COVID-19 Vaccine Moderna Information Sheet

Taiwan Centers for Disease Control, Ministry of Health and Welfare, June 12, 2021

COVID-19 Vaccine Moderna (mRNA-1273)

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.This COVID-19 vaccine should not be administered concomitantly with other vaccines. A minimum interval of 14 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 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 and anticoagulants 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-aXITBq4ggn5Hg2dveHBg) via your health care provider or local health department.
- 4.According to post-distribution surveillance worldwide, there have been reports of adverse events including myocarditis in a very small number of younger people within following use of an mRNA vaccine. The cases occurred mainly within a few days after vaccination. Vaccinated individuals who experience the onset of symptoms like chest pain, wheezing, or heart palpitations should seek immediate medical attention and inform the doctor of their vaccination history.
- 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)	Pain or swelling at the injection site; fatigue; headache; muscle ache; chills; joint aches; fever; swollen lymph nodes; nausea; vomiting
Common (≥1/100~ <1/10)	Rash, hives, or redness at the injection site
Uncommon (≥1/1,000 ~ <1/100)	Itchiness at the injection site
Very rare (<1/1000)	Facial palsy; swelling of the face
Not known	Immediate hypersensitivity reactions; other allergic reactions

Reference

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



Prevaccination Checklist and Consent Form for COVID-19 Vaccine Moderna

I have read the COVID-19 vaccine information sheet carefully. I understand the protect dications of COVID-19 Vaccine Moderna, as well as the precautions to take. I consequation by a physician.	•		
	Response of vaccine recipient		
Check list	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 immuno- suppressive therapy?			
Have you had a vaccine injected in the last 14 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 healthcare facility :			