COVID-19 Vaccine AstraZeneca

The Immunisation Advisory Centre

Information for healthcare professionals to support delivery of the AstraZeneca COVID-19 vaccine

Key Information

- Non-replicating adenoviral vector vaccine
- Brand name: COVID-19 Vaccine AstraZeneca
- Immunisation Handbook abbreviation: ChAd-CV
- Also known as: Vaxzevria and Covishield (Indian version)

Background

This vaccine is the most widely used COVID-19 vaccine in the world and is approved in 124 countries, including in UK, Australia, Canada, India and much of Europe.

It is a non-replicating viral vector vaccine, that uses a chimpanzee adenovirus (ChAdOx1) encoded with the SARS-CoV-2 spike protein gene, to deliver the instructions for the spike protein and induce a specific immune response. The adenovirus has been modified so that it can only express the spike protein gene and no other components of itself.

Safety Profile

Potential responses:

Clinical trial: The phase 3 study showed a higher rate of local solicited (anticipated) adverse events in the vaccinated group, compared to the placebo group (74.1% in the vaccinated group vs. 24.4% in the placebo group) and a higher rate of systemic solicited adverse events (71.6% vs 53.0%). The majority of solicited adverse events (92.6%) across both groups were mild or moderate in intensity. Events occurred more frequently following the first dose in comparison to the second dose in all age groups, a difference that was more marked in participants aged 18 to 64. Most adverse events resolved within 1 to 2 days after onset.

Australian experience: as part of the AusVaxSafety active surveillance, just over half of the people who received this vaccine in Australia reported a short-term adverse reaction within a 72-hour period following dose one. Fewer (25%) reported adverse events after dose 2. Common responses (reported in 30-40% of surveys) were fatigue, local reaction at site of injection, headache and muscle aches. Fever and gastrointestinal symptoms were reported less commonly. After dose one, around one in five reported missing their usual activities (majority for less than one day) compared with one in 20 after dose two. One in 100 people consulted a medical professional after the first dose and fewer people after dose two.

Serious adverse events

Thrombosis with thrombocytopenia syndrome:

A very rare (around 2 cases per 100,000) but increased risk of thrombosis with thrombocytopenia syndrome (TTS) has been identified with adenoviral vector vaccines like the AstraZeneca vaccine, typically occurring within 2–3 weeks (range 4 – 42 days) of vaccination and more prevalent in younger adults (<50 years). TTS is also known as vaccine-induced thrombotic thrombocytopenia (VITT).

The AstraZeneca vaccine is **contraindicated** for anyone with a history of major venous and/or arterial thrombosis in combination with thrombocytopenia following vaccination with any COVID-19 vaccine. Patients with a history of the following rare causes of thrombosis are also not advised to receive AstraZeneca vaccine:

- cerebral venous sinus thrombosis (CVST)
- idiopathic thrombosis in the abdomen such as in splanchnic circulation, including mesenteric, portal or splenic veins
- heparin-induced thrombocytopenia
- thrombosis associated with antiphospholipid syndrome.

It is recommended that individuals with a history of thrombosis, autoimmune disorders or thrombocytopenia discuss the benefits and risks of vaccination with a health professional or specialist.
This Australian document provides guidance around decision making (in the Australian COVID-19 context): COVID-19 vaccination – Weighing up the potential benefits against risk of harm from COVID-19 Vaccine AstraZeneca | Australian Government Department of Health

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Presentation of TTS:

If an AstraZeneca vaccine recipient has any of the following from around 4 days after vaccination, they should seek medical advice urgently:

- a severe headache that is not relieved with simple painkillers or is getting worse or feels worse when you lie down or bend over
- an unusual headache that may be accompanied by blurred vision, confusion, difficulty with speech, weakness, drowsiness or seizures (fits)
- rash that looks like small bruises or bleeding under the skin beyond the injection site
- shortness of breath, chest pain, leg swelling or persistent abdominal pain.

In Australia, presentation in younger individuals (under 50 years), predominantly after first dose, tend to be more severe, with clots presenting in unusual areas such as brain and abdomen; whereas cases in older adults tend to be less severe, with clots in typical areas, such as legs and lungs, and after the second dose.

Management of TTS:

Early detection of TTS may help to prevent more serious complications developing and appropriate management can help to prevent fatality. Patients presenting with headaches and low platelets should be thoroughly investigated for blood clots in the brain, including careful review of imaging results to identify early, small clots. Patients presenting with thrombosis after vaccination should also be investigated for low platelets. If not appropriately investigated, treatment with platelet transfusions or heparin-based anticoagulants can be harmful.

For further guidance of management of suspected cases of TTS:

- Guidance for primary care COVID-19 vaccination – Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine | Australian Government Department of Health
- Radiological investigations: The Royal Australian and New Zealand College of Radiologists have published Position Statements and Guidance | RANZCR
- VITT COVID-19 resources: Thrombosis and Haemostasis society of Australia and New Zealand (THANZ). https://www.thanz.org.au/resources/covid-19

Capillary Leak Syndrome:

Extremely rare cases of capillary leak syndrome (CLS) have been reported following vaccination with viral vector vaccines, predominantly in those who have had previous episodes (14 suspected cases in UK after 49 million doses, three of which had a history of CLS). This is an extremely rare relapsing-remitting condition and triggers for relapses are not well understood. As a precautionary measure, COVID-19 Vaccine AstraZeneca is **contraindicated** in people with a history of capillary leak syndrome.

Guillain-Barré Syndrome:

Guillain–Barré syndrome (GBS) is a rare neurological condition associated with viral and gastrointestinal infections. Evidence is emerging of a very rare association with the viral vector COVID-19 vaccines (in Europe, around four cases per million doses). Recent Australian passive surveillance data has reported an incidence of around ten cases per million doses of this vaccine and all cases were aged over 50 years.

People should seek medical attention if they experience symptoms that could suggest GBS, as early medical care can reduce severity and improve outcomes. Symptoms include weakness and paralysis in the hands or feet that can progress to the chest and face over a few days or weeks. Symptoms tend to affect both sides of the body.

Immune Thrombocytopenia:

In Australia there have been 87 reports of suspected immune thrombocytopenia (ITP; also known as idiopathic thrombocytopenic purpura) following vaccination with AstraZeneca vaccine in less than one in every 100,000 people vaccinated. These patients had an extremely low platelet count, and signs of thrombocytopenia, which may include unusual bruising, a nosebleed and/or blood blisters in the mouth. Symptoms occurred within a timeframe that suggested they could be linked to vaccination and no other obvious cause was identified based on the information provided.

Use in Pregnancy

COVID-19 AstraZeneca vaccine is not recommended during pregnancy. There are no theoretical safety concerns specific to this vaccine use in pregnancy, but data is limited on its use and there is more safety data available for the Pfizer vaccine, Comirnaty. Therefore, Comirnaty is the preferred vaccine to be given in pregnancy for NZ. Use of the AstraZeneca vaccine in pregnant people/women should be based on an assessment of whether the benefits of vaccination outweigh the potential risks.

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Use when Breastfeeding

AstraZeneca vaccine is safe to be given whilst breastfeeding.

Use after a first dose of Pfizer vaccine

Most experience concerning mixed COVID-19 vaccine schedules have been among people who had a first dose of AstraZeneca vaccine and second dose of Pfizer. One study, involving just over 100 people who had Pfizer followed by AstraZeneca vaccine, found that those who had a mixed schedule had higher antibody levels compared to people who had two doses of the AstraZeneca vaccine and comparable levels to those who had received two doses of the Pfizer vaccine.

Adverse reactions, mostly occurring within 2 days of vaccination, are more common among those who received the Pfizer vaccine followed by the AstraZeneca vaccine. For example, feverishness was reported by 41% of recipients of Pfizer for first dose and AstraZeneca for second dose, compared with 21% of recipients who had Pfizer vaccine for both doses. Similar increases were observed for chills, fatigue, headache, joint pain, malaise, and muscle ache, and those receiving Pfizer then AstraZeneca were 50% more likely to report taking paracetamol for symptoms than those who had two Pfizer doses (60% vs 41%).

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