

# COVID-19 Vaccine Moderna Information Sheet

Taiwan Centers for Disease Control,  
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## 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 by SARS-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 ( $\geq 38^{\circ}\text{C}$ ) 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-aXITBq4ggn5Hg2dveHBg>) 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 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
<b>Very common (<math>\geq 1/10</math>)</b>	Lymphadenopathy <sup>a</sup> ; pain or swelling at the injection site; fatigue; headache; muscle ache; chills; joint aches; pyrexia; nausea; vomiting
<b>Common (<math>\geq 1/100 \sim &lt; 1/10</math>)</b>	Rash, hives, or rash at the injection site; delayed injection site reaction
<b>Uncommon (<math>\geq 1/1,000 \sim &lt; 1/100</math>)</b>	Dizziness; Itchiness at the injection site
<b>Very rare (<math>\geq 1/10,000 \sim &lt; 1/1,000</math>)</b>	Acute peripheral facial paralysis <sup>b</sup> ; hypoesthesia; swelling of the face <sup>c</sup>
<b>Not known</b>	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.

b Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the Spikevax 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.

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



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# 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: \_\_\_\_\_