COVID-19 Vaccine AstraZeneca Information Sheet

**Taiwan Centers for Disease Control,
Ministry of Health and Welfare, Sep. 23, 2021**

COVID-19 Vaccine AstraZeneca (ChAdOx1-S)

COVID-19 Vaccine **AstraZeneca** is a replication-deficient adenovirus vector vaccine that encodes the SARS-CoV-2 spike protein(S protein) and is used to protect against COVID-19. This vaccine has received an emergency use authorization from the World Health Organization, the European Union, Taiwan, etc., and is suitable for adults 18 and older. Two doses of intramuscular injection are required for protection. In clinical trials, a full two-dose course was 61% effective at preventing symptomatic infections, based on a median follow-up of 80 days. [1] Analysis of clinical data shows that when the interval between the two doses is at least 12 weeks, protection can reach 81% following the completion of a full two-dose course.[2] Therefore, the Advisory Committee on Immunization Practices (ACIP) of the Ministry of Health and Welfare recommends an interval of at least eight weeks between the first and second dose, and an interval of 10-12 weeks for greater efficacy.

Before vaccination: contraindications and precautions

Contraindications to vaccination:

This vaccine must not be given to individuals with a history of severe allergic reactions to any of the vaccine components, who had a severe allergic reaction to the first dose, or who have experienced thrombosis with thrombocytopenia syndrome or who have previously experienced episodes of capillary leak syndrome.

Precautions:

1. Thrombosis with thrombocytopenia syndrome has been observed very rarely following the administration of COVID-19 Vaccine **AstraZeneca**. Please consult your doctor and assess related risks before inoculation.
2. Individuals who have experienced thrombosis with thrombocytopenia syndrome or heparin-induced thrombocytopenia in the past should avoid vaccination.
3. This vaccine should not be used interchangeably with other COVID-19 vaccine products. If two doses of different COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended.
4. There is currently no data on the immunogenicity and safety of concomitantly administering this COVID-19 vaccine with other vaccines. A minimum interval of 7days between this vaccine and other vaccines is recommended. If vaccines are administered at a shorter interval, no additional doses of either vaccine are recommended.
5. Vaccination should be postponed for individuals suffering from a fever or an acute moderate-to-severe illness.
6. Individuals with a weakened immune system, or who are receiving immunosuppressive therapy, may have a diminished immune response to the vaccine. (There is no data to assess administration on those who are immunocompromised or receiving immunosuppressive therapy.)
7. There is a lack of clinical trial data and safety information on COVID-19 vaccination for pregnant women. Observational studies show that pregnant women have a higher risk of developing severe symptoms if they are infected by SARS-CoV-2. Pregnant women at high risk of occupational exposure to SARS-CoV-2, or who have chronic diseases that increase their risk of severe illness, should weigh the risks and benefits of inoculation with their doctor before receiving the vaccine.
8. Vaccination is advised for lactating women who are part of a recommended group for vaccination (such as medical staff). There is not enough data to assess the safety of COVID-19 vaccines for lactating women or on the effects on nursing children. However, COVID-19 vaccines are generally considered safe. Women can continue to breastfeed after receiving a COVID-19 vaccine.

After vaccination: precautions and possible side effects

1. To ensure that medical treatment is available in the very rare event of a severe and sudden allergic reaction, **individuals should be observed at or near the vaccination site for at least 15 minutes after inoculation. Recipients should closely self-monitor for reactions in the 15 minutes after leaving the vaccination site.** People with a history of acute allergic reactions after a vaccine or other injection should remain at the vaccination site for at least 30 minutes after inoculation. Recipients who are taking antiplatelet or anticoagulant drugs, or who suffer from abnormal blood coagulation, should apply pressure on the injection site for at least two minutes after the injection and observe whether there is still bleeding or hematoma.
2. The most common side effects that occur after vaccination are pain, redness, and swelling at the injection site, which usually go away within several days. Other possible reactions include fatigue, headache, muscle ache, elevated body temperature, chills, joint pain, and nausea. These side effects are less likely in older adults, and are usually mild and disappear in a few days. **It is common to develop a fever (≥38°C) after vaccination. This usually goes away within 48 hours.**
3. **If a fever persists for more than 48 hours or you experience severe allergic reactions such as difficulty breathing, wheezing, dizziness, fast heartbeat, or rash, get urgent medical attention to clarify the cause.** Inform the doctor of all your symptoms, when they appeared, and the date of injection as a reference for diagnosis. Suspected severe adverse reactions can be reported to the Vaccine Adverse Event Reporting System (https://www.cdc.gov.tw/-Category/Page/3-aXlTBq4ggn5Hg2dveHBg) via your health care provider or local health department.
4. **If any of the following symptoms occur within 28 days after vaccination, please seek medical attention immediately and describe your vaccination history:** (1) severe persistent headache, vision changes or epilepsy; (2) severe and persistent abdominal pain for more than 24 hours; (3) severe chest pain or difficulty breathing; (4) swelling or pain in the lower limbs; (5) spontaneous bleeding, bruising, and purpura.
5. Although vaccination reduces the chance of contracting COVID-19, it is still possible to become infected with SARS-CoV-2. Vaccinated people should continue to follow epidemic prevention guidelines to protect their health.

Adverse reactions listed on package leaflet

Frequency	Side Effects
Very common(≥1/10)	Headache; nausea; muscle pain; joint pain; tenderness, pain, warmth, itching, or bruising [a] at injection site; fatigue; feeling unwell; fever; chills
Common(≥1/100 ~ <1/10)	Low levels of blood platelets [b]; vomiting; diarrhea; Pain in extremity; swelling or redness at injection site; fever (≥38°C); influenza-like Illness; asthenia
Uncommon(≥1/1,000 ~ <1/100)	Enlarged lymph nodes; loss of appetite; dizziness; drowsiness; lethargy; abnormal sweating; itching; rash; urticaria
Very rare(<1/10,000)	Thrombosis with thrombocytopenia syndrome [c]
Not known	Immediate hypersensitivity reactions; other allergic reactions; capillary leak syndrome; angioedema

a. Bruising at the injection site, with or without hematoma formation, is a rare side effect.

b. Refer to the updated package leaflet of the European Medicines Agency. In clinical trials, temporary mild low levels of blood platelets is common.

c. After the global rollout of COVID-19 Vaccine AstraZeneca, it was discovered that a very rare side effect of the vaccine is a condition involving blood clotting and a low blood platelet count. Clinical manifestations have included venous thrombosis, such as cerebral venous sinus thrombosis, visceral venous thrombosis, and arterial thrombosis.

References

1. https://www.who.int/publications/m/item/chadox1-s-recombinant-covid-19-vaccine
2. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00432-3/fulltext

Prevaccination Checklist and Consent Form for COVID-19 Vaccine AstraZeneca

☐ I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of COVID-19 Vaccine AstraZeneca, as well as the precautions to take. I consent to COVID-19 vaccination after an evaluation by a physician.

Check list	Response of vaccine recipient	
	Yes	No
Have you experienced thrombosis with thrombocytopenia syndrome or heparin-induced thrombocytopenia in the past?		
Have you ever had a severe allergic reaction to a vaccine or an injectable medication?		
Are you currently experiencing physical discomfort (such as a fever of 38°C and above, vomiting, or difficulty breathing)?		
Do you have a weakened immune system, for instance, because you're on an immunosuppressive therapy?		
Have you had a vaccine injected in the last 7 days?		
Are you currently pregnant?		
Body temperature: °C		

Vaccine recipient's full name: _____

National ID/resident certificate/passport number: _____

Date of birth (yyyy/mm/dd): _____

Phone number: _____

Home address: _____

City/county: _____ **Village/township/district:** _____

Name of person giving consent: _____

National ID/resident certificate/passport number: _____

☐ **I am the person being vaccinated** ☐ **Relationship to person given consent for vaccination:**

◆ Physician's evaluation

☐ **Vaccination recommended** ☐ **Vaccination not recommended. Reason(s)**

Date of evaluation (yyyy/mm/dd): _____

Physician's seal: _____ **Ten-digit code of medical institution:** _____