

ASTRAZENECA[®] COVID-19 VACCINE INFORMATION

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The AstraZeneca COVID-19 vaccine (ChAdOx1-S [recombinant]) is approved for people who are 18 years of age and older. Currently, there is limited information from clinical trials on the efficacy of AstraZeneca COVID-19 vaccine in individuals 65 years of age and older.

AstraZeneca COVID-19 vaccine is a solution for intramuscular injection that should be administered by a trained healthcare worker. The vaccine is a two-dose regimen.

Like all vaccines, this vaccine has specific storage and handling requirements that must be adhered to maintain its effectiveness. Failure to adhere to vaccine handling and cold chain requirements may reduce vaccine potency (resulting in lack of protection against COVID-19) and/or increased local reactions at the site of the vaccine administration. The loss of vaccine effectiveness due to cold chain exposures to adverse conditions is cumulative, permanent and irreversible.

Long Term Storage Prior to First Use

- AstraZeneca COVID-19 vaccine multi-dose vials are stored in refrigerated conditions between +2.0°C to +8.0°C until expiry date. Store in the original carton and protect from light until ready to use.
- Do not freeze.

Punctured Vials

AstraZeneca COVID-19 vaccine is preservative-free. Once the vial has been punctured, it can be stored:

- at room temperature up to +30°C for 6 hours, or
- refrigerated between +2.0°C to +8.0°C for 48 hours

A punctured vial at room temperature can be re-refrigerated. However, the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time after first puncture must not exceed 48 hours. After this time, the vial must be discarded.

NOTE: There are no available stability data on storing AstraZeneca COVID-19 vaccine in syringes that are drawn up in advance.

Any unused vaccine or waste material should be disposed of in accordance with local requirements. Report all COVID-19 vaccine doses wasted to the COVID-19 vaccine inventory team at 1-877-464-9675 ext. 50174 or email covid19vaccine@york.ca

Administration

AstraZeneca COVID-19 vaccine is a colourless to slightly brown, clear to slightly opaque solution. Inspect the AstraZeneca COVID-19 vaccine vials visually for foreign particulate matter and/or discolouration prior to administration. If either of these conditions exists, the vaccine should not be

administered. You may contact a public health pharmacist for further consultation and direction at 1-877-464-9675 ext. 50174 or email covid19vaccine@york.ca.

Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Allow to air dry for 10 seconds.

Withdraw each 0.5 mL dose of the vaccine from the vial using a new sterile needle and syringe for each injection. The dose in the syringe should be used promptly.

Eight or ten 0.5 mL doses may be extracted from a single multi-dose vial (depending on 4mL or 10mL vial). It may be possible to withdraw an additional 0.5mL dose(s) of vaccine. When withdrawing subsequent doses, puncture the vial stopper at a different area each time to avoid coring of the rubber.

Do not mix AstraZeneca COVID-19 vaccine with other vaccines/products in the same syringe

AstraZeneca COVID-19 vaccine should be administered by the intramuscular (IM) route only. Do not inject the vaccine intravascularly, subcutaneously or intradermally. The preferred site is the deltoid muscle of the upper arm. A needle length of ≥ 1 inch should be used as needles < 1 inch may be of insufficient length to penetrate muscle tissue in some adults.

Needle Size and Syringes

A ≥ 1 -inch needle and a 1-mL or 3-mL disposable syringe may be used. For dose administration, a 22-25G needle is recommended.

The syringe should have markings to enable 0.5 mL volume to be measured accurately. Common disposable syringes made of polypropylene or polycarbonate are suitable for use. The syringes must be sterile, non-pyrogenic and intended for human-use.

Warning: Vaccine-induced thrombotic thrombocytopenia (VITT)

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with AstraZeneca COVID-19 vaccine during post-authorization use. The majority of these cases occurred within the first 3 weeks following vaccination. Some cases had a fatal outcome.

Healthcare professionals should be alert to the signs and symptoms of thrombosis and thrombocytopenia. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling or pain, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms after vaccination including sudden onset of severe headaches, persistent or worsening headaches, blurred vision, confusion or seizures, or who experiences unusual skin bruising or petechiae beyond the site of vaccination after a few days, should seek prompt medical attention.

Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive the AstraZeneca COVID-19 vaccine if the potential benefits outweigh the potential risks. Individuals who have experienced major venous or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca COVID-19 vaccine should not receive a second dose of AstraZeneca COVID-19 vaccine.

Recommended Dose Regimen

AstraZeneca COVID-19 vaccine is administered as two 0.5 mL 4 to 12 weeks apart as per the product monograph.

Individuals who have already received one dose of AstraZeneca COVID-19 vaccine may choose to receive AstraZeneca COVID-19 vaccine or an mRNA COVID-19 vaccine product (ie. Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine) as the second dose to complete the vaccination series, provided the minimum intervals and age indications are met.

Individuals who have experienced major venous or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca COVID-19 vaccine should not receive a second dose of AstraZeneca COVID-19 vaccine.

For the most current vaccine eligibility requirements and administration intervals between the 1st and 2nd doses, consult with latest guidance from the Ministry of Health.

Non-Medicinal Ingredients

AstraZeneca COVID-19 vaccine does not contain any preservatives, animal-derived products, eggs, gelatin, gluten, lactose, latex, mercury, peanut or tree nut derivatives, thimerosal, or soy

Non-medicinal ingredients include:

- Disodium edetate dihydrate (EDTA)
- Ethanol (0.002g)
- L-Histidine
- L-Histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80
- Sodium chloride
- Sucrose
- Water for injection

The vial does not contain natural rubber latex.

Reporting Adverse Events Following Immunization

If a patient experiences a side effect following immunization with AstraZeneca COVID-19 vaccine, complete the [Adverse Events Following Immunization \(AEFI\) Form](#) and submit to York Region Public Health via fax at 905-898-5213 or call our Nurses Line at 1-877-464-9675 ext. 73452.

Secure Disposal of Vaccine Vials, Labels, and Packaging

Health care providers should be aware of fraudulent activities related to COVID-19 vaccines during this stage of vaccine programming in Canada and internationally where there is limited supply of vaccine compared to demand. There have been reports of fraudulent attempts to sell vaccine doses by non-government and private entities.

It is important to take the following steps to reduce the potential for the re-use of COVID-19 vaccine vials, labels, and packing for fraudulent activities:

- Remove or destroy (tear-off or mark-up) the vial label prior to disposal
- Destroy and discard vial trays, boxes, and all associated vaccine packaging so that they cannot be reused
- Securely store and dispose of empty vials

The Ministry of Health and Health Canada are working together with vaccine manufacturers, importers, and law enforcement agencies to investigate any reports of fraudulent attempts to sell vaccine doses by non-government/private entities. All fraudulent activity involving COVID-19 vaccines should be reported to Ministry of Health at EOCoperations.moh@ontario.ca for further investigation.

Contact York Region Public Health

If you have any questions about the AstraZeneca COVID-19 vaccine or about COVID-19, call York Region Public Health's phone line for health care professionals at 1-877-464-9675 ext. 77280, staffed from 8:30 a.m. to 4:30 p.m., Monday to Friday. For COVID-19 vaccine distribution, call 1-877-464-9675 ext. 50174 or email covid19vaccine@york.ca.