

FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT ASTRAZENECA COVID-19 VACCINE

Q1: What vaccine is being registered?

A1: The Drug Control Authority (DCA) in its 354th meeting has granted **COVID-19 Vaccine AstraZeneca Solution for Injection** (Product Registration Holder: AstraZeneca Sdn. Bhd.; Manufacturer: Medimmune Pharma B.V. Netherland) a **CONDITIONAL REGISTRATION** on 2nd March 2021.

Each vial of COVID-19 Vaccine AstraZeneca contains 4ml (8 doses) or 5ml (10 doses).

Each dose (0.5ml) of COVID-19 Vaccine AstraZeneca contains not less than 5×10^{10} viral particles of recombinant, replicant-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S recombinant).

Q2: What are the conditions of the registration?

A2: Since the registration application is via “Conditional registration of Pharmaceutical Products during Disaster”, the approval is based on rolling submission of the latest data, the Product Registration Holder (PRH) will need to ensure all outstanding documents are to be submitted and deemed satisfactory by NPRA according to the timeline given.

Apart from that, the PRH is required to monitor the safety profile of the registered vaccine and inform NPRA soonest possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submitting Monthly Safety Summary Report to NPRA.

The validity of this conditional approval is one (1) year. During this period, the DCA will periodically be updated with all necessary information related to the quality, safety and efficacy of this vaccine. The conditional registration can be revoked if the conditions are not fulfilled by the PRH or if the benefit over risk of the vaccine is no longer deemed beneficial.

Q3: Why is COVID-19 Vaccine AstraZeneca granted a conditional registration?

A3: Clinical studies for COVID-19 Vaccine AstraZeneca are currently still on-going. The current interim analysis provided show a positive benefit over risk and hence making this available to the nation. However, further monitoring of the efficacy and safety will be needed in order to ensure that the benefit-risk balance of this vaccine remains positive.

Q4: Who can be given COVID-19 Vaccine AstraZeneca?

A4: COVID-19 Vaccine AstraZeneca is indicated for the active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals **18 years of age and older**. The use of this vaccine should be in accordance with the recommendations by the Ministry of Health Malaysia.

Q5: Who can't be given COVID-19 Vaccine AstraZeneca?

A5: COVID-19 Vaccine AstraZeneca should not be given to individuals who are known to have allergic reactions to any of the ingredients in the vaccine [*L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80 (E 433), Ethanol, Sucrose, Sodium chloride and Disodium edetate (dihydrate)*].

The second dose of the vaccine **should not be given** to individuals who had a severe allergic reaction after the first dose of this vaccine.

Q6: Can immunocompromised individuals receive COVID-19 Vaccine AstraZeneca?

A6: At the moment, there are insufficient clinical evidence to support vaccination in immunocompromised individuals, including those receiving immunosuppressant therapy. However, these recommendations may change as more clinical data is obtained. Please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine.

Q7: If I have the following conditions, or receiving or have received these treatments, can I receive the vaccine?

A7: Please consult your doctor if you:

- have any form of allergies, bleeding disorder, or taking any blood thinning medications
- recently or currently receiving treatment for cancer, organ or stem cell transplantation
- had a previous history of COVID-19 infection, had previously received another COVID-19 vaccine (whether during an immunisation program or was involved as a subject in a COVID-19 clinical study) or previously received passive antibodies therapy for COVID-19

You may receive the vaccine even if you have the above conditions. However, please speak with your doctor before deciding if you are a suitable candidate.

Q8: How is COVID-19 Vaccine AstraZeneca given?

A8: COVID-19 Vaccine AstraZeneca should be injected into the deltoid muscle of the upper arm as a course of 2 doses (0.5mL each). The second dose is to be taken between 28 to 84 days after the first dose.

Q9: How well does COVID-19 Vaccine AstraZeneca prevent COVID-19?

A9: In the pooled analysis of the two on-going phase III clinical trials, the vaccine was 59.5% (95%CI 45.8-69.7) effective in preventing symptomatic COVID-19 disease following completion of 2 doses of the vaccine regime. This fulfilled the efficacy standard as recommended by WHO, where the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%, and the lower bound of confidence interval (CI) should be >30%. More data is expected from ongoing Phase III trials on a rolling review basis.

Q10: How long will COVID-19 Vaccine AstraZeneca provide protection?

A10: As the clinical trial is still currently ongoing, no data is available to inform about the duration of protection that the vaccine will provide. This however will be made known once updated data is available.

Q11: Can people who have already had COVID-19 get COVID-19 Vaccine AstraZeneca?

A11: Available data indicate that COVID-19 Vaccine AstraZeneca is safe when given in people with evidence of prior COVID-19 disease. Since previously infected individuals can be at risk of COVID-19 (i.e. reinfection), vaccination may be offered to them. However, please speak with your doctor before deciding if you are a suitable candidate.

Q12: Can pregnant or breastfeeding women receive COVID-19 Vaccine AstraZeneca?

A12: Pregnant or breastfeeding women were excluded in the clinical trials. Since no data on the safety and efficacy of this vaccine is available in these population, current evidence is unable to make recommendation for these groups until further available data is obtained. However, please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine.

Q13: Can elderly receive COVID-19 Vaccine AstraZeneca?

A13: The vaccine is indicated for people aged 18 years and above. However, based on the current available clinical data, there is limited number of subjects aged 55 years and above recruited and analysed therefore the data in this population are limited. Based

on early phase data, administration of COVID-19 Vaccine AstraZeneca to individuals aged 55 years and above has shown adequate and similar neutralizing antibodies titres as in younger adults. At present, it is recommended that vaccination for people aged 55 and above should be cautiously considered, its necessity should be evaluated based on their health condition and exposure risk.

Q14: Can children receive COVID-19 Vaccine AstraZeneca?

A14: Currently in Malaysia, the vaccine is indicated for individuals 18 years of age and older. This is because there is not enough data yet to determine the effectiveness and safety of this vaccine in those under 18 years old. Hence children below the age of 18 should not take the vaccine until further data is made available.

Q15: What are the side effects of COVID-19 Vaccine AstraZeneca?

A15: COVID-19 Vaccine AstraZeneca can cause the following side effects:

- Very common side effects (may affect more than 1 in 10 people): headache, nausea, myalgia, arthralgia, injection site tenderness, injection site pain, injection site warmth, injection site pruritus, injection site bruising, fatigue, malaise, feverishness and chills.
- Common side effects (may affect up to 1 in 100 people): injection site swelling, injection site erythema, fever ($\geq 38^{\circ}\text{C}$), vomiting and diarrhoea.
- Uncommon side effects (may affect up to 1 in 1000 people): lymphadenopathy, decreased appetite, dizziness, somnolence, hyperhidrosis, pruritus and rash.
- There is a remote chance that the vaccine could cause a severe allergic reaction even though the causal relationship has not been ascertained yet. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. Signs of a severe allergic reaction can include difficulty in breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body or dizziness and weakness.

Recipient will be monitored 15 minutes after the administration of this vaccine at the vaccination centre.

During marketing of COVID-19 Vaccine AstraZeneca in Malaysia, NPRA will monitor its use to ensure effectiveness and safety. Please inform your healthcare providers or report any side effects to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Q16: Can COVID-19 Vaccine AstraZeneca cause thromboembolic events (blood clots) following vaccination?

A16: Based on the known clinical data, thromboembolic events are not among the known or typical side effects of COVID-19 Vaccine AstraZeneca. Following vaccination of COVID-19 Vaccine AstraZeneca, very rare cases of blood clots in combination with low level of blood platelets has been reported. The severe cases of blood clots often in different or unusual locations (e.g. brain, bowel, liver, spleen) and excessive clotting or bleeding throughout the body. The majority of these cases occurred within the first fourteen days following vaccination and occurred mostly in women under 60 years of age. Some cases had a fatal outcome.

Please seek immediate medical attention if you develop shortness of breath, chest pain, leg swelling, or persistent abdominal pain following vaccination.

Also, please seek immediate medical attention if you experience after a few days severe or persistent headaches or blurred vision after vaccination, or experience skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days.

Q17: What should I do after I am vaccinated?

A17: All individuals should continue to follow the country's SOP. Practice the 3Ws (**Wash, Wear, Warn**) and avoid the 3Cs (**Crowded** space, **Confined** space, **Close** conversation).

For further information regarding COVID-19 Vaccine AstraZeneca Solution for Injection, please refer to the Package Insert and Patient Information Leaflet.

<https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21036009ACZ>

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