

# 阿斯特捷利康 COVID-19 疫苗接種須知

衛生福利部疾病管制署 2021 年 6 月 12 日

## AstraZeneca COVID-19 Vaccine Notice

Taiwan Centers for Disease Control, June 12, 2021

### 阿斯特捷利康 COVID-19 疫苗 ( ChAdOx1-S )

阿斯特捷利康 ( AstraZeneca ) COVID-19 疫苗是含有 SARS-CoV-2 病毒棘蛋白 ( S protein ) 之非複製型腺病毒載體疫苗，用於預防 COVID-19。本疫苗已通過 WHO、歐盟等先進國家及我國緊急授權使用，適用 18 歲以上，採 2 劑肌肉注射，並於臨床試驗中位數 80 天的追蹤期間證實可預防 61% 有症狀感染之風險<sup>1</sup>。另依臨床試驗資料分析，當接種間隔 12 週以上且完成 2 劑接種，保護力可達 81%<sup>2</sup>。基此，我國衛生福利部傳染病防治諮詢會預防接種組 ( ACIP ) 建議兩劑間隔至少 8 週，而間隔 10-12 週，疫苗接種效益更佳。

#### AstraZeneca COVID-19 Vaccine (ChAdOx1-S)

The AstraZeneca COVID-19 vaccine is a non-replicating adenovirus vector vaccine that contains SARS-CoV-2 virus S proteins and protects against COVID-19. The vaccine has already received Emergency Use Authorization (EUA) from the World Health Organization, the European Union and most advanced countries as well as in Taiwan for use on individuals aged 18 or over. It involves two intramuscular injections, with a clinical trial median 80 day tracking period confirming 61% protection against the risk of symptomatic infection. Moreover, an analysis of clinical trial data indicates that two doses of the vaccine at an interval of more than 12 weeks, offers 81% protection. As such, the Advisory Committee on Immunization Practices (ACIP) under the Ministry of Health and Welfare suggests a minimum interval of 8 weeks between vaccine shots, noting that an interval of 10-12 week optimizes the vaccination effect.

### 疫苗接種禁忌與接種前注意事項

- ◆ **接種禁忌：**對於疫苗成分有嚴重過敏反應史、先前接種本項疫苗劑次曾發生嚴重過敏反應或血栓合併血小板低下症候群者，不予接種。

#### Vaccination Contraindications and Pre-Vaccination Precautions

- ◆ Vaccination contraindications: Individuals with a history of severe adverse reactions to elements in the vaccine, who experienced a severe adverse reaction on taking the first dose of the vaccine or suffer from Thrombosis with Thrombocytopenia Syndrome (TTS) should not take the vaccine.

- ◆ **注意事項：**

1. **阿斯特捷利康 ( AstraZeneca )** COVID-19 疫苗與注射後非常罕見的血栓併血小板低下症候群可能有關聯，接種前請與醫師討論評估相關風險後再接種。
2. 過去曾發生血栓合併血小板低下症候群，或肝素引起之血小板低下症者，應避免接種。
3. 本疫苗不得與其他廠牌交替使用。若不慎接種了兩劑不同廠牌 COVID-19 疫苗時，不建議再接種任何一種產品。
4. 本疫苗不得與其他疫苗同時接種，與其他疫苗的接種間隔建議至少 14 天，如小於上述間隔，則各該疫苗亦無需再補種。
5. 發燒或正患有急性中重度疾病者，宜待病情穩定後再接種。
6. 免疫功能低下者，包括接受免疫抑制劑治療的人，對疫苗的免疫反應可能減弱。(尚無免疫低下者或正在接受免疫抑制治療者的數據)
7. 目前缺乏孕婦接種 COVID-19 疫苗之臨床試驗及安全性資料，而臨床觀察性研究顯示孕婦感染 SARS-CoV-2 病毒可能較一般人容易併發重症。孕婦若為 COVID-19 之高職業暴露風險者或具慢性疾病而易導致重症者，可與醫師討論接種疫苗之效益與風險後，評估是否接種。
8. 若哺乳中的婦女為建議接種之風險對象(如醫事人員)，應完成接種。目前對哺乳中的婦女接種 COVID-19 疫苗的安全性、疫苗對母乳或受哺嬰兒之影響尚未完全得到評估，但一般認為並不會造成相關風險。接種 COVID-19 疫苗後，仍可持續哺乳。

◆ **Precautions:**

1. There is a possible connection between the vaccine and extremely rare post-vaccination Thrombosis with Thrombocytopenia Syndrome so prior to getting vaccinated discuss the matter with a doctor and evaluate the related risk before deciding to proceed.
2. Those who have previously suffered from TTS or Heparin-induced Thrombocytopenia (HIT) should not get vaccinated.
3. This vaccine should not be used alternately with other brands of vaccine. If an individual inadvertently receives two doses of different COVID-19 vaccines it is recommended they have no more vaccinations.
4. This vaccine should not be used with other vaccines for simultaneous inoculation. A minimal vaccination interval of 14 days is suggested between vaccines, but if the period is less than the above interval there is no need for a supplementary shot of either vaccine.
5. Individuals with a fever or who are currently experiencing an acute moderate or serious illness should wait until their health stabilizes before getting vaccinated.
6. Individuals who are immuno-compromised, including those undergoing immuno-suppressive therapy are likely to have a weak immune response to the vaccine (there is no data available on the immuno-compromised or those undergoing immuno-suppressive therapy).
7. Currently there is no clinical trial and safety data on the inoculation of pregnant women with COVID-19 vaccines, but clinical observational studies indicate that pregnant women infected with the SARS-CoV-2 virus more easily develop severe complications. If a pregnant woman is at high risk of occupational exposure to COVID-19 or has a chronic illness likely to result in severe complications, she should discuss the benefits and risks of vaccination with a doctor before deciding whether to get inoculated.
8. Women who are breastfeeding and belong to an at-risk group for who vaccination is recommended (such as medical personnel) should get vaccinated. No comprehensive evaluation has yet been conducted on the safety of COVID-19 vaccines for breastfeeding women, or the impact of the vaccine on breast milk or breastfed infants, but it is generally considered to not result in related risks. After receiving a COVID-19 vaccine breastfeeding mothers can continue to breastfeed.

## 接種後注意事項及可能發生之反應

### Post-vaccination Precautions and Potential Reactions

1. 為即時處理接種後發生率極低的立即型嚴重過敏反應，**接種後應於接種單位或附近稍作休息留觀 15 分鐘，離開後請自我密切觀察 15 分鐘**，但針對先前曾因接種疫苗或任何注射治療後發生急性過敏反應之民眾，接種後仍請於接種單位或附近留觀至少 30 分鐘。使用抗血小板或抗凝血藥物或凝血功能異常者施打後於注射部位加壓至少 2 分鐘，並觀察是否仍有出血或血腫情形。
2. 疫苗接種後可能發生的反應大多為接種部位疼痛、紅腫，通常於數天內消失，其他可能反應包含疲倦、頭痛、肌肉痠痛、體溫升高、畏寒、關節痛及噁心，這些症狀隨年齡層增加而減少，通常輕微並於數天內消失。**接種疫苗後可能有發燒反應( $\geq 38^{\circ}\text{C}$ )，一般約 48 小時可緩解。**
3. **如有持續發燒超過 48 小時、嚴重過敏反應如呼吸困難、氣喘、眩暈、心跳加速、全身紅疹等不適症狀，應儘速就醫釐清病因**，請您就醫時告知醫師相關症狀、症狀發生時間、疫苗接種時間，以做為診斷參考。若為疑似疫苗接種後嚴重不良事件，可經由醫療端或衛生局所協助通報至「疫苗不良事件通報系統」(<https://www.cdc.gov.tw/Category/Page/3-aXITBq4ggn5Hg2dveHBg>)。
4. **接種疫苗後 28 天內，若出現以下任一症狀，請立即就醫並說明疫苗接種史**：(1)嚴重持續性頭痛、視力改變或癲癇；(2)嚴重且持續腹痛超過 24 小時以上；(3)嚴重胸痛或呼吸困難；(4)下肢腫脹或疼痛；(5)皮膚出現自發性出血點、瘀青、紫斑等。
5. 完成疫苗接種後，雖可降低罹患 COVID-19 的機率，但仍有可能感染 SARS-CoV-2，民眾仍需注重保健與各項防疫措施，以維護身體健康。

1. In order to facilitate a rapid response to any extremely rare post-vaccination immediate severe allergic reaction, after receiving a vaccine shot recipients are required to remain in the vaccine location or nearby for a period of 15 minutes. After leaving, please closely observe your reaction for a further 15 minutes. Individuals who have previously experienced a severe allergic reaction to vaccination or injection therapy are required to wait 30 minutes in the vaccination location or nearby. After vaccination those on antiplatelet or anticoagulant medication, or individuals with coagulation disorders should press down on the injection site for a minimum of 2 minutes and check whether it is still bleeding or there is a hematoma.
2. The most common potential post-vaccination response is swelling and soreness at the injection site, which generally disappears after a few days. Other reactions include fatigue, headache, muscle soreness, elevated body temperature, chills, joint pain and nausea. These symptoms diminish with age, but are generally mild and fade after a few days. After receiving a vaccine shot it is possible recipients could develop a fever ((38), which generally eases in about 48 hours.
3. If a vaccine recipient experiences a fever that persists for longer than 48 hours or a severe allergic reaction, including difficulty breathing, shortness of breath, dizziness, accelerated heartbeat or a body rash, seek immediate medical attention. Inform the doctor of your symptoms, when the symptoms occurred and when you were vaccinated as a diagnostic reference. If the symptoms are believed to be a post-vaccination Serious Adverse Event (SAE) they can be reported through a medical practitioner or the Ministry of Health and Welfare to the Vaccine Adverse Event Reporting System (VAERS).  
(<https://www.cdc.gov.tw/Category/Page/3-aXITBq4ggn5Hg2dveHBg>)。
4. If you experience any of the symptoms listed below within 28 days of receiving a vaccination please seek immediate medical attention and explain you vaccination history: (1) Severe persistent headache, changes in visual acuity, seizures; (2) Severe and persistent abdominal pain lasting longer than 24 hours; (3) Severe chest pain or difficulty breathing; (4) Swelling or pain in the lower extremities; (5) Spontaneous bleeding spots, bruising or purpura on the skin.
5. Although getting vaccinated reduces the chances of catching COVID-19, it is still possible to be infected with SARS-CoV-2 and so vaccination recipients need to look after their health and continue to take various pandemic prevention measures.

## 仿單所列之不良反應

頻率	症狀
極常見 (≥1/10)	頭痛；噁心；肌痛；關節痛；接種部位觸痛、疼痛、發熱、搔癢、瘀青 <sup>a</sup> ；倦怠；不適；發熱；發冷
常見 (≥1/100 ~ <1/10)	血小板低下症 <sup>b</sup> ；嘔吐；腹瀉；注射部位腫脹、紅斑；發燒(≥ 38°C)
不常見 (≥1/1,000 ~ <1/100)	淋巴結腫大、食慾減退、頭暈、嗜睡；多汗；搔癢；皮疹
極罕見 (<1/10,000)	血栓合併血小板低下症 <sup>c</sup>
目前尚不清楚	立即型過敏；過敏

a 注射部位瘀青包括注射部位血腫 (少見)；b 參照歐洲藥品管理局更新仿單；c 在國際間開始接種 AstraZeneca COVID-19 疫苗後，發現有嚴重且極罕見的個案發生血栓合併血小板低下症候群，臨床表現包含靜脈血栓，例如：腦靜脈竇栓塞、內臟靜脈栓塞，以及動脈血栓。

### 參考資訊

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](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00432-3/fulltext)

## Adverse Reactions on Labeling

Frequency	Symptoms
Extremely common (≥1/10)	Headache, nausea, muscle soreness, joint pain, tenderness, pain, heat, itchiness and bruising at the injection site, fatigue, discomfort, fever, chills.
Common (≥1/100 ~ <1/10)	Thrombocytopenia, <sup>b</sup> vomiting, diarrhea, swelling, erythema (redness/swelling) at the injection site, fever (≥ 38°C)
Uncommon (≥1/1,000 ~ <1/100)	Swollen lymph nodes, lack of appetite, dizziness, lethargy, excessive sweating, itching, rash
Extremely rare (<1/10,000)	Thrombosis with Thrombocytopenia Syndrome <sup>c</sup>
Currently unclear	Immediate hypersensitivity; allergies

a. Bruising at the injection site including hematoma (rare); b. European Medicines Agency updated labeling; c. After the international roll out of the AstraZeneca COVID-19 vaccine, severe but extremely rare cases of Thrombosis with Thrombocytopenia Syndrome were discovered the clinical manifestations of which include venous thrombosis, for example cerebral veno-sinus thrombosis, splanchnic vein thrombosis and arterial thrombosis.

### Reference information

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](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00432-3/fulltext)



# 阿斯特捷利康 COVID-19 疫苗接種評估及意願書

已詳閱 COVID-19 疫苗接種須知，瞭解阿斯特捷利康 ( AstraZeneca ) COVID-19 疫苗之保護效力、副作用及禁忌與注意事項，並同意經醫師評估後接種。

評估內容	評估結果	
	是	否
1. 過去是否曾發生血栓合併血小板低下症候群，或肝素引起之血小板低下症。		
2. 過去注射疫苗或藥物是否有嚴重過敏反應史。		
3. 現在身體有無不適病徵(如發燒 38°C、嘔吐、呼吸困難等)。		
4. 是否為免疫低下者，包括接受免疫抑制劑治療者。		
5. 過去 14 天內是否曾接種其他疫苗。		
6. 目前是否懷孕。		
7. 體溫：            °C		

被接種者姓名：\_\_\_\_\_ 身分證/居留證/護照字號：\_\_\_\_\_

出生日期：(西元) \_\_\_\_\_年\_\_\_\_\_月\_\_\_\_\_日      聯絡電話：\_\_\_\_\_

居住地址：\_\_\_\_\_縣市\_\_\_\_\_鄉鎮市區\_\_\_\_\_

立意願書人：\_\_\_\_\_ 身分證/居留證/護照字號：\_\_\_\_\_

本人       關係人：被接種者之\_\_\_\_\_

## ◆ 醫師評估

適合接種                       不適宜接種；原因\_\_\_\_\_

評估日期：\_\_\_\_\_年\_\_\_\_\_月\_\_\_\_\_日

醫療院所十碼代碼：\_\_\_\_\_ 醫師簽章：\_\_\_\_\_

