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

**Biological Page**

<table>
<thead>
<tr>
<th>Section 7:</th>
<th>Biological Product Information</th>
<th>Standard #: 07.223</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created by:</td>
<td>Provincial Immunization Program Standards and Quality</td>
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<tr>
<td>Approved by:</td>
<td>Provincial Immunization Program Standards and Quality</td>
<td></td>
</tr>
<tr>
<td>Approval Date:</td>
<td>August 2, 2023</td>
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</tr>
</tbody>
</table>

**5 to 11 years of age**
(orange cap with orange label)

**12 years of age and older**
(gray cap with gray 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**

### Primary series:
- All individuals 5 to 11 years of age.

### Booster dose:
- All individuals 5 to 11 years of age.
- Refer to booster dose section for additional details.

### Primary series:
- All individuals 12 years of age and older.

### Booster dose:
- All individuals 12 years of age and older.
- Refer to booster dose section for additional details.

**Preferred Use**

| Dose | 0.2 mL (10mcg) | 0.3 mL (30mcg) |
| Route | IM in the deltoid or vastus lateralis muscle |

**Schedule**

See below Schedule for individuals with certain immunocompromising conditions

**Primary series: 2 doses (healthy individuals 5 years of age and older)**

- Dose 1: Day 0
- Dose 2: At least 8 weeks after dose 1

**Note:**

- Recommended spacing between doses is at least 8 weeks.
- Minimum spacing between doses is 3 weeks. However, minimum spacing is not to be used for scheduling purposes and should only be used to assess the validity of doses given in error.
- If a primary series was started with an original monovalent vaccine (either mRNA or non-mRNA), a bivalent Omicron-containing vaccine can be used to complete the series.
- For individuals 12 to 29 years of age, Pfizer-BioNTech Comirnaty bivalent BA.4/5 is preferred over Moderna Spikevax bivalent BA.4/5 due to a lower risk of myocarditis and/or pericarditis observed after dose 1 and dose 2 of the primary series with Pfizer-BioNTech Comirnaty original (30 mcg) compared to Moderna Spikevax original (100 mcg).
### Schedule for individuals with certain immunocompromising conditions

<table>
<thead>
<tr>
<th>Primary Series: 3 doses (5 years of age and older)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dose 1: Day 0</td>
</tr>
<tr>
<td>• Dose 2: 28 days after dose 1</td>
</tr>
<tr>
<td>• Dose 3: 8 weeks after dose 2</td>
</tr>
</tbody>
</table>

**Note:**

- It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of a bivalent mRNA COVID-19 vaccine. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines. A bivalent mRNA vaccine should be administered except in the event of contraindication or refusal.

- For children who initiated their primary series between 6 months and 4 years of age, and who received at least one dose of Pfizer original (monovalent) vaccine, a total of 4 doses are required to complete the primary series.

- It is recommended that the interval between dose 1 and dose 2 be 28 days and the interval between dose 2 and dose 3, and between dose 3 and 4 if required, be 8 weeks.

- The interval between dose 2 and dose 3, and between dose 3 and 4 if required, 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 of risk from COVID-19 among those who are moderately to severely immunocompromised. In addition, 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.

- If a primary series was started with an original monovalent vaccine (either mRNA or non-mRNA), a bivalent Omicron-containing vaccine can be used to complete the series.

- Individuals who are moderately to severely immunocompromised may benefit from a primary series with Moderna Spikevax bivalent compared to Pfizer-BioNTech Comirnaty bivalent BA.4/5.

- However, for individuals 12 to 29 years of age, Pfizer-BioNTech Comirnaty bivalent BA.4/5 is preferred over Moderna Spikevax bivalent BA.4/5 due to a...
5 to 11 years of age
(orange cap with orange label)

12 years of age and older
(gray cap with gray label)

Lower risk of myocarditis and/or pericarditis observed after dose 1 and dose 2 of the primary series with Pfizer-BioNTech Comirnaty original (30 mcg) compared to Moderna Spikevax original (100 mcg).

- Moderna can be provided if preferred by an individual or their specialist. See the precautions section for further information on myocarditis/pericarditis.

- Immunocompromised individuals who are 5 years of age or older may receive a mixed primary series schedule. Regardless of which COVID-19 vaccine product is offered, the previous dose(s) should be counted, and the series should not be restarted.

- Specific immunocompromising conditions that make an individual eligible for an additional bivalent mRNA COVID-19 dose in the primary series or additional booster include:
  - Solid organ transplant recipients – pre-transplant and post-transplant
  - Hematopoietic stem cell transplant 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 while 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:
    - 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
    - Individuals on 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 3 dose primary series.
- Immunization of 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 if 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 who had their post-HSCT vaccine series interrupted by CAR T-cell therapy, see the following HSCT guidance:
  - Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients
  - Immunization for Adult HSCT Recipients
  - Immunization for Child HSCT Recipients

<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>
<tbody>
<tr>
<td>Note:</td>
<td>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 risk of 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.</td>
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<td>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 (except for those with MIS-C who should wait at least 90 days).</td>
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<td>Infection prior to initiation or completion of a primary</td>
<td>Individuals <strong>without</strong> certain immunocompromising conditions AND no history of multisystem 8 weeks after a positive test.</td>
</tr>
<tr>
<td>5 to 11 years of age (orange cap with orange label)</td>
<td>12 years of age and older (gray cap with gray label)</td>
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<tr>
<td>--------------------------------------------------</td>
<td>----------------------------------------------------</td>
</tr>
<tr>
<td>Individuals <strong>with</strong> certain immunocompromising</td>
<td>4 to 8 weeks after a positive test.</td>
</tr>
<tr>
<td>conditions (as listed above) AND no history of MIS-C.</td>
<td></td>
</tr>
<tr>
<td>History of MIS-C (regardless of immunocompromised</td>
<td>Receive the vaccine when clinical recovery has been</td>
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<tr>
<td>status).</td>
<td>achieved or at least 90 days since the onset of MIS-C,</td>
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<td></td>
<td>whichever is longer.</td>
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</tbody>
</table>

**Booster Doses**

**5 to 11 years of age (Orange cap with orange label)**

- A single bivalent booster dose is recommended for children 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 least 6 calendar months after the last dose of COVID-19 vaccine (regardless of vaccine type) or infection.

**Note:** Healthy children 5 to 11 years of age who already received an original (non-bivalent) booster dose are considered up to date and an additional Omicron-containing bivalent booster dose is not indicated.

**Additional booster dose for children 5 to 11 years of age:**

- Children who have **immunocompromising conditions** listed above or any of the following conditions who previously received an original (non-bivalent) COVID-19 booster dose are eligible for an Omicron-containing bivalent booster dose:
  - Cerebrovascular disease
  - Chronic liver diseases
  - Chronic lung diseases
  - Cystic fibrosis
  - Diabetes mellitus: type I and II
  - Disabilities (Down Syndrome, learning, intellectual, or developmental disabilities; spinal cord injuries)
  - Heart conditions (cardiomyopathies, coronary artery disease, heart failure, etc.)
  - Mental health disorders
  - Obesity
  - Primary immunodeficiency diseases
  - Tuberculosis

- 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.

**12 years of age and older (Gray cap with gray label)**
### 5 to 11 years of age  
(orange cap with orange label)

- All individuals 12 years of age and older are eligible for a single bivalent booster dose.
  - At least 6 calendar months after completion of a primary series or any non-bivalent booster dose (*regardless of vaccine type*) or infection.
- 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.
- 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.

### 12 years of age and older  
(gray cap with gray label)

- The following individuals are eligible for an additional bivalent COVID-19 booster dose:
  - Individuals 65 years of age and older.
  - Individuals 18 years of age and older who are residents of a long-term care facility or other congregate care living setting.
  - Individuals 18 years of age and older who are moderately to severely immunocompromised (due to underlying condition or treatment).
    - At least 6 calendar months after previous bivalent booster dose or infection.
    - A shortened interval of at least 3 calendar months between the previous COVID-19 vaccine dose (or infection) and the Omicron-containing bivalent booster may be considered for individuals who are living in a long-term care facility or in other congregate care living settings. However, 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.
    - 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.

### Additional booster dose for adults

- Applicable congregate care settings include, but are not limited to, all private and public long-term care facilities, licensed supportive living facilities and seniors’ lodges including First Nations elder care lodges. Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Clients 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).

### Contraindications/Precautions

**Contraindications:**
- 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). 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.
5 to 11 years of age (orange cap with orange label)

- 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.

- 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.4/5) 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 (10 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.

- Available evidence from Canada and internationally show that overall, the safety profile of bivalent mRNA COVID-19 vaccine boosters is comparable to that of original mRNA vaccine boosters among individuals 5 years of age and older.

- Despite the limited evidence on the use of bivalent vaccines as a primary series, the precautionary principle indicates that scientific uncertainty should not prevent decision makers from taking action to reduce risks associated with COVID-19.

- Use of bivalent vaccines for the primary series primes naïve individuals with both Omicron and original SARS-CoV-2 variants which will help to maximize the breadth of immunity at the earliest opportunity.

12 years of age and older (gray cap with gray label)

Myocarditis/Pericarditis

- Very rare cases of myocarditis and/or pericarditis following immunization with Pfizer-BioNTech vaccines have been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescent and young adults. Typically, the onset of symptoms has been within a few days following receipt of the vaccine.

- The risk of myocarditis and/or pericarditis after a primary series dose of an original mRNA COVID-19 vaccine in children 5 to 11 years of age is now known to be substantially lower compared to the risk following mRNA COVID-19 vaccines in individuals 12 to 29 years of age (in whom the risk of myocarditis and/or pericarditis is the highest) and individuals 30 to 49 years of age (in whom there is no preference between Pfizer-BioNTech Comirnaty original or Moderna Spikevax original for the primary series). However, it should be noted that the low rates of myocarditis and/or pericarditis with the primary series in children 5 to 11 years of age have been in the context of the predominant use of Pfizer-BioNTech Comirnaty original (10 mcg) in this age group.

- 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.

- 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 these individuals have questions or concerns about their 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 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 be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.

- 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.

- 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.

- Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.

- It is unknown if individuals with a history of previous myocarditis are at higher risk of vaccine-associated myocarditis.

- 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.

- 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.

- A possible association between Pfizer-BioNTech Comirnaty bivalent BA.4/5 booster and ischemic stroke in persons 65 years of age and older was identified by the US Vaccine Safety Datalink (VSD) in January 2023. To date, the totality of the US data suggests that it is very unlikely that the potential signal in VSD represents a true clinical risk and a similar signal has not been identified in Canada, Israel, Europe, and Singapore. Monitoring of the potential safety signal is ongoing.

### Pregnancy

- A complete COVID-19 vaccine series should be offered to pregnant individuals regardless of trimester of pregnancy. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.

- The safety and efficacy of Pfizer-BioNTech Bivalent Original/Omicron BA.4/5 in pregnant women has not yet been established.

- However, data available on the original mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. The bivalent COVID-19 mRNA vaccines can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.

  - Evidence to date shows that COVID-19 immunization during pregnancy is safe and does not increase risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or other adverse pregnancy/birth outcomes.
5 to 11 years of age
(orange cap with orange label)

12 years of age and older
(gray cap with gray label)

- It is recommended that individuals consult with their primary health care provider or obstetrician for any vaccine related questions or concerns.
- However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.

Additional resources:
Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy

**Lactation**

- It is unknown whether this vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded.
- Recent reports have shown that breastfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine the level of protection these antibodies might provide to the baby.
- A complete COVID-19 vaccine primary series is recommended for individuals who are breastfeeding.
  - It is recommended that individuals consult their primary health care provider or medical specialist for any vaccine related questions or concerns.
  - However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.

**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 individuals and 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.
- To minimize the risk of COVID-19 transmission, individuals with COVID-19-like symptoms should defer their immunization appointment.

**Possible Reactions**

The safety of a primary vaccination course or booster dose of Comirnaty Original & Omicron BA.4/BA.5 for individuals 5 years of age and older is inferred from:

- safety data from clinical trials which evaluated primary and booster vaccination with Comirnaty;
- safety data for a booster dose of Comirnaty Original & Omicron BA.4/BA.5; and
- post marketing safety data with Comirnaty.

**Common:**
- Pain, redness, and swelling at the injection site
- Fever, chills
- Fatigue

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- Pain, redness, and swelling at the injection site
- Fever, chills
- Fatigue
### 5 to 11 years of age
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- Headache, myalgia, arthralgia
- Vomiting, diarrhea
- Pain in extremity*
- Nausea*

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

**Rare:**
- Anaphylaxis
- Allergic reaction
- Facial swelling/Bell’s Palsy*
- Myocarditis/pericarditis*
- Erythema multiforme*
- Hypoaesthesia* (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

*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 *

Refer to product monograph for more detailed information

### 12 years of age and older
(gray cap with gray label)

- Headache, myalgia, arthralgia
- Pain in extremity*
- Nausea*, vomiting, diarrhea

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

**Rare:**
- Anaphylaxis
- Allergic reaction
- Facial swelling/Bell’s Palsy*
- Myocarditis/pericarditis*
- Erythema multiforme*
- Hypoaesthesia* (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

*No reported cases following Pfizer-BioNTech Omicron-containing bivalent during the study period; however, these were reported following Pfizer-BioNTech (original)

Refer to product monograph for more detailed information

### Composition

<table>
<thead>
<tr>
<th>0.2 mL dose contains:</th>
<th>0.3 mL dose contains:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tozinameran encodes for the viral spike protein of SARS-CoV-2 Original strain and famtozinameran encodes for the viral spike protein of SARS-CoV-2 Omicron BA.4/BA.5 strain.</td>
<td>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.</td>
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### 5 to 11 years of age
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<table>
<thead>
<tr>
<th>Non-medicinal ingredients:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipid nanoparticles (these help the mRNA enter the cell):</td>
</tr>
<tr>
<td>• ALC-0315 = ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
</tr>
<tr>
<td>• ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (PEG)</td>
</tr>
<tr>
<td>Other Lipids: (provide structural integrity of the nanoparticles)</td>
</tr>
<tr>
<td>• 1,2-distearoyl-sn-glycero-3-phosphocholine</td>
</tr>
<tr>
<td>• cholesterol</td>
</tr>
<tr>
<td>pH Stabilizers:</td>
</tr>
<tr>
<td>• tromethamine</td>
</tr>
<tr>
<td>• tromethamine hydrochloride</td>
</tr>
<tr>
<td>Other:</td>
</tr>
<tr>
<td>• sodium chloride</td>
</tr>
<tr>
<td>• sucrose (protects the nanoparticles when frozen)</td>
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<tr>
<td>• water for injection</td>
</tr>
</tbody>
</table>

No adjuvants or preservatives

### 12 years of age and older
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No adjuvants or preservatives

<table>
<thead>
<tr>
<th>Blood/Blood Products</th>
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</thead>
<tbody>
<tr>
<td>Does not contain blood/blood products</td>
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<table>
<thead>
<tr>
<th>Bovine/Porcine Products</th>
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<tbody>
<tr>
<td>Does not contain bovine/porcine products</td>
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<thead>
<tr>
<th>Latex</th>
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<tbody>
<tr>
<td>Does not contain latex</td>
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<th>Interchangeability</th>
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**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.

- Currently there are 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, 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.
• Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference.

Note:
• 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 Rhlg) 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 from the date of manufacture.
• 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
Vaccine:
• 6 doses per vial
• 10 multiple dose vials per carton
### Preparation/Reconstitution

<table>
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<tr>
<th>Age Group</th>
<th>Details</th>
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<tr>
<td><strong>5 to 11 years of age</strong>&lt;br&gt; (orange cap with orange label)</td>
<td>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. <strong>Thaw vaccine before use:</strong>&lt;br&gt; - Vials may be thawed in the refrigerator (+2°C to +8°C) or at room temperature (up to +25°C).&lt;br&gt;  - Thaw for 30 minutes at room temperature.&lt;br&gt;  - Thaw for 6 hours in the refrigerator; and allow the vial to come to room temperature before use.&lt;br&gt; <strong>Dilute before use:</strong>&lt;br&gt;  1. Before dilution, invert gently 10 times to mix. Do not shake.&lt;br&gt;  2. Dilution with sterile 0.9% Sodium Chloride Injection is required. (Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.)&lt;br&gt;  3. Cleanse the vial stopper with a single-use antiseptic swab.&lt;br&gt;  4. Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) COVID-19 Vaccine vial using a needle 21-gauge or narrower.&lt;br&gt;    - 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.&lt;br&gt;  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.&lt;br&gt;  6. Gently invert the vial again 10 times to mix. Do not shake.&lt;br&gt;  7. Inspect the vial to confirm there are no particulates and no discoloration is observed.&lt;br&gt;  8. Record the date and time of dilution on the Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) COVID-19 Vaccine vial label.</td>
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<tr>
<td><strong>12 years of age and older</strong>&lt;br&gt; (gray cap with gray label)</td>
<td><strong>Thaw vaccine before use:</strong>&lt;br&gt; - Vials may be thawed in the refrigerator (+2°C to +8°C) or at room temperature (up to +25°C).&lt;br&gt;  - Thaw for 30 minutes at room temperature.&lt;br&gt;  - Thaw for 6 hours in the refrigerator; and allow the vial to come to room temperature before use.&lt;br&gt; <strong>Mix Before Use:</strong>&lt;br&gt;  - Before use, mix by inverting vial gently 10 times. Do not shake.&lt;br&gt;  - After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.&lt;br&gt;  - Do not use if liquid is discoloured or if particles are observed after mixing.&lt;br&gt;  - Discard any unused vaccine 12 hours after first puncture</td>
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### Vaccine Code
- **5 to 11 years of age (orange cap with orange label):** COVPB5-11mRNA45
- **12 years of age and older (gray cap with gray label):** COVPBmRNABA45

### Antigen Code
- **5 to 11 years of age:** COVID-19-21
- **12 years of age and older:** COVID-19-20

### Licensed for
- **5 to 11 years of age:**
  - Primary series or booster dose for children 5 to 11 years of age.
  - Off-license use:
    - Third dose in a primary series for individuals who are moderately to severely immunocompromised.

- **12 years of age and older:**
  - Primary series or booster dose for individuals 12 years of age and older.
  - Off-license use:
    - Third dose in a primary series for individuals who are moderately to severely immunocompromised.
    - Additional bivalent booster dose for eligible individuals 12 years of age and older.

### Program Notes:
- 2022 October 7: Pfizer-BioNTech Bivalent (Original and Omicron BA.4/5) vaccine 12 years of age and older licensed for use in Canada as a booster.
- 2022 October 24: Pfizer-BioNTech Bivalent (Original and Omicron BA.4/5) vaccine 12 years of age and older implemented in Alberta as a booster.
- 2022 December 09: Pfizer-BioNTech Bivalent (Original and Omicron BA.4/5) vaccine for 5 to 11 years of age licensed for use in Canada as a booster.
- 2023 January 05: Pfizer-BioNTech Bivalent (Original and Omicron BA.4/5) vaccine for 5 to 11 years of age implemented in Alberta as a booster.
- 2023 March 20: Updated to include additional bivalent booster dose indications for eligible individuals and updated booster spacing considerations to 6 months between last dose or infection for Pfizer-BioNTech Bivalent (Original and Omicron BA.4/5) vaccine 12 years of age and older. Updated booster spacing considerations to 6 months after last dose or infection for Pfizer-BioNTech Bivalent (Original and Omicron BA.4/5) vaccine for 5 to 11 years of age.
- 2023 August 01: The Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) vaccines for 5 to 11 years of age and 12 years of age and older are recommended for use for a primary series. The biological pages for the Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) vaccine for 5 to 11 years and the Pfizer-BioNTech Bivalent (Original and Omicron BA.4/BA.5) vaccine for 12 years of age and older have been combined into this document.

### Related Resources:
- Alberta Health Services Website (2022). COVID-19 Vaccine Information
- See [CVDvaccine](#) for additional information

### References:


5. Expert opinion of Alberta Advisory Committee on Immunization, December 2022.


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