Moderna (Spikevax) LP.8.1 COVID-19 Vaccine Information Sheet

Taiwan Centers for Disease Control,
Ministry of Health and Welfare, Jul 31, 2025

Moderna (Spikevax) LP.8.1 COVID-19 Vaccine

The Moderna LP.8.1 COVID-19 vaccine contains **a single-stranded messenger RNA (mRNA) encoding the spike protein of the SARS-CoV-2 (LP.8.1) variant**. This vaccine is available to individuals aged 6 months and older in the vaccination program to help prevent COVID-19 infection.

◆ Target Group for the Vaccination Program

Based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) under the Ministry of Health and Welfare, this vaccine is available to adults aged 65 and older; indigenous people aged 55–64; residents and staff of nursing homes and long-term care facilities; pregnant women; high-risk individuals aged 6 months and older; health care and public health personnel; childcare staff in kindergartens; professional staff in childcare institutions and home-based childcare providers (nannies); parents of infants under 6 months of age; children aged 6 months to under 6 years; and adults aged 50–64 without high-risk conditions. This vaccine is administered according to the following schedule, intervals, and dosage:

◆ Administration Schedule and Intervals

Age(s)	COVID-19 Vaccination History	Administration	
		Number of Doses	Administration interval
For children aged 6 months through 4 years	Unvaccinated against the COVID-19 vaccine	Two doses	2 doses should be separated by at least 4 weeks (28 days)
	Previously received the JN.1 COVID-19 vaccine	One dose	Separated by at least 12 weeks (84 days) from the previous dose of the JN.1 COVID-19 vaccine
For individuals aged 5 years and older	Unvaccinated against the COVID-19 vaccine	One dose	-
	Previously received the JN.1 COVID-19 vaccine	One dose	Separated by at least 12 weeks (84 days) from the previous dose of the JN.1 COVID-19 vaccine

◆ Dosage

Package Type	**Prefilled syringe, 0.5 mL/syringe**	**Multiple-Dose Vial, 2.5 mL/vial**
Age(s)	For individuals aged 12 years and older	For children aged 6 months through 11 years
Dosage per Dose	**0.5mL (50mcg mRNA)**	**0.25mL (25mcg mRNA)**

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 any previous dose of Spikevax.

◆ **Precautions:**

1. **This vaccine can be administered at the same time with other vaccines in different arm, or administered at any interval, to ensure traceability of possible reactions. Furthermore, for infants under 2 years old, it is recommended to administer the vaccine in the anterolateral thigh muscle. For children aged 2 years and older, it is recommended to administer the vaccine in the deltoid muscle of the non-dominant arm.**
2. Vaccination should be postponed for individuals suffering from a fever or an acute moderate-to-severe illness.
3. The use of Spikevax in pregnant women is mainly based on experience from the administration of Spikevax (original). Extensive clinical observational data shows that undesirable pregnancy outcomes have not increased with the administration of Spikevax (original) during the second and third trimesters. Although data on pregnancy outcomes following administration during the first trimester are limited, no increased risk of miscarriage has been observed. Clinical observational data shows that pregnant women infected with SARS-CoV-2 may be more susceptible to severe complications than the general population. Pregnant women are advised to discuss the risks and benefits of inoculation with their doctor before receiving the vaccine.
4. The use of Spikevax in lactating women is mainly based on experience from the administration of Spikevax (original). However, no effects on the breastfed newborns/infants are anticipated since the systemic exposure of the breastfeeding women to the vaccine is negligible. Observational data have not shown any adverse effects on breastfed newborns/infants following vaccination of breastfeeding mothers with Spikevax (original). Women can continue to breastfeed after receiving a COVID-19 vaccine.
5. **This vaccine can be used in patients with a history of a majority of chronic cardiovascular diseases**, including coronary artery diseases, myocardial infarction, stable heart failure, heart arrhythmia, rheumatic heart disease, Kawasaki disease, most congenital heart diseases, and patients with implanted cardiac devices. It is not recommended to adopt special measures concerning inoculation of said patients. No data has shown a higher risk of myocarditis or pericarditis after vaccination with an mRNA vaccine for patients with a history of cardiovascular disease versus the general population.
6. **Individuals with a history of any of the following diseases are advised to consult their cardiologist or infectious disease doctor** for the best administration schedule and possible precaution(s): inflammatory heart diseases (such as myocarditis, pericarditis and endocarditis), acute rheumatic fever, dilated cardiomyopathy in individuals aged between 12 and 29, complex or severe congenital heart diseases (including the Fontan circulation), acute decompensated heart failure, and heart transplant.
7. The Taiwan CDC, experts from ACIP under the Ministry of Health and Welfare, and the Taiwan Society of Pediatric Cardiology jointly prepared the “Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines”, which was published in September 2021, to provide clinical treatment information and recommendations:
https://www.cdc.gov.tw/File/Get/es0pwDYE2zL2Y3kCjxpdqQ

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 vaccination or other injections should remain at the vaccination site for at least 30 minutes after inoculation. Recipients who are taking anticoagulants or antiplatelet medications, or who have coagulation disorders, should apply pressure to the injection site for at least 2 minutes after the injection and monitor for any bleeding or hematoma.
2. Possible reactions after inoculation
   - **If a fever persists for more than 48 hours or you experience severe symptoms** such as difficulty breathing, asthma, vertigo, fast heartbeat, or widespread rash, **get urgent medical attention to clarify the cause**. Inform the doctor of all your symptoms, when they appeared, and the date of inoculation as a reference for diagnosis. **Suspected severe adverse reactions can be reported to the Vaccine Adverse Event Reporting System (https://vaers.cdc.gov.tw) via your health care provider or the local public health department.**
   - The most common side effects that occur after vaccination are pain, redness, and swelling at the injection site, which **usually resolve within several days**. Other possible reactions include fatigue, headache, muscle ache, fever, chills, joint pain, and nausea, which are **generally mild and typically subside within several days**. A fever (≥38°C) may occur after vaccination, but it usually resolves within 48 hours.
   - **Extremely rare cases of myocarditis and pericarditis have been observed after vaccination with the mRNA COVID-19 vaccines**. According to vaccine safety surveillance and observational studies, both the World Health Organization (WHO) Global Advisory Committee on Vaccine Safety (GACVS)[2] and Taiwan ACIP recommend that a person should seek medical attention immediately if symptoms of myocarditis or pericarditis occur within 28 days after vaccination. These symptoms include chest pain, tight chest or other discomfort, palpitations (irregular heartbeat, skipped beats, or fluttery), syncope (fainting), shortness of breath, exercise intolerance (for example, becoming out of breath after walking a few steps or feeling too weak to climb stairs), etc. **Seek medical attention immediately and inform the doctor of your vaccination history. Clinicians need to determine whether the myocarditis or pericarditis is caused by SARS-CoV-2 infection, other viral infections, or other conditions.**
   - Results of VAERS surveillance show that the reporting rate of myocarditis or pericarditis after mRNA vaccination in Taiwan is similar to that observed by international vaccine safety surveillance. The analysis indicated that, among young males in Taiwan, the reporting rate of myocarditis or pericarditis after mRNA vaccination is higher than the background rate. **There is no post-marketing safety data to confirm the risk of myocarditis following the administration of the Spikevax LP.8.1 monovalent vaccine.**
   - Suspected adverse reactions statistics may be affected by several factors such as a country's vaccination policy and execution thereof, completeness of passive vaccine safety surveillance, willingness to report, criteria for reporting, and data review. **Reporting rates are not equivalent to actual incidence rates. Expert review and empirical evidence are required to clarify whether an adverse event is causally related to the vaccination.**
3. Vaccination reduces the chance of contracting COVID-19 and the likelihood of hospitalization and death. However, infections with SARS-CoV-2 is still possible. Vaccinated people should continue to take health precautions and follow public health guidelines to protect themselves.

Adverse reactions listed on package leaflet

Adverse reactions and frequencies in the 7 days after the primary dose of Spikevax (original), based on the result of the phase III clinical trials[1]

Age / Adverse reactions	Frequency					
	6 to 23 months of age	24 to 36 months of age	37 months to 5 years old	6-11 years old	12-17 years old	18 years and older
Irritability / Crying	81.5%	71.0%	-	-	-	-
Injection site pain	56.2%	76.8%	83.8%	98.4%	97%	92%
Sleepiness	51.1%	49.7%	-	-	-	-
Fatigue	-	-	61.9%	73.1%	75%	70%
Loss of appetite	45.7%	42.4%	-	-	-	-
Fever	21.8%	26.1%	20.9%	25.7%	14%	15.5%
Axillary swelling / Tenderness	12.2%	11.5%	14.3%	27%	35%	19.8%
Injection site swelling	18.4%	15.7%	8.2%	22.3%	28%	14.7%
Injection site erythema	17.9%	17.9%	9.5%	24%	26%	10%
Headache	-	-	22.9%	62.1%	78%	64.7%
Myalgia	-	-	22.1%	35.3%	54%	61.5%
Chills	-	-	16.8%	34.6%	49%	45.4%
Nausea / Vomiting	-	-	15.2%	29.3%	29%	23%
Arthralgia	-	-	12.8%	21.3%	35%	46.4%

Adverse reactions from Spikevax (original) clinical trials and post-marketing experience in individuals aged 6 months and older[1]

Frequency	Adverse reactions
Very common (≥1/10)	Lymphadenopathy [a]; Injection site pain; Injection site swelling; Injection site erythema; Fatigue; Headache; Myalgia; Chills; Arthralgia; Pyrexia; Nausea/vomiting; Decreased appetite [b]; Irritability/crying [b]; Sleepiness [b]
Common (≥1/100 ~ <1/10)	Injection site urticaria; Rash; Delayed injection site reaction; Diarrhoea
Uncommon (≥1/1,000 ~ <1/100)	Dizziness; Injection site pruritus; Abdominal pain [c]; Urticaria [d]
Rare (≥1/10,000 ~ <1/1,000)	Acute peripheral facial paralysis [e]; Hypoaesthesia; Paraesthesia; Facial edema [f]
Very rare (<1/10,000)	Myocarditis; Pericarditis
Not known	Anaphylaxis; Hypersensitivity; Erythema multiforme; Extensive swelling of vaccinated limb; Menorrhagia [g]

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. This was observed in the paediatric population (6 months to 5 years of age).
c. Abdominal pain was observed in the paediatric population (6 to 11 years of age): 0.2% in the Spikevax (original) group and 0% in the placebo group.
d. Urticaria has been observed with either acute onset (within a few days after vaccination) or delayed onset (up to approximately two weeks after vaccination).
e. Throughout the safety follow-up period, acute peripheral facial nerve palsy (facial paralysis) was reported by 3 subjects in the Spikevax (original) group and 1 subject in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
f. Two serious adverse events of facial edema developed in vaccine recipients; both of them had prior dermal fillers injection. The two recipients developed edema 1 and 3 days, respectively, after vaccination.
g. Most cases appeared to be non-serious and temporary in nature.

Reference

1. https://mcp.fda.gov.tw/
2. https://www.who.int/news/item/27-10-2021-gacvs-statement-myocarditis-pericarditis-covid-19-mrna-vaccines-updated

Prevaccination Checklist and Consent Form for Moderna (Spikevax) LP.8.1 COVID-19 Vaccine

(Aged 6 months to under 18 years)

Taiwan Centers for Disease Control,
Ministry of Health and Welfare, Jul 31, 2025

1. I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of **Moderna (Spikevax) LP.8.1 COVID-19 Vaccine**, as well as the precautions to take. I confirm that vaccination shall be administered only after evaluation by a physician.

☐ I consent	to the vaccination of my child with **Moderna (Spikevax) LP.8.1 COVID-19 Vaccine**.
☐ I do not consent	

2. Vaccination information

Vaccine recipient's full name: _____

National ID/residence certificate/passport number: _____

Date of birth (yyyy/mm/dd): _____

Phone number: _____

Parent or guardian's signature: _____

◆ **Prevaccination self-screening**

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 or above, vomiting, or difficulty breathing)?		
Has it been at least 12 weeks (84 days) since your previous JN.1 COVID-19 vaccine dose?		

※ **For children aged 6 months to 4 years who are unvaccinated against COVID-19, the interval between the two doses is at least 4 weeks (28 days).**

◆ **Body temperature: _____ ° C**

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Physician's evaluation

☐**Vaccination recommended** ☐**Vaccination not recommended. Reason(s)**_____

Date of evaluation (yyyy/mm/dd): _____

Ten-digit code of medical institution: _____**Physician's signature/seal:** _____

Prevaccination Checklist and Consent Form for Moderna (Spikevax) LP.8.1 COVID-19 Vaccine (Institutional Residents)

Taiwan Centers for Disease Control,
Ministry of Health and Welfare, Jul 31, 2025

1. I (a family member or the responsible person of the institution) have read the COVID-19 vaccine information sheet carefully. I (a family member or the responsible person of the institution) understand the protective efficacy, side effects, and contraindications of **Moderna (Spikevax) LP.8.1 COVID-19 Vaccine**, as well as the precautions to take. I confirm that vaccination shall be administered only after evaluation by a physician.

☐ I (a family member or the responsible person of the institution) **consent**	to the vaccination of the vaccine recipient with **Moderna (Spikevax) LP.8.1 COVID-19 Vaccine.**
☐ I (a family member or the responsible person of the institution) **do not consent**	

2. Vaccination information

Vaccine recipient's full name: _____

National ID/residence certificate/passport number: _____

Date of birth (yyyy/mm/dd): _____

Phone number: _____

Name of person giving consent: _____

☐I am the vaccine recipient. ☐I am not the vaccine recipient. Relationship to the recipient: _____

◆ **Prevaccination self-screening**

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 or above, vomiting, or difficulty breathing)?		
Has it been at least 12 weeks (84 days) since your previous JN.1 COVID-19 vaccine dose?		

◆ **Body temperature: _____ ° C**

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Physician's evaluation

☐**Vaccination recommended** ☐**Vaccination not recommended. Reason(s)**_____

Date of evaluation (yyyy/mm/dd): _____

Ten-digit code of medical institution: _____**Physician's signature/seal:** _____