莫德納 COVID-19 疫苗接種須知

衛生福利部疾病管制署 2021 年 6 月 1 2 日

Moderna COVID-19 Vaccine Notice

Taiwan Centers for Disease Control, June 12, 2021

莫德納 COVID-19 疫苗 (mRNA-1273)

莫德納(Moderna)之 COVID-19 疫苗是 SARS-CoV-2 病毒棘蛋白之 mRNA 疫苗。本疫苗已通過美國、歐盟等先進國家及我國緊急授權使用,適用於 18 歲以上,接種 2 劑,並於臨床試驗中位數為 9 週的追蹤期間,證實可預防 94%有症狀之感染 ¹。我國衛生福利部傳染病防治諮詢會預防接種組(ACIP)建議兩劑接種間隔至少 4 週(28 天)。

Moderna COVID-19 Vaccine (mRNA-1273)

The Moderna COVID-19 vaccine is an mRNA vaccine based on the SARS-CoV-2 viral spike protein and has already received. Emergency Use Authorization (EUA) in the United States, the European Union and most advanced countries as well as in Taiwan for use on individuals aged 18 or over. It involves two injections, with a clinical trial median 9 week tracking period confirming 94% protection against symptomatic infection. As such, the Advisory Committee on Immunization Practices (ACIP) under the Ministry of Health and Welfare suggests a minimum interval of 4 weeks (28 days) between vaccine shots.

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,或先前接種本項疫苗劑次曾發生嚴重過敏反應者,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 or who experienced a severe adverse reaction to the first dose should not take the vaccine.

◆ 注意事項:

- 1. 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。
- 2. 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。
- 3. 發燒或正患有急性中重度疾病者,宜待病情穩定後再接種。

- 4. 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)
- 5. 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。
- 6. 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. The 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.
- 2. The 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.
- 3. Individuals with a fever or who are currently experiencing an acute moderate or serious illness should wait until their health stabilizes before getting vaccinated.
- 4. 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).
- 5. 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 first discuss the benefits and risks of vaccination with a doctor before deciding whether to get inoculated.
- 6. 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 breastfeed 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(≥38℃),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-aXITBq4gqn5Hq2dveHBq)。

- 4. 依據各國疫苗上市後安全性監測,曾有報告極少數年輕族群在接種 mRNA 疫苗後發生心肌炎等的不良反應事件,大多發生在接種後數天內。建議接種 mRNA 疫苗後,應注意如出現胸痛、喘或心悸等症狀,請立即就醫並說明疫苗接種史。
- 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 in 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).
 - $(\underline{https://www.cdc.gov.tw/Category/Page/3-aXlTBq4ggn5Hg2dveHBg}) \circ \\$
- 4. Following safety monitoring in countries since various vaccines went on sale, there have been reports that an extremely small number of young people have experienced adverse reactions after taking mRNA vaccines that include myocarditis, most of which occurred within two days of being vaccinated. After receiving an mRNA vaccine if recipients develop chest pain, shortness of breath, heart palpitations or similar symptoms they should immediately seek medical attention and explain their vaccination history to the doctor.
- 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	接種部位疼痛、腫脹;疲倦;頭痛;肌肉痛;畏寒;關節痛;發燒;淋巴結腫大;噁心;		
(≥1/10)	嘔吐		
常見	接種部位紅斑;蕁麻疹;泛紅		
(≥1/100 ~ <1/10)	女怪口D 位 紅 以 , 等 顺 7乡 , /之 私		
不常見	接種部位搔癢		
(≥1/1,000 ~ <1/100)	按性中性性		
罕見	药五油细麻麻 · Bed IBBE		
(<1/1000)	顏面神經麻痺;臉部腫脹		
目前尚不清楚	立即型過敏性反應;過敏		

Adverse Reactions on Labeling

Frequency	Symptoms	
Extremely common (≥1/10)	Pain and swelling at the injection site, fatigue, headache, muscle soreness, chills, joint pain, fever, swollen lymph nodes, nausea, vomiting.	
Common (≥1/100 ~ <1/10)	Erythema (redness/swelling) at the injection site, hives, flushing.	
Uncommon (≥1/1,000 ~ <1/100)	Itchiness at the site of injection	
Extremely rare (<1/10,000)	Facial palsy, facial swelling	
Currently unclear	Immediate hypersensitivity; allergies	

Reference information

https://www.who.int/publications/m/item/moderna-covid-19-vaccine-(mrna-1273)

莫德納 COVID-19 疫苗接種評估及意願書

Moderna COVID-19 Vaccination Evaluation and Agreement

		e vaco	
評 估 內 容 Evaluation Content		Evalaution Outcome	
	Yes	No	
. 過去注射疫苗或藥物是否有嚴重過敏反應史 ·			
Have you previously experienced a severe allergic reaction to a vaccination or medication?			
. 現在身體有無不適病徵(如發燒 38℃、嘔吐、呼吸困難等)。			
Do you currently have any symptoms or discomfort (for example a fever of 38°C,			
vomiting or difficulty breathing)?			
. 是否為免疫低下者,包括接受免疫抑制劑治療者。			
Are you immunocompromised or currently undergoing immuno-suppressive			
therapy?			
. 過去 14 天內是否曾接種其他疫苗。			
Have you taken any other vaccination within the past 14 days?			
. 目前是否懷孕。			
Are you pregnant?			
。			
Body temperature: °C			
按接種者姓名 Vaccine recipient name:身分證/居留證/護照字號 ID No. / ARC No. / Passp	oort No. :		
			
出生日期 Date of Birth : (西元)年 Y月 M日 D 聯絡電話 TEL :			
居住地址 Address:縣市 County/City			
፲意願書人 Signed by:身分證/居留證/護照字號 ID No. / ARC No. / Passport No:			