COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty) - Ultra Frozen Vaccine
Adult Formulation 12 Years of Age and Older

Biological Page

<table>
<thead>
<tr>
<th>Section 7: Biological Product Information</th>
<th>Standard #: 07.203</th>
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<tbody>
<tr>
<td>Created by: Province-wide Immunization Program Standards and Quality</td>
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<td>Approved by: Province-wide Immunization Program Standards and Quality</td>
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<tr>
<td>Approval Date: December 14, 2020</td>
<td>Revised: July 19, 2022</td>
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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 12 years of age and older.
Note:
- A complete series with an mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.
- Pfizer-BioNTech COVID-19 vaccine is preferentially recommended for individuals 12 years up to and including 29 years of age to start and/or complete their primary series. This is due to a lower risk of myocarditis with the Pfizer-BioNTech vaccine compared to Moderna COVID-19 vaccine in this age group.
- The Pfizer-BioNTech COVID-19 vaccine may be recommended preferentially in those 18 years up to and including 29 years of age as a booster dose, as there is limited information about the risk of myocarditis following a booster dose with the Moderna COVID-19 vaccine at this time and lower reported rates of myocarditis following immunization with Pfizer BioNTech (30 mcg) COVID-19 vaccine compared to Moderna (100 mcg) COVID-19 vaccine used in primary series.

Preferred Use N/A

Dose 0.3 mL (30 mcg)

Route IM in the deltoid or vastus lateralis muscle

Schedule
Primary series 2 doses
- Dose 1: day 0
- Dose 2: 8 weeks after dose 1

Optimal spacing between dose 1 and dose 2 is 8 weeks.
- Data 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.
- As such, the very good protection already provided by COVID-19 vaccines may be further improved when the interval between the first and second doses are extended.
- 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.
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- When choosing to use a longer dose interval, the risk of infection between doses needs to be considered based on the extent of local transmission, and person’s risk of exposure to the virus. Individuals can consult with their health care provider if they have questions about when to get the second dose.

**Notes:**
- A shortened interval between dose 1 and dose 2 (no less than 21 days) as per product monograph may be considered in certain situations: required for travel, work requirement, increased risk for infection based on local transmission and the degree of individual risk exposure.
- Minimum spacing between doses 1 and 2 is 19 days and is required for a dose to be considered valid.
- 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 individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines. An mRNA vaccine should be administered except in the event of contraindication or refusal.

- 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.

- Due to the lower risk of myocarditis with the Pfizer-BioNTech COVID-19 vaccine compared to Moderna COVID-19 vaccine in individuals 12 years up to and including 29 years of age, Pfizer-BioNTech COVID-19 vaccine is preferentially recommended for this age group to start and/or complete their primary series.

- Specific immunocompromising conditions that make an individual eligible:
  - Solid organ transplant (SOT) recipients – pre-transplant and post-transplant.
  - Hematopoietic stem cell transplant (HSCT) recipients – pre-transplant and post-transplant while in an 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).
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<tr>
<td>o Individuals on anti-B cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab).</td>
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<tr>
<td>o Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.</td>
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<tr>
<td>o Individual receiving chimeric antigen receptor (CAR)-T-cell therapy.</td>
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<td>o Individuals on:</td>
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<tr>
<td> long term high-dose systemic steroid treatment (prednisone equivalent of equal to or greater than 2 mg/kg/day or 20 mg/day if weight greater than 10 kg, for 14 days or greater), or</td>
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<tr>
<td> alkylating agents, or</td>
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<tr>
<td> antimetabolites (e.g. methotrexate, azathioprine, mycophenolate), or</td>
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<tr>
<td> tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or</td>
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<tr>
<td> other agents that are significantly immunosuppressive at clinicians’ discretion.</td>
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<tr>
<td>o HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS).</td>
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<tr>
<td>o Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).</td>
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**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 (initiation and interval) based on the individual's treatment and unique circumstances.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible to restart their COVID-19 vaccine series beginning at least 3 months post-transplant. Consultation with their HSCT physician is not necessary as long as the initial clearance letter has been received to proceed with inactivated vaccines.
- CAR-T cell therapy recipients without a prior history of HSCT who received COVID-19 vaccine pre-CAR-T 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 Adult HSCT Transplant Recipients
  o Immunization of Child HSCT Transplant Recipients

### Booster Dose Indications
- Booster doses should be offered to provide stronger protection for those who have a waning immune response to vaccines, focusing on individuals who are at higher risk for severe COVID-19 outcomes. An mRNA vaccine should be administered as the booster dose except in the event of contraindication or refusal.
- The Pfizer-BioNTech COVID-19 vaccine may be recommended preferentially in those 12 years up to and including 29 years of age as a booster dose, as there is limited information about the risk of myocarditis following a booster dose with the Moderna COVID-19 vaccine at this time and lower reported rates of myocarditis following immunization with Pfizer BioNTech (30 mcg) COVID-19 vaccine compared to Moderna (100 mcg) COVID-19 vaccine used in primary series.
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### First Booster Dose Indications
- **Individuals 12 to 17 years of age**
  - Based on recommendations of the Alberta Advisory Committee on Immunization, first booster doses can be offered to all individuals 12 to 17 years of age who have previously received a complete primary series of a COVID-19 vaccine.
  - It is strongly recommended that a booster dose of COVID-19 vaccine be offered to those 12 to 17 years of age at higher risk for severe COVID-19 outcomes, including:
    - those with certain immunocompromising conditions who received a 3-dose primary series
    - those with underlying medical conditions
    - First Nations, Metis and Inuit youth
    - residents of congregate living settings
  - **First booster dose:** at least 5 calendar months after the last dose of the primary series.

- **Individuals 18 years of age and older**
  - First booster doses are recommended for those who have previously received a complete primary series of a COVID-19 vaccine.
  - **First booster dose:** at least 5 calendar months after the last dose of the primary series.

### Notes:
- Minimum spacing between primary series and booster dose is 28 days.
- A booster dose is any additional dose of COVID-19 vaccine received after completion of the recommended primary series.

### Second Booster Dose Indications
- **Individuals 18 years of age and older**
  - Second booster doses are available for all individuals 18 years of age and older who previously received a complete COVID-19 vaccine primary series and a first booster dose.
  - **Second booster dose:** at least 5 calendar months after the first booster dose.

It is strongly recommended that second booster doses be offered to individuals in the following groups who are at higher risk of severe COVID-19 outcomes:
- Residents of seniors congregate living facilities regardless of age
  - Applicable congregate settings include all private and public long-term care facilities, licensed supportive living facilities and seniors’ lodges including First Nations elder care lodges.
- Individuals 50 years of age and older

**Note:** Second booster doses will correspond to a fourth dose for immunocompetent individuals who received a two-dose primary series, but will correspond to a fifth dose for immunocompromised individuals who received a three-dose primary series.

### Additional Doses for Travel Purposes Only
- **Individuals 12 years of age and older**
  - Receiving an additional dose for travel purposes is not considered clinically necessary.
  - Albertans who received a viral vector vaccine series or a mixed vaccine series may be eligible for up to two additional doses of COVID-19 vaccine to meet international travel requirements for primary series.
  - Individuals traveling to countries where a booster dose is required within a certain timeframe (e.g. 6 months) following a primary series are eligible to receive an additional dose of COVID-19 vaccine to meet those requirements. In some circumstances this may be a fourth dose or fifth dose of COVID-19 vaccine.
  - It is up to the traveler to know the COVID-19 vaccine requirements for their destination.
  - For additional doses the spacing needs to be at least 28 days after the previous dose.
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#### Interval Between Previous COVID-19 Infection and COVID-19 Immunization

For individuals with a history of confirmed COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.

**Notes:**
- Please see [CMOH Order 02-2022](#) and [Order 04-2022](#) for definition of confirmed COVID-19 infection.
- 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 without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C)</th>
<th>8 weeks after symptom onset or positive test (if asymptomatic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of MIS-C (regardless of immunocompromised status)</td>
<td>Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C</td>
<td>4 to 8 weeks after symptom onset or positive test (if asymptomatic)</td>
</tr>
</tbody>
</table>

| Infection after primary series | Individuals eligible for booster doses | 3 months after symptom onset or positive test (if asymptomatic) AND at least 5 months after last dose |

#### Contraindications/Precautions

**Contraindications:**
- Known severe hypersensitivity to any component of the vaccine.
  - One non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions is polyethylene glycol (PEG). This potential allergen may be found in bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens

**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,
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<tr>
<td>care solutions, products such as ultrasound gel, laxatives, cough syrup, and some food and drinks.</td>
<td>cosmetics, contact lens care solutions, skin products and some food and drinks.</td>
</tr>
<tr>
<td>• Anaphylaxis to a previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication. See <a href="#">COVID-19 Immunization for Individuals with Allergies and Other Health Conditions</a> for recommendations.</td>
<td>• Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.</td>
</tr>
<tr>
<td>• Anaphylaxis to previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication. See <a href="#">COVID-19 Immunization for Individuals with Allergies and Other Health Conditions</a> for recommendations.</td>
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**Precautions:**
- Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.
- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
- Administration should be postponed in individuals suffering from acute severe febrile illness.
- Immunization of children with a previous history of MIS-C should be postponed until clinical recovery has been achieved or until it has been 90 days or greater since diagnosis, whichever is longer.

**Myocarditis**
- Cases of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine) have been reported during post-authorization use in Canada and internationally, including from Israel, the United States and Europe. However, the risk is considered rare.
- Available information indicates that cases of myocarditis and pericarditis:
  - occur more commonly after the second dose,
  - more often in adolescents and young adults (12 to 29 years of age),
  - more often in males, and
  - more frequently following Moderna COVID-19 vaccine than Pfizer-BioNTech COVID-19 vaccine.
- Typically onset of symptoms begins within a week after the receipt of an mRNA COVID-19 vaccine. The majority of cases are mild and individuals tend to recover quickly and investigation into long term outcomes is ongoing.
- Both the Alberta Advisory Committee on Immunization (AACI) and the National Advisory Committee on Immunization (NACI) recommend that Pfizer-BioNTech COVID-19 vaccine be preferentially recommended for individuals 12 years up to and including 29 years of age due to lower risk of myocarditis following immunization with the Pfizer-BioNTech vaccine compared to Moderna COVID-19 vaccine in this age group. Should individuals aged 12 years up to and including 29 years of age wish to receive Moderna COVID-19 vaccine, they can continue to do so with informed consent.
- As there is limited information about the risk of myocarditis following a booster dose with the Moderna COVID-19 vaccine at this time, the Pfizer-BioNTech COVID-19 vaccine may be recommended preferentially in those 18 years and older up to and including 29 years of age as a booster dose, however, Moderna COVID-19 vaccine could be provided if preferred by the individual.
- It is unknown if individuals with a history of previous myocarditis and/or pericarditis are at higher risk of vaccine associated myocarditis and/or pericarditis.
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<tr>
<td><strong>o</strong> 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.</td>
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<tr>
<td><strong>o</strong> 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.</td>
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<tr>
<td><strong>•</strong> 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.</td>
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<tr>
<td><strong>•</strong> 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>
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<tr>
<td>**<strong>o</strong> 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. If another dose of vaccine is offered, the Pfizer-BioNTech vaccine should be offered due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30mcg vaccine compared to the Moderna 100mcg vaccine.</td>
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<tr>
<td><strong>o</strong> Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.</td>
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<tr>
<td><strong>•</strong> 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 symptoms, which include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.</td>
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<tr>
<td><strong>•</strong> 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>
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### Immunocompromised and Auto-Immune Disorders
- **Participants in the COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial.**
- **Participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, however, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions.**
- **Real-world data in these individuals has not detected any safety signals, however, there is evidence of a diminished immune response in individuals who are immunocompromised and those with auto-immune disorders who are receiving immunosuppressive therapy. The type of immunosuppressive therapy or condition affected the immune response to COVID-19 vaccines.**
- **COVID-19 vaccine can be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder.**
  - **o** It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions.**
  - **o** However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.
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- Response for immunizers if individual has not consulted with their primary health care provider: “Vaccine studies are not complete on the use of this vaccine in immunocompromised individuals or those with auto-immune disorders. Emerging data has not detected any safety issues. We recommend you speak to your physician regarding the timing of immunization based on your treatment or if you have questions about the immunization, but it is not required to receive the vaccine.”

**Exceptions:**
- SOT client require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine.
- HSCT clients do not require consultation as long as the initial clearance letter has been received to proceed with inactivated vaccine.

**Additional resources:**
- [COVID-19 Scientific Advisory Group Rapid Evidence Report](#)
- [Advisory Committee on Immunization Practices (ACIP) interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines](#)

**Pregnancy**

- The safety and efficacy of Pfizer-BioNTech COVID-19 Vaccine in pregnant women has not yet been established in the clinical trials, however preliminary data on mRNA vaccines administered in pregnancy is now available from post marketing surveillance with no safety signals detected.
- COVID-19 vaccine can be offered to pregnant individuals in the eligible group as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.
  - 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.
    - Response for immunizers if individual has not consulted with their primary health care provider: “Vaccine studies are not complete on the use of this vaccine in pregnant women. Early information has not identified any safety issues. If you have questions about the immunization, we recommend you speak to your physician but it is not required to receive the vaccine.”

**Additional resources:**
- [Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy](#)

**Lactation**

- It is unknown whether Pfizer-BioNTech COVID-19 Vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded.
- However, based on how these vaccines work, COVID-19 vaccines are not expected to be a risk to lactating individuals or their breastfed newborns/infants.
- COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding.
  - It is recommended that individuals consult with 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.
    - Response for immunizers if individual has not consulted with their primary health care provider: “Vaccine studies are not complete on the use of this vaccine in breastfeeding women. Early information has not identified any safety issues. If you have questions about the immunization, we recommend you speak to your physician but it is not required to receive the vaccine.”
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#### 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. They should isolate, seek testing and get immunized as per guidance in the ‘Interval between previous COVID-19 infection and COVID-19 immunization’ section.
  - 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 COVID-19 vaccine has been mounted in individuals. It is still unknown what antibody level correlates with protection against COVID-19 and serology testing in many labs may also not detect antibodies developed as a response to vaccine. Serology testing should not be used as evidence to inform whether vaccine doses have been effective.

#### Possible Reactions

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

**Uncommon:**
- Lymphadenopathy
- Feeling unwell
- Arm pain
- Asthenia, lethargy
- Decreased appetite
- Hyperhydrosis
- Night sweats

**Rare:**
- Allergic reactions
- Anaphylaxis
- Myocarditis/pericarditis
- Facial paralysis/Bell’s palsy
- As with any immunization, unexpected or unusual side effects can occur.

Refer to product monograph for more detailed information.
# COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)

## Ultra Frozen Vaccine

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<tr>
<td><strong>Composition</strong></td>
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<tr>
<td>Each 0.3 mL dose contains:</td>
<td>Each 0.3 mL dose contains:</td>
</tr>
<tr>
<td>Lipids nanoparticles (these help the mRNA enter the cell):</td>
<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>
<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</td>
<td>• ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (PEG)</td>
</tr>
<tr>
<td>Other Lipids: (provide structural integrity of the nanoparticles)</td>
<td>Other Lipids: (provide structural integrity of the nanoparticles)</td>
</tr>
<tr>
<td>• 1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>• 1,2-distearoyl-sn-glycero-3-phosphocholine</td>
</tr>
<tr>
<td>• cholesterol</td>
<td>• cholesterol</td>
</tr>
<tr>
<td>Salts: (help maintain the vaccine pH)</td>
<td>Salts: (help maintain the vaccine pH)</td>
</tr>
<tr>
<td>• bibasic sodium phosphate dihydrate</td>
<td>• sodium chloride</td>
</tr>
<tr>
<td>• monobasic potassium phosphate</td>
<td>• tromethamine hydrochloride</td>
</tr>
<tr>
<td>• potassium chloride</td>
<td>• tromethamine</td>
</tr>
<tr>
<td>• sodium chloride</td>
<td>Other:</td>
</tr>
<tr>
<td>Other:</td>
<td>• sucrose (protects the nanoparticles when frozen)</td>
</tr>
<tr>
<td>• sucrose (protects the nanoparticles when frozen)</td>
<td>• water for injection</td>
</tr>
<tr>
<td>• water for injection</td>
<td>No adjuvants or preservatives</td>
</tr>
</tbody>
</table>

### Blood/Blood Products

- Contains no human blood/blood products

### Bovine/Porcine Products

- Contains no bovine/porcine products

### Latex

- Does not contain latex

### Interchangeability

- Current evidence shows that providing a different mRNA COVID-19 vaccine product is safe and effective for subsequent doses. The Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine are similar and should be considered interchangeable except in the situations listed below.
  - Due to the lower risk of myocarditis with the Pfizer-BioNTech COVID-19 vaccine compared to Moderna COVID-19 vaccine in individuals 12 years up to and including 29 years of age in the primary series:
    - The Pfizer-BioNTech COVID-19 vaccine is preferentially recommended for this age group to start and/or complete their primary series (including individuals with certain immunocompromising conditions).
    - The Pfizer-BioNTech COVID-19 vaccine may also be recommended preferentially in those 18 years up to and including 29 years of age as a third (booster) dose, as there is limited information about the risk of myocarditis following a third (booster) dose with the Moderna COVID-19 vaccine at this time.
**COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)
Ultra Frozen Vaccine
Adult Formulation 12 Years of Age and Older**

<table>
<thead>
<tr>
<th>Purple Cap – Requires Dilution</th>
<th>Gray Cap – Dilution NOT Required</th>
</tr>
</thead>
</table>

**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 12 years of age and older.
- Currently there is no data on the impact of the COVID-19 mRNA vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.
  - If tuberculin skin testing or an IGRA test is required for baseline screening, it should be administered and read before administration of any COVID-19 vaccine immunization or delayed for at least 28 days after a dose of COVID-19 vaccine.
  - Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed.
  - If tuberculin skin testing is required for other reasons (e.g., contact tracing, immigrants, query LTBI), testing should not be delayed, as these are theoretical considerations. However, re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.
- 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 received 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:** Anti-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 the 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.
## COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)
### Ultra Frozen Vaccine
#### Adult Formulation 12 Years of Age and Older

<table>
<thead>
<tr>
<th>Purple Cap – Requires Dilution</th>
<th>Gray Cap – Dilution NOT Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td></td>
</tr>
<tr>
<td>• Frozen – white to off-white solution</td>
<td>• Thawed (prior to mixing) – may contain white to off-white opaque particles.</td>
</tr>
<tr>
<td>• Thawed – may contain white to off-white opaque particles</td>
<td>• Thawed (after mixing) – white to off-white solution with no visible particulates.</td>
</tr>
<tr>
<td>• Thawed and reconstituted – off white solution with no visible particulates</td>
<td></td>
</tr>
</tbody>
</table>

### Storage
- Can be stored in a freezer between -90°C to -60°C until expiry printed on the label, or the extended expiry in AVI.
- If an ultra-low temperature freezer is not available, the thermal container in which the vaccine arrives may be used as temporary storage up to 30 days when consistently refilled to the top of the container with dry ice.
- Vials can be stored at -25°C to -15°C in laboratory grade freezers for up to 2 weeks.
- Prior to dilution, thawed vials can be stored:
  - in the refrigerator at +2°C to +8°C for up to 31 days, or
  - at room temperature (up to +25°C) for no more than 2 hours.
- Do not refreeze.
- After thawing and mixing with 0.9% sodium chloride diluent, the vaccine can be stored at +2°C to +25°C for up to 6 hours.
- Diluent is single use. Once the 1.8 mL required is drawn from the diluent vial and added to the antigen vial, the diluent vial MUST be discarded. It cannot be used to dilute multiple vials of vaccine.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- After dilution, the vaccine vials can be handled in room light conditions.
- Before being thawed, can be stored in a freezer between -90°C to -60°C storage for up to 12 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:**
  - 6 doses per vial
  - 1170 doses per package
- **Diluent:**
  - Diluent is provided in 10 mL plastic vials (latex-free, preservative-free).
  - Packaged in cartons of 25 vials and can be stored at room temperature.
- **Vaccine:**
  - 6 doses per vial
  - 10 multiple dose vials per carton
### COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)
#### Ultra Frozen Vaccine
#### Adult Formulation 12 Years of Age and Older

<table>
<thead>
<tr>
<th>Preparation/Reconstitution</th>
<th>Purple Cap – Requires Dilution</th>
<th>Gray Cap – Dilution NOT Required</th>
</tr>
</thead>
</table>

**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.

**Mix Before Use**
- Before use, mix by inverting vial gently 10 times. Do not shake.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discoloured or if particles are observed after mixing.
- Discard any unused vaccine 12 hours after first puncture.

**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 1.8 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 1.8 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 1.8 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.
### COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)
**Ultra Frozen Vaccine**  
**Adult Formulation 12 Years of Age and Older**

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>8. Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.</td>
<td></td>
</tr>
<tr>
<td>9. Store between +2°C to +25°C.</td>
<td></td>
</tr>
<tr>
<td>10. Discard any unused vaccine 6 hours after dilution.</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Pre-loading vaccine into syringes is not supported. The immunizing health practitioner must draw up the vaccine dose at the time of administration.

**Vaccine Code**  
COVPBmRNA

**Antigen Code**  
COVID-19-1

**Licensed Use**
- Primary series: 12 years of age and older
- Booster: 18 years of age and older at least 6 calendar months after completion of the primary series

**Off-License Use**
- First booster dose for individuals 12 to 17 years of age
- First booster dose for individuals 18 years of age or older given less than 6 calendar months from the second dose
- Second booster dose for eligible individuals
- Additional doses for travel purposes

**Program Notes**
- 2020 December 16: Implemented in Alberta.
- 2021 January 13: Interval between dose 1 and dose 2 extended to 42 days except for LTC/DSL residents.
- 2021 March 10: Interval between dose 1 and dose 2 extended up to 4 months for all populations.
- 2021 April 21: Exceptions to extended interval to include SOT, HSCT, and individuals with malignant hematologic disorders and non-hematologic malignant solid tumors receiving specific types of active treatment, and individuals on anti-CD20 monoclonal antibodies.
- 2021 April 26: Eligibility to include unlicensed use in children turning 12 to 15 years of age this calendar year with high-risk underlying health conditions as defined in Phase 2B of Alberta’s COVID-19 immunization program.
- 2021 May 4: Updated considerations for pregnancy and lactation.
- 2021 May 5: Licensure updated to include individuals 12 to 15 years of age.
- 2021 May 20: Updated to include storage of thawed undiluted vials at +2°C to +8°C from 5 days to 31 days.
- 2021 May 28: Exceptions to extended interval expanded to include individuals with chronic kidney disease on peritoneal or hemodialysis.
- 2021 June 14: Spacing between administration of COVID-19 vaccine and other vaccines changed to 14 days (from 28 days); removed recommendation to delay pregnancy by 28 days or more after the administration of COVID-19 vaccine.
- 2021 June 16: Updated interchangeability section.
- 2021 July 6: Updated to incorporate safety information from Health Canada on myocarditis/pericarditis; removed scheduling information for extended interval (4 months) between dose 1 and 2 and exceptions for extended interval.
- 2021 August 3: Updated information on myocarditis/pericarditis.
- 2021 August 30: Updated information on additional doses for immunocompromised, residents of seniors congregate living facilities and for travel.
- 2021 September 8: Updated recommendations for co-administration of COVID-19 vaccines and other inactivated vaccines.
- 2021 September 17: Updated to align with NACI recommendations for immunocompromising conditions eligible for additional dose of COVID-19 vaccine.
| **COVID-19 Vaccine - mRNA Pfizer BioNTech (Comirnaty)** |  |
| Ultra Frozen Vaccine |  |
| **Adult Formulation 12 Years of Age and Older** |  |
| **Purple Cap – Requires Dilution** |  |
| **Gray Cap – Dilution NOT Required** |  |

- 2021 October 6: Updated third dose eligibility to include individuals 75 years of age and older; First Nation, Metis and Inuit people 65 years of age and older; updated recommendations for co-administration of COVID-19 vaccines with all other vaccines.
- 2021 October 25: Updated to specify the minimum interval between monoclonal antibodies/convalescent plasma used for treatment of COVID-19 infection and COVID-19 vaccines.
- 2021 November 8: Updated ‘third dose’ eligibility to include individuals 70 years of age and older, FNMI people 18 years of age and older, individuals 18 years of age and older who received only a viral vector vaccine series, and frontline HCWs with an interval of less than 8 weeks between dose 1 and dose 2.
- 2021 November 17: Updated the “Other Considerations” section to state that individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be provided COVID-19 vaccine as soon as their isolation period is over; licensed use updated as per November 9, 2021 product monograph – booster doses licensed for 18 years and older.
- 2021 November 26: Updated to include preferential recommendation for Pfizer-BioNTech COVID-19 vaccine for individuals 12 years to 29 years of age due to a lower risk of myocarditis following immunization with the Pfizer-BioNTech vaccine compared to Moderna in this age group. Interval between dose 1 and dose 2 updated to align with NACI’s recommended optimal spacing of 8 weeks.
- 2021 December 6: Updated booster eligibility to include all adults 18 years of age and older in a phased approach starting with those 60 years of age and older.
- 2021 December 17: Updated wording with respect to interchangeability.
- 2021 December 21: Interval for third (booster) doses changed from at least 6 months to at least 5 months after last dose of the primary series for all individuals 18 years of age and older.
- 2022 January 20: Updated booster dose eligibility to include individuals 18 years of age and older with certain immunocompromising conditions.
- 2022 February 14: Updated to incorporate NACI recommendation on re-immunization following myocarditis; clarified wording on individuals with history of COVID-19 infections; adolescents 12 to 17 years of age with underlying health conditions and immunocompromising conditions eligible for booster dose; First Nations, Metis and Inuit individuals 12 to 17 years of age eligible for a booster dose.
- 2022 March 2: Updated to incorporate NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization.
- 2022 March 14: Updated booster dose eligibility to include all individuals 12 to 17 years of age.
- 2022 April 12: Updated to incorporate second booster dose eligibility and additional dose eligibility for travel purposes; included link to “COVID-19 Immunization for Individuals with Allergies and Other Health Conditions”.
- 2022 June 6: Updated to include recommendation for immunization post CAR-T cell therapy and extended storage time in an ultra-frozen state.
- 2022 July 19: Updated to expand second booster dose eligibility to include all individuals 18 years of age and older; updated recommendations for timing of COVID-19 vaccines and receipt of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prophylaxis of COVID-19.

**Related Resources**

- Alberta Health Services Website (2021). COVID-19 Vaccine Information
- Preparation of Pfizer-BioNTech COVID-19 Vaccine For 12 Years of Age and Older
- See [www.CVDvaccine.ca](http://www.CVDvaccine.ca) for additional information

**References**

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</table>


15. Pfizer Training Resources. 2020 December 8