

# MVC COVID-19 Vaccine Information Sheet

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## MVC COVID-19 Vaccine

**MVC COVID-19 Vaccine** is a protein subunit vaccine containing the SARS-CoV 2 recombinant spike protein, and is used to prevent COVID-19. This vaccine is authorized for production in Taiwan and indicated for use on adults 20 and older. A full course is two doses administered at an interval of 28 days. This vaccine does not contain replication-competent SARS-CoV-2 viral particles and cannot cause the recipient to become infected with COVID-19. In clinical trials, the vaccine demonstrated a good safety profile. In addition, an analysis of clinical trial results found that for MVC COVID-19 Vaccine recipients, the geometric mean titer of neutralizing antibodies was 3.4 times that of COVID-19 Vaccine AstraZeneca recipients, using the lower bound of the 95% confidence interval. This is higher than the required 0.67 times. Using the lower bound of the 95% confidence interval, the sero-response rate of MVC COVID-19 Vaccine recipients was 95.5%, higher than the required 50%. In terms of its immunogenicity and its recipients' serum neutralizing antibody titer after recovery, this vaccine is comparable to an approved, imported COVID-19 vaccine product.

## 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.

### Precautions:

1. Do not get this vaccine if you had a severe allergic reaction to a previous dose.
2. Vaccination should be postponed for individuals suffering from a fever or an acute moderate-to-severe illness.
3. 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.
4. 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.
5. 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.)
6. 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.
7. 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 for persistent bleeding or hematoma.
2. The most common side effects that occur after vaccination are pain, redness, and swelling at the injection site. A cold pack can be applied to the affected area. Do not scratch the injection site. Common adverse reactions (see table below) are typically mild or moderate, and most of the adverse reactions are relieved or resolved within seven days after vaccination.
3. **If you develop redness and abscess formation at the injection site; a persistent fever; or 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 your vaccination history as a reference for diagnosis. Ask your doctor to report to the Vaccine Adverse Event Reporting System (<https://www.cdc.gov.tw/Category/Page/3-aXIT-Bq4ggn5Hg2dveHBg>) via your health care provider or local health department.
4. 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</b> ( $\geq 1/10$ )	Headache; diarrhea; pain at the injection site; malaise; induration at injection site
<b>Common</b> ( $\geq 1/100 \sim < 1/10$ )	Dizziness; drowsiness; vomiting; muscle ache; redness at the injection site;
<b>Uncommon</b> ( $\geq 1/1,000 \sim < 1/100$ )	Fever; Itching at the injection site; chills; rash; nasopharyngitis; oropharyngeal pain; palpitations
<b>Very Rare</b> ( $\geq 1/10,000 \sim < 1/1,000$ )	Facial palsy*; elevated eye pressure

\*During safety monitoring in the clinical follow-up period, one recipient of the MVC COVID-19 Vaccine reported acute peripheral facial nerve palsy. This adverse reaction occurred 13 days after the recipient's second dose.



# Prevaccination Checklist and Consent Form for MVC COVID-19 Vaccine

I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of this vaccine, 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 healthcare facility: \_\_\_\_\_