莫德納 COVID-19 疫苗接種須知

衛生福利部疾病管制署 2021 年 9 月 23 日

莫德納 COVID-19 疫苗（Spikevax）

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 12 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*。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）。

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。

◆ 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. 目前尚無資料顯示與其他疫苗同時接種對免疫原性與安全性的影響。COVID-19 疫苗與其他疫苗的接種間隔建議至少 7 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。

接種後注意事項及可能發生之反應

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.依據疫苗上市後資料，**接種本項疫苗後曾出現極罕見的心肌炎和心包膜炎病例。這些病例主要發生在接種後 14 天內，較常發生在接種第二劑之後以及年輕男性，但評估後本項疫苗用於年輕族群的整體臨床效益仍大於其風險。若在接種疫苗後，出現疑似心肌炎或心包膜炎的症狀 (例如：急性和持續性胸痛、呼吸急促或心悸)，務必立即就醫。**

4.**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-aXlTBq4ggn5Hg2dveHBg)

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。

仿單所列之不良反應

頻　率	症　狀
極常見 (≥1/10)	淋巴腺腫大[a]；接種部位疼痛、腫脹；疲倦；頭痛；肌肉痛；畏寒；關節痛；發熱；噁心；嘔吐
常見 (≥1/100 ~ <1/10)	接種部位紅斑；蕁麻疹；皮疹；延遲性注射部位反應
不常見 (≥1/1,000 ~ <1/100)	頭暈；接種部位搔癢
罕見 (≥1/10,000 ~ <1/1,000)	顏面神經麻痺[b]；感覺遲鈍；臉部腫脹[c]
目前尚不清楚	立即型過敏性反應；過敏；心肌炎；心包膜炎

a 淋巴腺病變所指的是與注射部位同側的腋下淋巴腺腫大。亦曾有某些案例發生於其他淋巴結（如頸部、鎖骨上）。
b 在安全性追蹤期間，Spikevax 組有三位受試者、安慰劑組有一位受試者通報出現急性周邊性顏面癱瘓（或麻痺）。疫苗組受試者是在接種第 2 劑後 22 天、28 天和 32 天時發生此不良反應。
c 在疫苗組中，於先前曾注射皮膚填充劑的受試者發生兩例嚴重的臉部腫脹不良事件，此兩例分別發生於接種疫苗後 1 天和後 2 天。

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

如果您願意加入『V-Watch 疫苗接種 - 健康回報』，請您掃描接種院所提供之 QR code，並於疾管家提醒您時回覆健康情形，以應用於疫苗安全性評估。感謝您的協助！

莫德納 COVID-19 疫苗接種評估及意願書

☐ 已詳閱 COVID-19 疫苗接種須知，瞭解莫德納（Moderna）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. 過去注射疫苗或藥物是否有嚴重過敏反應史。		
2. 現在身體有無不適病徵 (如發燒 38℃、嘔吐、呼吸困難等)。		
3. 是否為免疫低下者，包括接受免疫抑制劑治療者。		
4. 過去 7 天內是否曾接種其他疫苗。		
5. 目前是否懷孕。		
6. 體溫：_____ ℃		

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：_____

COVID-19 Vaccine Moderna Information Sheet

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

COVID-19 Vaccine Moderna (Spikevax)

COVID-19 Vaccine **Moderna** is an mRNA vaccine that encodes the SARS-CoV-2 spike protein. This vaccine has received an emergency use authorization from countries including Taiwan and the United States, as well as the European Union. It is suitable for use on adults 18 and older, and two doses are required for protection. In clinical trials, a full two-dose course was 94% effective at preventing symptomatic infections, based on a median follow-up of nine weeks.* The Advisory Committee on Immunization Practices (ACIP) of the Ministry of Health and Welfare recommends an interval of at least four weeks (28 days) between the first and second dose.

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, or who had a severe allergic reaction to the first dose.

Precautions:

1. 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.
2. There is currently no data on the immunogenicity and safety of concomitantly administering this COVID-19 vaccine with other vaccines. A minimum interval of 7 days between this vaccine and other vaccines is recommended. If vaccines are administered at a shorter interval, no additional doses of either vaccine are recommended.
3. Vaccination should be postponed for individuals suffering from a fever or an acute moderate-to-severe illness.
4. 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.)
5. 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 bySARS-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.
6. 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 clinic for at least 15 minutes after inoculation. Recipients should closely self-monitor for reactions in the 15 minutes after leaving the vaccination clinic.** People with a history of acute allergic reactions after a vaccine or other injection should remain at the vaccination clinic for at least 30 minutes after inoculation. Recipients who are taking anticoagulants and antiplatelet drugs, or who have blood clotting abnormalities, should apply pressure on the injection site for at least two minutes after the injection and observe for signs of excessive bleeding or hematoma.

2. The most common side effects that occur after vaccination are pain, redness, or swelling at the injection site, which usually go away within several days. Other possible reactions include fatigue, headache, muscle ache, fever, chills, joint pain, and nausea. Common side effects are less likely in older adults, and are usually mild and short-lived. **It is common to develop a fever (≥38°C) after vaccination. This usually goes away within 48 hours.**

3. **Very rare cases of myocarditis and pericarditis have been observed following vaccination with an mRNA Vaccine. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. However, the benefits of BioNTech (BNT162b2) COVID-19 vaccination for younger people are still considered to outweigh its known risks. Vaccinated individuals who experience symptoms of myocarditis or pericarditis after vaccination should seek medical attention immediately.**

4. **If a fever persists for more than 48 hours or you experience severe symptoms such as difficulty breathing, wheezing, fast heartbeat, or rash, get urgent medical attention to clarify the cause.** Report all symptoms, when they appeared, and the date of injection to your health care provider 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.

5. Although vaccination reduces the chance of contracting COVID-19, it is still possible to become infected withSARS-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)	Lymphadenopathy [a]; pain or swelling at the injection site; fatigue; headache; muscle ache; chills; joint aches; pyrexia; nausea; vomiting
Common (≥1/100~ <1/10)	Rash, hives, or rash at the injection site; delayed injection site reaction
Uncommon (≥1/1,000 ~ <1/100)	Dizziness; Itchiness at the injection site
Very rare (≥1/10,000 ~ <1/1,000)	Acute peripheral facial paralysis [b]; hypoaesthesia; swelling of the face [c]
Not known	Immediate hypersensitivity reactions; other allergic reactions; myocarditis; pericarditis

a Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site. Other lymph nodes(e.g., cervical, supraclavicular) were affected in some cases.

bThroughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in theSpikevax group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days,and 32 days after Dose 2.

cThere were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination.

Reference

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

Taiwan CDC (MOHW)
cares about you

Prevaccination Checklist and Consent Form for COVID-19 Vaccine Moderna

☐ I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of COVID-19 Vaccine Moderna, 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 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:** _____

新冠疫苗接種未滿 20 歲同意書

本人　　已詳閱「莫德納（Moderna）之 COVID-19 疫苗接種須知」並同意子女接受施打。

子女姓名：

子女身份證字號：

家長姓名：

身分證字號：

聯絡電話：

中華民國　　年　　月　　日