**COVID-19 Vaccine - ChAdOx1-S [recombinant]**  
AstraZeneca (Vaxzevria)/COVISHIELD Vaccine  
**Biological Page**

<table>
<thead>
<tr>
<th>Section 7:</th>
<th>Biological Product Information</th>
<th>Standard #: 07.205</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created by:</td>
<td>Province-wide Immunization Program Standards and Quality</td>
<td></td>
</tr>
<tr>
<td>Approved by:</td>
<td>Province-wide Immunization Program Standards and Quality</td>
<td></td>
</tr>
<tr>
<td>Approval Date:</td>
<td>March 10, 2021</td>
<td>Revised: April 11, 2022</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>AstraZeneca</th>
<th>Verity Pharmaceuticals Inc. &amp; Serum Institute of India (In partnership with AstraZeneca)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Classification</td>
<td>• Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS CoV 2 Spike (S) glycoprotein.</td>
<td></td>
</tr>
<tr>
<td>Indications for Provincially Funded Vaccine</td>
<td>Persons 18 years of age and older</td>
<td>AstraZeneca/COVISHIELD may be considered for individuals 18 years of age and older for whom mRNA vaccines are contraindicated (e.g., anaphylaxis to PEG), individuals who decline mRNA COVID-19 vaccine, or as a second dose for individuals who have received AstraZeneca/COVISHIELD to complete a two dose series.</td>
</tr>
<tr>
<td>Note:</td>
<td>• A complete series with an mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.</td>
<td></td>
</tr>
<tr>
<td>Preferred Use</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td>0.5 mL</td>
<td></td>
</tr>
<tr>
<td>Route</td>
<td>IM in the deltoid or vastus lateralis muscle</td>
<td></td>
</tr>
</tbody>
</table>

**Schedule**  
See below Schedule for Individuals with Certain Immunocompromising Conditions  
**Primary series 2 doses**  
- Dose 1: day 0  
- Dose 2: 8 to 12 weeks (56 to 84 days)*  

Optimal spacing between dose 1 and dose 2 is at least 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.  
- 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:**  
- Minimum spacing between doses is 28 days.  
- In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series.  
- Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization based on the individual’s treatment.
### AstraZeneca (Vaxzevria) COVID-19 Vaccine

**Second dose for individuals who have been immunized with AstraZeneca/COVISHIELD vaccine:**

- For individuals with a contraindication or declination of mRNA COVID-19 vaccine, second dose of AstraZeneca/COVISHIELD vaccine will be given as per schedule indicated above.
- For other individuals, the series can be completed with either an AstraZeneca/COVISHIELD or mRNA (Pfizer/Moderna) vaccine based on the individual's choice. See [https://www.alberta.ca/covid19-vaccine.aspx](https://www.alberta.ca/covid19-vaccine.aspx) information on second doses to help individuals make the choice. Regardless of the choice of vaccine product, it is recommended to wait for a least 8 weeks after the first dose to receive the second dose in order to get maximum benefit.

### 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.

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.

**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).
- **Individuals on anti-B cell therapies** – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab).
- **Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.**
- **Individual receiving chimeric antigen receptor (CAR)-T-cell therapy.**
- **Individuals on:**
  - 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
  - alkylating agents, or
### AstraZeneca (Vaxzevria) COVID-19 Vaccine

- 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 advanced untreated HIV infection or those with acquired immunodeficiency syndrome (AIDS).
  - Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).

### Notes:
- Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization based on the individual’s treatment.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible for three doses of COVID-19 vaccine beginning 6 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.

### Booster Dose Indications

A booster dose should be offered to provide stronger protection for those who have waning immune responses to vaccines against the Delta variant and also provide protection against the emerging Omicron variant.
- An mRNA vaccine should be administered as the booster dose except in the event of contraindication or refusal.
- Booster doses are recommended for those:
  - who have previously received 2 doses of a two dose COVID-19 vaccine series (i.e., the booster is their third dose),
  - who have previously received 1 dose of Janssen COVID-19 vaccine (i.e., the booster dose is their second dose),
  - with certain immunocompromising conditions who have previously received 3 doses of COVID-19 vaccine for their primary series (i.e., the booster is their fourth dose).

### Individuals 18 years of age and older

- 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.

### Individuals Who Have Received Two AstraZeneca/COVISHIELD Doses

- It is recommended that an mRNA COVID-19 vaccine be offered to individuals 18 years of age and older who have received only two AstraZeneca/COVISHIELD doses.
- A dose of mRNA vaccine is recommended at least 5 calendar months after the second dose of AstraZeneca/COVISHIELD.
- This does not apply to viral vector vaccine (AstraZeneca/COVISHIELD or Janssen) recipients who have received one or more doses of an mRNA vaccine.

### Additional Doses for Travel Purposes Only

Individuals 18 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 mRNA vaccine to meet international requirements.
- 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.
**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>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>
<td></td>
</tr>
<tr>
<td>History of MIS-C (regardless of immunocompromised status)</td>
<td>Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer</td>
<td></td>
</tr>
</tbody>
</table>

| Infection after primary series but before booster dose | Individuals eligible for booster dose | 3 months after symptom onset or positive test (if asymptomatic) AND at least 5 months from completing the primary series |

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**Contraindications/Precautions**

**Contraindications:**
- Persons under 18 years of age
- Known severe hypersensitivity to any component of the vaccine
  - One non-medicinal ingredient in the vaccine that has the potential to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 may be found in medical preparations (e.g. vitamin oils, tablets, anticancer agents) and cosmetics.
- Anaphylaxis to previous dose of AstraZeneca or COVISHIELD COVID-19 vaccine. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.
- Experienced previously major venous and/or arterial thrombosis with thrombocytopenia following immunization with AstraZeneca/COVISHIELD COVID-19 vaccine.
<table>
<thead>
<tr>
<th>AstraZeneca (Vaxzevria) COVID-19 Vaccine</th>
<th>COVISHIELD COVID-19 Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Previous history of capillary leak syndrome (CLS). CLS is a rare disease characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia.</td>
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</tbody>
</table>

**Precautions:**
- 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.
- Prior to receiving the AstraZeneca/COVISHIELD vaccine, individuals should be informed of what is currently known about the risk of the rare but serious events characterized by thrombosis with thrombocytopenia, immune thrombocytopenia (ITP) and Guillain-Barre syndrome (GBS) that were reported following immunization with the vaccine. This should be part of the benefit-risk discussion to help them make an informed decision.
- Capillary leak syndrome has been observed very rarely following immunization with AstraZeneca/COVISHIELD vaccine. See: Important Safety Information on AstraZeneca COVID-19 Vaccine and COVISHIELD: Risk of Capillary Leak Syndrome

**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 autoimmune 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.
  - It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions.
  - 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 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:**
### AstraZeneca (Vaxzevria) COVID-19 Vaccine

| **Pregnancy** | • The safety and efficacy of AstraZeneca/COVISHIELD COVID-19 vaccine in pregnant women has not yet been established.  
| | • AstraZeneca/COVISHIELD COVID-19 vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or obstetrician determines that the benefits outweigh the potential risks for the woman and fetus.  
| | o However, the individual may also be immunized without consulting their primary health care provider or obstetrician following their acknowledgment of:  
| | | ▪ the absence of evidence on the use of a viral vector COVID-19 vaccine in this population, and  
| | | ▪ the preference for pregnant women to receive an mRNA vaccine due to published safety data and concerns about the complexities of the treatment of Vaccine-Induced Immune Thrombotic Thrombocytopenia in pregnancy should it occur after immunization.  
| | See ‘Safety Information: Risk of Thrombosis with Thrombocytopenia’ section below.  
| | o 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. We recommend that you do not receive the immunization until you have discussed the potential risks and benefits with your doctor. However, it is your choice whether to proceed without consulting your doctor.”  
| | • Additional resources:  

### Lactation

| • It is unknown whether AstraZeneca 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.  
| • AstraZeneca/COVISHIELD COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding.  
| o It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.  
| o However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine. Breastfeeding individuals can be immunized following routine informed consent discussion.  
| o 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.”

### 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.  
| o 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.  
| o 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
<table>
<thead>
<tr>
<th><strong>AstraZeneca (Vaxzevria) COVID-19 Vaccine</strong></th>
<th><strong>COVISHIELD COVID-19 Vaccine</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
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</tbody>
</table>

### Safety Information: Risk of Thrombosis with Thrombocytopenia and Immune Thrombocytopenia (ITP)

- A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely in Europe and Canada following immunization with AstraZeneca COVID-19 Vaccine.
- This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia.
- This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).
- This entity is associated with the development of antibodies that "activate" platelets, which stimulate the formation of clots and result in thrombocytopenia.
- The exact mechanism by which the AstraZeneca vaccine triggers VITT is still under investigation. At this time, no other risk factors have consistently been identified in patients who develop VITT.
- Cases have been reported in women and men in all age groups.
- Published estimates of the risk of VITT from countries with moderate to high data quality range from 1 case per 26,500 to 1 case per 127,300 first doses of AstraZeneca/COVISHIELD administered. The risk of VITT in Canada as of May 8, 2021 has been estimated to be approximately 1 per 55,000 first doses. The rate is evolving as cases continue to be reported and investigated, and varies between countries. The rate of VITT after a second dose is not clear yet, but data from the United Kingdom currently suggests it is much rarer than after first doses – roughly 1 case per 600,000 doses were reported after 9 million second doses given.
- Health Canada has assessed the available data and after a thorough, independent assessment of the currently available scientific data, Health Canada has concluded that these very rare events may be linked to use of the vaccine. This is in line with the findings of other regulators. As a result, the Department has updated warnings in the product information to inform Canadians of the possible side effects and to provide information about the signs and symptoms and when to seek prompt medical attention following immunization.
- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and or thrombocytopenia and be aware of VITT including how to diagnose and treat the condition.
- Those immunized should be instructed to seek immediate medical attention if they develop symptoms of thromboembolism and/or thrombocytopenia between days 4 and 42 following receipt of the AstraZeneca vaccine such as:
  - severe headache that does not go away,
  - seizure,
  - difficulty moving part(s) of body,
  - new blurry vision that does not go away,
  - difficulty speaking,
  - shortness of breath,
  - chest pain,
  - severe abdominal pain,
  - new severe swelling, pain, or colour change of an arm or a leg
- Cases of Immune Thrombocytopenia (ITP) have been reported very rarely within the first four weeks after receiving AstraZeneca COVID-19 vaccine, including serious cases with very low platelet counts.
### AstraZeneca (Vaxzevria) COVID-19 Vaccine

- If an individual has a history of ITP, healthcare professionals should consider the risk of developing low platelet levels prior to administering the vaccine. In individuals with a history of ITP, it is recommended to monitor platelet levels following immunization with the AstraZeneca COVID-19 vaccine.

See:
- **Important Safety Information on AstraZeneca COVID-19 Vaccine and COVISHIELD: Risk of Thrombosis with Thrombocytopenia**
- **Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) Following Adenovirus Vector COVID-19 Vaccination**
- **Health Canada provides update on safety review of AstraZeneca and COVISHIELD COVID-19 vaccines**

### Possible Reactions

#### Common
- Pain, tenderness, redness, bruising, warmth, itching, swelling, and induration at the injection site
- Fever, chills
- Fatigue, malaise
- Headache, arthralgia, myalgia
- Nausea, vomiting, diarrhea
- Pain in legs or arms
- Influenza-like symptoms (fever, sore throat, runny nose, cough, chills)

#### Uncommon
- Hyperhydrosis
- Decreased appetite
- Lymphadenopathy
- Pruritus
- Rash
- Dizziness
- Somnolence
- Abdominal pain

#### Rare:
- Anaphylaxis
- Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)
- Capillary Leak Syndrome
- Guillain-Barre Syndrome
- As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.

### Composition

Each 0.5 mL dose contains:

COVID-19 Vaccine (ChAdOx1-S* recombinant) $5 \times 10^{10}$ viral particles *Recombinant, replication-deficient chimpanzee adenovirus vector encoding the unmodified SARS-CoV-2 Spike (S) glycoprotein (GP) produced in genetically modified human embryonic kidney (HEK) 293 cells by recombinant DNA technology.

**Essential Amino Acids**
- L-Histidine
- L-Histidine hydrochloride monohydrate

**Stabilizer**
- Magnesium chloride hexahydrate
- Polysorbate 80
- Ethanol
- Disodium edetate dihydrate (EDTA)
<table>
<thead>
<tr>
<th><strong>AstraZeneca (Vaxzevria) COVID-19 Vaccine</strong></th>
<th><strong>COVISHIELD COVID-19 Vaccine</strong></th>
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<tbody>
<tr>
<td><strong>Others</strong></td>
<td></td>
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<tr>
<td>• Sucrose</td>
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<tr>
<td>• Sodium chloride</td>
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<tr>
<td>• Water for injection</td>
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<tr>
<td>No adjuvants or preservatives</td>
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<tr>
<td><strong>Blood/Blood Products</strong></td>
<td>Contains no human blood/blood products</td>
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<tr>
<td><strong>Bovine/Porcine Products</strong></td>
<td>Contains no bovine/porcine products.</td>
</tr>
<tr>
<td><strong>Latex</strong></td>
<td>Does not contain latex.</td>
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<tr>
<td><strong>Interchangeability</strong></td>
<td>The vaccine series can be completed with either an AstraZeneca/COVISHIELD or mRNA (Pfizer/Moderna) vaccine based on the individual’s choice. See <a href="#">Second dose for AstraZeneca recipients</a> for information on second doses to help individuals make the choice.</td>
</tr>
<tr>
<td><strong>Administration with Other Products</strong></td>
<td>AstraZeneca/COVISHIELD COVID-19 vaccine may be co-administered with, or at any time before or after other vaccines (including live, inactivated, adjuvanted or unadjuvanted vaccines).</td>
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<td></td>
<td>Currently there is no data on the impact of the COVID-19 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.</td>
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<td></td>
<td>o 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 or delayed for at least 28 days after a dose of COVID-19 vaccine.</td>
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<tr>
<td></td>
<td>o Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed.</td>
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<td></td>
<td>o 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.</td>
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<tr>
<td></td>
<td>COVID-19 vaccines should be delayed for at least 90 days after the receipt of SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment of COVID-19 infection. This applies to people who received these therapies before receiving any COVID-19 vaccine dose and between doses.</td>
</tr>
<tr>
<td></td>
<td>Timing of administration and potential interference between COVID-19 vaccine and monoclonal products or convalescent plasma as part of COVID-19 treatment are currently unknown and administering these products close together may result in less effectiveness of the COVID-19 vaccine.</td>
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<td></td>
<td>A deferral for at least 90 days is based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon within the 90 days after initial infection.</td>
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<td></td>
<td>This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses.</td>
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<td></td>
<td>COVID-19 vaccine doses inadvertently received within 90 days after receipt of passive antibody therapy do not need to be repeated.</td>
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<tr>
<td></td>
<td>Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment of COVID-19 infection are currently unknown and the primary care provider or medical specialist should be consulted on a case-by-case basis.</td>
</tr>
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<td>AstraZeneca (Vaxzevria) COVID-19 Vaccine</td>
<td>COVISHIELD COVID-19 Vaccine</td>
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<tr>
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<tr>
<td>• Viral vector 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.</td>
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</tr>
</tbody>
</table>

**Appearance**
- The solution is colourless to slightly brown, clear to slightly opaque and particle free.

**Storage**
- Can be stored in a refrigerator between +2°C to +8°C storage until expiry.
- Punctured vials can be stored at room temperature up to +30°C for 6 hours.
- Punctured vials can be stored in a refrigerator (+2 to +8°C) for 48 hours.
- Punctured vials can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours. After this time, the vial must be discarded.
- Do not freeze.

**Packaging**
- **Vaccine:**
  - 10 doses per vial
  - 5 mL of solution in a 10-dose vial (clear type I glass) with stopper (elastomeric with aluminum overseal)
  - 10 vials per package

**Preparation/Reconstitution**
- No reconstitution is required.

**Vaccine Code**
- COVAUVec
- COVSIIVec

**Antigen Code**
- COVID-19-5
- COVID-19-8

**Licensed Use**
- 18 years of age and older

**Off-License Use**
- Booster dose/additional doses

**Program Notes**
- 2021 February 26: Licensed for use in Canada.
- 2021 March 10: Implemented in Alberta.
- 2021 March 29: Indications for use changed to 55 years of age and older. Pause on use in individuals under 55 years of age.
- 2021 April 19: Indications for use changed to 40 years of age and older.
- 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 who have received AstraZeneca/COVISHIELD vaccine as the first dose.
- 2021 April 30: Indications for use update – may be offered to individuals 30 years of age and older living or working in areas with high rates of transmission with approval from the Government of Alberta.
- 2021 May 6: Updated considerations for pregnancy and lactation.
- 2021 May 18: Updated indications for use of the vaccine; clarified interval recommendation for profoundly immunocompromised.
- 2021 May 28: Exceptions to extended interval expanded to include individuals with chronic kidney disease on peritoneal or hemodialysis.
- 2021 May 31: Updated recommendations on second dose schedule and vaccine product.
- 2021 June 3: Updated VITT rates, VITT symptom list and interchangeability section.
- 2021 June 14: Monitoring period for VITT updated to 42 days (changed from 28 days); 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 29: Updated to incorporate safety information from Health Canada on capillary leak syndrome (CLS).
- 2021 September 10: Updated information on additional doses for immunocompromised, residents in senior congregate living facilities and for travel; 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.
- 2021 October 6: Updated third dose eligibility to include individuals 75
AstraZeneca (Vaxzevria)
COVID-19 Vaccine

years of age and older and 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.
- 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 15: Expanded booster dose eligibility for health care workers.
- 2021 December 21: Interval for third (booster) doses changed from at least 6 months to at least 5 months after last dose of 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: Clarified wording on individuals with history of COVID-19 infection.
- 2022 March 2: Updated to incorporate NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization.
- 2022 April 12: Updated to incorporate additional dose eligibility for travel purposes; included link to “COVID-19 Immunization for Individuals with Allergies and Other Health Conditions”.

Related Resources

References
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