). See exception below for HSCT / CAR T-cell therapy recipients.
- 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.
- If requested by their specialist, a shortened interval of at least 3 calendar months between the previous COVID-19 vaccine dose (or infection) and the Omicron-containing bivalent booster dose may be provided for HSCT and/or CAR T-cell therapy recipients. A written request from the specialist is not required if the client provides verbal confirmation.
<table>
<thead>
<tr>
<th>Preferred Use</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>Booster 0.2 mL (10 mcg)</td>
</tr>
<tr>
<td>Route</td>
<td>IM in the deltoid or vastus lateralis muscle</td>
</tr>
</tbody>
</table>

### Schedule
**Booster dose**
- At least 6 calendar months after the last dose of COVID vaccine (regardless of vaccine type) or infection

**Note:**
- A longer interval of at least 6 calendar months leads to a better immune response against COVID-19 that is also expected to last longer, because it allows time for the immune response to mature in breadth and strength.

### Contraindications/
**Precautions**
- Known severe hypersensitivity to any component of the vaccine.
- Two non-medicinal ingredients in the vaccine have been associated with allergic reactions in other products:
  - 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.
  - Tromethamine (trometamol or Tris) – component 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.
- 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.
- There are no clinical data currently available for the use of Pfizer-BioNTech bivalent (Original & Omicron BA.4/BA.5) vaccine in children 5 to 11 years of age. However, indirect data (clinical and post-market safety data from Pfizer-BioNTech Comirnaty BA.1 Bivalent and Comirnaty original (non-bivalent) mRNA vaccine, respectively) suggest that Pfizer-BioNTech Comirnaty BA.4/5 Bivalent (30 mcg) will likely be well tolerated with a similar safety profile to Comirnaty original (non-bivalent)(10 mcg) and Comirnaty BA.1 Bivalent (10 mcg), when used as a booster dose.

### Myocarditis/Pericarditis
- The safety of a booster dose of Pfizer-BioNTech Original & Omicron BA.4/BA.5 at 10 mcg in children 5 to less than 12 years of age is inferred primarily from the safety profile of COMIRNATY at 10 mcg administered as a booster dose in this age bracket.
- 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 effects cannot be completely ruled out.
<table>
<thead>
<tr>
<th><strong>COVID-19 Vaccine - mRNA Pfizer BioNTech Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine (Comirnaty)</strong></th>
<th><strong>Pediatric Formulation 5-11 Years of Age</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>events that occurs at the frequency less often than 1 in 1,000 would not be detected with that trial size.</td>
</tr>
<tr>
<td></td>
<td>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).</td>
</tr>
<tr>
<td></td>
<td>From the safety surveillance data from the U.S.:</td>
</tr>
<tr>
<td></td>
<td>o 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.</td>
</tr>
<tr>
<td></td>
<td>o 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.</td>
</tr>
<tr>
<td></td>
<td>o 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.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.2</td>
</tr>
<tr>
<td></td>
<td>o However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>o 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.</td>
</tr>
<tr>
<td></td>
<td>It is unknown if individuals with a history of previous myocarditis are at higher risk of vaccine-associated myocarditis.</td>
</tr>
<tr>
<td></td>
<td>Anyone receiving an mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Other Considerations</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.</td>
</tr>
<tr>
<td></td>
<td>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 should not be used as evidence to inform whether vaccine doses have been effective.</td>
</tr>
<tr>
<td></td>
<td>Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.</td>
</tr>
</tbody>
</table>
COVID-19 Vaccine - mRNA Pfizer BioNTech Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine (Comirnaty) 
Pediatric Formulation 5-11 Years of Age

- 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.

Possible Reactions

There is currently no clinical evidence on the safety of this bivalent vaccine in children 5 – 11 years of age. Therefore, reactions are inferred from the safety data following a booster dose of Pfizer-BioNTech original (non-bivalent) vaccine in this age group. In addition, safety data for individuals 12 years and older who received Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) vaccine is considered supportive of its use in younger individuals, and those reactions are included here with *.

**Common:**
- Pain, redness, and swelling at the injection site
- Fever, chills
- Fatigue
- Headache, myalgia, arthralgia
- Vomiting, diarrhea
- Lymphadenopathy
- Pain in extremity*
- Nausea*

**Uncommon:**
- Malaise*
- Asthenia*
- Decreased appetite*
- Hyperhidrosis*
- Lethargy*
- Night sweats*

**Rare:**
- Anaphylaxis
- Allergic reaction
- Facial swelling/Bell’s Palsy*
- Myocarditis/pericarditis*
- Erythema multiforme*
- Hypoesthesia* (decreased sense of touch or sensation, numbness) or paraesthesia* (tingling, itching or prickling sensation)
- Skin rash*
- As with any immunization, unexpected or unusual side effects can occur

Refer to product monograph for more detailed information

Composition

Each 0.2 mL dose contains:
Tozinameran encodes for the viral spike protein of SARS-CoV-2 Original strain and famtozinameran encodes for the viral spike(s) protein of SARS-CoV-2 Omicron BA.4/BA.5 strain.

Non-medicinal ingredients:

**Lipid nanoparticles (these help the mRNA enter the cell):**
- ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diy)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (PEG)

**Other Lipids: (provide structural integrity of the nanoparticles)**
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- cholesterol

**pH Stabilizers:**
- tromethamine
<table>
<thead>
<tr>
<th>COVID-19 Vaccine - mRNA Pfizer BioNTech Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine (Comirnaty) Pediatric Formulation 5-11 Years of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingredients:</strong></td>
</tr>
<tr>
<td>• tromethamine hydrochloride</td>
</tr>
<tr>
<td><strong>Other:</strong></td>
</tr>
<tr>
<td>• sodium chloride</td>
</tr>
<tr>
<td>• sucrose (protects the nanoparticles when frozen)</td>
</tr>
<tr>
<td>• water for injection</td>
</tr>
<tr>
<td>No adjuvants or preservatives</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blood/Blood Products</th>
<th>Contains no human blood/blood products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bovine/Porcine Products</td>
<td>Contains no bovine/porcine products</td>
</tr>
<tr>
<td>Latex</td>
<td>Does not contain latex</td>
</tr>
</tbody>
</table>

**Interchangeability**

- Can be used as a booster dose following any previously received COVID-19 vaccines.

**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.
- There are currently limited data available on whether the reactogenicity of COVID-19 vaccines is increased with concurrent administration of other vaccines. No specific safety concerns have been identified to date. Studies to assess the safety and immunogenicity of concurrent administration of COVID-19 vaccines with other vaccines are ongoing.
- 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 post- COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered in order to avoid missing persons with TB infection.
- **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, the response was 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 received the monoclonal antibodies or convalescent plasma for their infection. **Note:** Anti-
| COVID-19 Vaccine - mRNA Pfizer BioNTech Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine (Comirnaty)  
Pediatric Formulation 5-11 Years of Age |
|------------------------------------------------|
| SARS-CoV-2 monoclonal antibodies or convalescent plasma should not be administered concomitantly with COVID-19 vaccines (i.e. administer on different days).  
- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis 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. |
| **Appearance** |  
- Thawed (prior to mixing) – may contain white to off-white opaque particles.  
- Thawed (after mixing) – white to off-white with no visible particles. |
| **Storage** |  
- Before being thawed, can be stored in a freezer between -90°C to -60°C storage for up to 18 months.  
- Do not store at -25°C to -15°C.  
- 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 first puncture, the vaccine can be stored at +2°C to +25°C for up to 12 hours.  
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.  
- Thawed vials can be handled in room light conditions. |
| **Packaging** | Vaccine:  
- 10 doses per vial  
- 10 multiple dose vials per carton |
| **Preparation/Reconstitution** | The Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) 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:**  
- 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 6 hours in the refrigerator; and allow the vial to come to room temperature before use.  
**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 Bivalent (Original and Omicron BA.4/BA.5) 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. |
### COVID-19 Vaccine - mRNA Pfizer BioNTech Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine (Comirnaty) Pediatric Formulation 5-11 Years of Age

- This is to prevent any vaccine loss through spraying out due to higher pressure.
- Gently invert the vial again 10 times to mix. Do not shake.
- Inspect the vial to confirm there are no particulates and no discoloration is observed.
- Record the date and time of dilution on the Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) COVID-19 Vaccine vial label.
- Store between +2°C to +25°C.
- 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>COVPB5-11mRNA45</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigen Code</td>
<td>COVID-19-21</td>
</tr>
<tr>
<td>Licensed for</td>
<td>A booster dose for individuals 5 to 11 years of age and at least 6 months after completion of a primary series.</td>
</tr>
</tbody>
</table>

**Program Notes:**
- 2023 January 5: Implemented in Alberta.
- 2023 March 1: Updated language to align with other COVID-19 vaccine biological pages.
- 2023 March 21: Updated booster spacing considerations to 6 months after last dose or infection.
- 2023 June 30: Storage updated to indicate product can be stored for up to 18 months prior to being thawed.

**Related Resources:**
- Alberta Health Services Website (2022). COVID-19 Vaccine Information
- See [www.CVDvaccine.ca](http://www.CVDvaccine.ca) for additional information

**References:**
COVID-19 Vaccine - mRNA Pfizer BioNTech Bivalent (Original and Omicron BA.4/BA.5) – Frozen Vaccine (Comirnaty)  
Pediatric Formulation 5-11 Years of Age


