

AstraZeneca & COVISHIELD (SII) COVID-19 vaccines

A brief overview (Updated) March 31, 2021

AstraZeneca & COVISHIELD COVID-19 vaccines

- Health Canada authorized both applications for AstraZeneca & COVISHIELD vaccines with conditions on February 26, 2021, under the [interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19](#)
- The vaccines are ChAdOx1-S recombinant vaccines (viral vector-based), developed by AstraZeneca and Oxford University.
 - AstraZeneca COVID-19 vaccine is manufactured by AstraZeneca
 - COVISHIELD COVID-19 vaccine is manufactured by Serum Institute of India (SII)
 - Health Canada has reviewed the manufacturing information for these vaccines and found them to be comparable.

How do viral vector-based vaccines work?

- Both AstraZeneca and COVISHIELD COVID-19 vaccines use viral vector-based technology, and are recombinant vaccines (non-replicating/inactivated vaccines).
- Viral vector-based vaccines use a harmless virus, such as an adenovirus, as a delivery system. When a person is given the vaccine, the vector virus contained within the vaccine produces the SARS-COV-2 spike protein.
 - This protein is found on the surface of the virus that causes COVID-19 infection.
 - This protein will not cause COVID-19 infection or make the individual sick.
- Through this process, the body is able to build a strong immune response against the spike protein without exposing the individual to the virus that causes COVID-19 infection.

Indications, dosage, & scheduling

- **Indications/eligibility:** 55 years* of age and older without contraindications
- **Scheduling & dosing:** 2 dose series, 0.5ml intramuscular injections given 4-12 weeks apart (label recommendation)
 - BC program will observe 4 month interval between doses

*March 29, 2021: NACI updated recommendations that AstraZeneca/COVIDSHIELD (SII) should not be used in adults under 55 years of age at this time while the safety signal of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) with the vaccine is investigated further

Clinical implications for indications of use

- Adults 55 years of age and older may still be offered the AstraZeneca vaccine with informed consent, given the increased risk of hospitalization and death due to COVID-19 disease in this population and since VTE appears to be a rarer event in this age group.
- Anyone receiving the AstraZeneca COVID-19 vaccine should be informed of this potential adverse event and advised to seek immediate medical attention if they develop symptoms of thromboembolism and/or thrombocytopenia (eg. SOB, chest pain, leg swelling, persistent abdominal pain, neurological symptoms including sudden onset of severe or worsening headaches or blurred vision, skin bruising [other than injection site]) between days 4 and 20 following receipt of the AstraZeneca vaccine.

Vial presentation

- Multi-dose vials
 - AstraZeneca can come in 8-dose or 10-dose presentations
 - COVIDSHIELD (SII) comes in 10-dose presentation
- Preservative-free
- No reconstitution required
- The vaccine is colourless to slightly brown, clear to slightly opaque solution.

Storage

- Unopened vials: Refrigerator temperature between 2 to 8°C, store until expiration date
- Once punctured:
 - 6 hours at room temperature, up to 30°C,
 - or**
 - 48 hours in a refrigerator (2 to 8°C).

The vial 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.

Contraindications

- Individuals with hypersensitivity to an active ingredient or to any other ingredient in the vaccine

Ingredients

- **Medicinal ingredient**
 - Adenovirus vector vaccine
- **Non-medicinal ingredients**
 - disodium edetate dihydrate (EDTA)
 - ethanol
 - L-histidine
 - L-histidine hydrochloride monohydrate
 - magnesium chloride hexahydrate
 - polysorbate 80 (**potential allergen**)
 - sodium chloride
 - sucrose
 - water for injection

Side effects

- **Most commonly reported:** injection site tenderness (75.3%), injection site pain (54.2%), fatigue (62.3%), headache (57.5%), myalgia (48.6%), malaise (44.2%), pyrexia (33.6%), chills (31.9%), arthralgia (27.0%), and nausea (21.9%).

Vaccine efficacy

- In clinical trials, overall vaccine efficacy in participants who received 2 standard doses of the vaccine, suggests an efficacy rate of 62%
 - With protection starting from approximately 3 weeks after the first dose of vaccines and persists up to 12 weeks.
- While a second dose is recommended to be given at a 4-12 week interval after the first dose, evidence suggests that efficacy increases with longer dosing intervals.

Main differences between COVID-19 vaccines	mRNA: Pfizer-BioNTech & Moderna	Viral vector-based: AstraZeneca & COVIDSHIELD
Mechanism of action	New vaccine technology: instructs our cells to create spike protein which presents on the surface of our cell to trigger an immune response	Technology used in vaccines such as Hepatitis B: COVID-19 viral vector-based vaccines use an inactivated/non-replicating virus (eg. adenovirus) as a vector to produce the spike protein which triggers an immune response
Potential allergens	Polyethelene glycol (PEG)	Polysorbate 80
Vaccine efficacy (VE)	After completion of series: VE ~ 95% 2 weeks after 1 dose: > 90% VE for most individuals	After completion of series: VE ~ 62%
Interchangeability	Not interchangeable	Interchangeable within the series, but not interchangeable with other COVID-19 vaccines (eg. mRNA)
Storage	Limited refrigerator storage (+2°C to +8°C) Pfizer-BioNTech (up to 5 days) Moderna (up to 30 days)	Can be stored in refrigerator (+2°C to +8°C) until listed expiry date

Health Canada Links:

- AstraZeneca COVID-19 product monograph

<https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf>

- COVISHIELD COVID-19 product monograph

<https://covid-vaccine.canada.ca/info/pdf/covishield-pm-en.pdf>

- AstraZeneca & COVISHIELD “what you should know”

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/astrazeneca.html>