

COVID-19 Vaccine (ChAdOx1-S [recombinant])

AstraZeneca COVID-19 Vaccine
COVISHIELD

Supplier: AstraZeneca

Supplier: Verity Pharmaceuticals

INDICATIONS:

- Individuals 55 years of age and older ^A
- Vaccination will occur in phases. Sequencing of populations for whom the vaccine is currently indicated in British Columbia is available on the BCCDC [COVID-19 Vaccine Eligibility](#) page.

These vaccines are not approved for use in those less than 18 years of age.

DOSES AND SCHEDULE:

Adults 55 years of age and older: 2 doses given as 0.5 mL IM, 4 months apart. ^{B, C}

ADMINISTRATION:

- No reconstitution required.
- Following withdrawal of all available 0.5 mL doses, the residual vaccine from up to three vials may be withdrawn into the same syringe to constitute a full dose provided the vials are from the same manufacturer and the same lot number. See [addendum](#) for more information.

Storage and Handling:

- Unopened multidose vial:
 - +2°C to +8°C up to the end of its expiry date, kept in the original packaging and protected from light. Do not freeze.
- Opened multidose vial:
 - After first vial puncture, the vaccine is stable at room temperature (up to +30°C) for **6 hours** OR at +2°C to +8°C for **48 hours**.
 - After the first puncture, the vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative refrigerated storage time must not exceed 48 hours. After this time, the vial must be discarded.
 - The vaccine can be pre-loaded into a syringe for up to 6 hours at room temperature (up to +30°C).
 - Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry.
 - During use, vials/syringes may be handled in room light conditions.

^A Although the vaccines are authorized for those 18 years of age and older, due to a safety signal identified in Europe following use of the AstraZeneca vaccine, [NACI](#) has recommended that neither of the ChAdOx1-S vaccines be used in people under 55 years of age. [Health Canada](#) has updated the product monographs for both products to include information about observed events of thromboembolic/thrombocytopenia, as these vaccines are comparable.

^B The two ChAdOx1-S vaccines are interchangeable within the vaccine series, however they are not interchangeable with other COVID-19 vaccines (e.g., mRNA vaccines).

^C While the approved minimum interval between dose 1 and 2 is 4 weeks, the preferred shortest interval is 12 weeks. As such, an acceptable range for administration of the second dose is 12 weeks to 4 months after the first dose. If administration of the second dose is delayed beyond 4 months, the second dose should be provided as soon as possible and the series does not need to be restarted.

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BOOSTER DOSES:

No booster doses are recommended at this time.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine.

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80.

Other components: disodium edetate dihydrate, ethanol, L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, sucrose.

PRECAUTIONS:

- For the following populations, a complete COVID-19 vaccine series may be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in these populations:
 - immunosuppressed due to disease or treatment
 - those with an autoimmune condition ^A
 - pregnancy and breastfeeding ^B
- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period.
- Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
- There is insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, COVID-19 vaccination should be deferred for at least 90 days as a precautionary measure to avoid potential interference of the antibody therapy with vaccine-induced immune response.
- Due to the theoretical risk that viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results, these tests should be administered and read before COVID-19 immunization or delayed for at least 4 weeks after immunization. COVID-19 immunization may take place at any time after all steps of tuberculin skin testing have been completed.

^A For more information see the [CRA Recommendation on COVID-19 Vaccination in Persons with Autoimmune Rheumatic Disease](#).

^B For more information see the [SOGC Statement on COVID-19 Vaccination in Pregnancy](#).

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SPECIAL CONSIDERATIONS:

- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.
- Wait a period of at least 14 days after the administration of each ChAdOx1-S vaccine dose before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response.
- Wait for a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine to prevent erroneous attribution of an adverse event following immunization to a particular vaccine.
- A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed SARS-CoV-2 infection.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.

ADVERSE EVENTS:

Local: pain, swelling, redness, pruritus

Systemic: fatigue, headache, myalgia, chills, arthralgia, fever, malaise, nausea.

A potential increased risk of serious blood clots has been observed within 4 to 16 days following receipt of the AstraZeneca vaccine. This adverse event is being referred to as Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) and is estimated to occur in approximately 1 in 100,000 to 1 in 1,000,000 vaccine recipients. Most but not all of these cases have occurred in women under 55 years of age. Symptoms warranting medical attention include: blurred vision, difficulty speaking, a seizure, difficulty moving parts of the body, shortness of breath, chest pain, new severe swelling, pain or colour change of an arm or a leg, persistent abdominal pain, or abnormal bruising, reddish or purple spots or blood blisters under the skin, or bleeding beyond the site of vaccination.

REFERENCES:

1. [AstraZeneca product monograph](#)
2. [COVISHIELD product monograph](#)
3. [National Advisory Committee on Immunization: Recommendations on the use of COVID-19 Vaccine\(s\)](#)

ADDENDUM: Pooling residual vaccine from up to three vials to constitute an extra dose

Following withdrawal of all available 0.5 mL doses, a full 0.5 mL dose may be constituted from the residual vaccine volume from up to three separate vials, provided the vials are from the **same manufacturer** and **same lot number**. In order to minimize the risk of microbial contaminants and maintain product quality, the following processes should be followed:

- Only vials containing *residual* vaccine volume are to be used to prepare a full dose when using multiple vials to constitute a single dose. Residual volume should *not* be combined with contents from a different vial that still contains at least one full dose of the vaccine (to

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ADDENDUM (continued):

minimize the chance of contaminating the contents of a vial that still contains multiple doses of the vaccine).

- Given this vaccine does not contain preservative, and therefore has a short timeline for its use following first vial puncture (i.e., 6 hours), pooling of residual vaccine from two or three vials must occur as soon as possible - it is *not* recommended to save multiple vials with residual volume for use at one time (e.g., the end of the clinic).
- Perform hand hygiene before handling the vaccine. Strictly adhere to aseptic technique while handling the vaccine and minimize the number of vial punctures.
- Firmly and briskly wipe the surface of the rubber stopper with an alcohol swab for initial *and subsequent uses*, being sure to apply friction, and allow it to dry for at least 10 seconds.
- To assist with the withdrawal of residual vaccine from the vial, invert the vial and ensure the end of the needle is below fluid level and situated in the groove of the vial stopper.
- Once the residual vaccine is withdrawn, keep the needle in the vial when expelling air bubble(s) to minimize vaccine wastage.
- Check the syringe to ensure it contains the total 0.5 mL dose prior to administration.
- If not administered immediately, the syringe should be clearly labeled with the date and time of the vial with the shortest timeframe for use.