Moderna (Spikevax) XBB.1.5 COVID-19 Vaccine

Information Sheet

Taiwan Centers for Disease Control,
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Moderna (Spikevax) XBB.1.5 COVID-19 Vaccine

The Moderna XBB.1.5 COVID-19 vaccine contains **a single-stranded messenger RNA (mRNA) encoding the spike protein of the Omicron XBB.1.5 variant**. This vaccine has been authorized for emergency use in Taiwan. It is suitable for use in **individuals 6 months of age and older**.

◆ Administration Schedule and Intervals

Age(s)	**Vaccination History**	**Administration**	
		Number of Doses	**Administration interval**
For children 6 months through 4 years of age	without prior vaccination	Two doses	2 doses separated by at least 4 weeks (28 days)
	received one primary dose of the Moderna COVID-19 vaccine	One dose	Separated by at least 4 weeks (28 days) from the previous dose
	received one or two primary doses of the Pfizer-BioNTech COVID-19 vaccine	One dose or Two doses	Complete the three-dose vaccination accordingly (the first and second doses with an interval of at least 4 weeks; the second and third doses with an interval of at least 8 weeks)
	received the primary series	One dose	Separated by at least 3 months (12 weeks; 84 days) from the previous dose
For individuals aged 5 years and older	without prior vaccination	One dose	-
	received prior vaccination	One dose	Separated by at least 3 months (12 weeks; 84 days) from the previous dose

◆ Dosage

Package Type	XBB.1.5 mRNA 50 mcg / 0.5 ml	
Age(s)	For children 6 months through 11 years of age	For individuals aged 12 years and older
Per dose	**0.25mL (25mcg mRNA)**	**0.5mL (50mcg 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 and other vaccines could be administered at the same time in different arm or administered at any interval for traceability of possible reactions.**
2. Vaccination should be postponed for individuals suffering from a fever or an acute moderate-to-severe illness.
3. Immunocompromised individuals. Including those receiving immunosuppressant therapy, may show a diminished immune response to the vaccine. (There is no data to assess administration on those who are immunocompromised or receiving immunosuppressive therapy.
4. Spikevax (original) can be used during pregnancy. A large amount of information from pregnant women vaccinated with Spikevax (original) during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no increased risk for miscarriage has been seen. 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.
5. 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.
6. **This vaccine can be used in patients with a history of most chronic cardiovascular diseases**, including coronary artery diseases, heart arrhythmia, myocardial infraction, stable heart failure, rheumatic heart disease, Kawasaki disease, most congenital heart diseases, and patients with heart implants. Special measurements are not recommended for 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.
7. **Individuals with history of any of the following diseases are advised to consult their cardiologist or infectious disease doctor** for the best administration schedule and possible special measurement(s): inflammatory heart diseases (such as myocarditis, pericarditis and endocarditis), acute rheumatic fever, dilated cardiomyopathy in individuals aged between 11 and

29, complex or severe congenital heart diseases (including Fontan circulation), acute decompensated heart failure, and heart transplant.

8. The Taiwan CDC, specialists from the Advisory Committee on Immunization Practices (ACIP) at the Ministry of Health and Welfare, and Taiwan Society of Pediatric Cardiology have co-edited the "Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines" in September 2021 for clinical treatment and recommendations: https://www.cdc.gov.tw/File/Get/es0pwDYE2zL2Y3kCjxpdqQ

After vaccination: precautions and possible side effects

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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 site for at least 30 minutes after inoculation. Recipients who are taking anticoagulants or antiplatelet drugs, or who have blood clotting abnormalities, should apply pressure on the injection site for at least 2 minutes after the injection and observe for signs of excessive 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, wheezing, vertigo, 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-aXlTBq4ggn5Hg2dveHBg) via your health care provider or local health department.**

   - 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, fever, chills, joint pain, and nausea. Side effects are less frequent 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.

- **Rare and mostly mild cases of myocarditis and pericarditis have been observed in adolescents after vaccination with the mRNA COVID-19 vaccines**. According to vaccine safety surveillance and observational researches, both the World Health Organization's Global Advisory Committee on Vaccine Safety (GACVS)[2] and Taiwan's 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 (a heartbeat that feels irregular, fluttery, or as if it is skipping a beat); syncope (fainting), shortness of breath; exercise intolerance (for example, becoming out of breath after walking a few steps or being unable to climb stairs). **Inform the doctor of your vaccination history. Clinicians will need to rule out other potential causes of myocarditis and pericarditis, which include SARS-CoV-2 infection, other viral infections and 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 U.S., Canada, Japan, and other countries have monitored the reporting rate of myocarditis or pericarditis among younger people after mRNA vaccination (Moderna or Pfizer/ BioNTech) and found that such rare adverse events occurred more commonly after the second dose than the first dose. **There is no post-market safety data to confirm the risk of myocarditis following the administration of the Spikevax XBB.1.5 monovalent vaccine.**

- Statistics from suspected adverse reactions may be affected by a country's vaccination policy and execution thereof, completeness of passive vaccine safety surveillance, willingness to report, criteria for reporting, and data review, among other factors. **Reporting rates are not equivalent to actual incidence rates. Expert review and empirical clarification are required to verify the occurrence of an adverse reaction and to establish a causal link between it and vaccination.**

3. Vaccination reduces the chance of contracting COVID-19 and the likelihood of hospitalization and death. However, it is still possible to become infected with SARS-CoV-2. Vaccinated people should continue to take health precautions and follow epidemic prevention guidelines to protect themselves.

4. After vaccination, a **COVID-19 Vaccination Record** will be issued, or new records will be added to a person's existing COVID-19 vaccination record. Please keep this card in a safe place. This card must be presented at the next dose administration. Once it is filled in with information about all vaccine doses, the card can be used as proof of vaccination.

Adverse reactions listed on package leaflet

Adverse reactions and frequency rate that may occur after Spikevax XBB.1.5 vaccine administration are similar to those reported by people who received the original vaccine and the bivalent vaccine (BA.4/5).

Adverse reactions and frequency rate in the 7 days after each dose of Spikevax (original), as observed during Phase III clinical trials[1]

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%	97%	92%
Sleepiness	51.1%	49.7%	-	-	-	-
Fatigue	-	-	61.9%	73%	75%	70%
Loss of appetite	45.7%	42.2%	-	-	-	-
Fever	21.8%	26.1%	20.9%	26%	14%	16%
Axillary swelling / Tenderness	12.2%	11.5%	14.3%	27%	35%	20%
Injection site swelling	18.4%	15.7%	8.2%	22%	28%	15%
Injection site erythema	17.9%	17.9%	9.5%	24%	26%	10%
Headache	-	-	22.9%	62%	78%	65%
Myalgia	-	-	22.1%	35%	54%	62%
Chills	-	-	16.8%	35%	49%	45%
Nausea / Vomiting	-	-	15.2%	29%	29%	23%
Arthralgia	-	-	12.8%	21%	35%	46%

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

Frequency	Adverse reaction(s)
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 [d]; Irritability/crying [d]; Sleepiness [d]
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 [e]
Rare (≥1/10,000~<1/1,000)	Acute peripheral facial paralysis [b]; Hypoaesthesia; Paraesthesia; Facial swelling [c]
Very rare (<1/10,000)	Myocarditis; Pericarditis
Not known	Immediate hypersensitivity; Anaphylaxis; Erythema multiforme; Extensive swelling of vaccinated limb; Heavy menstrual bleeding [f]

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 (original) 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 on Day 1 and Day 3, respectively, following vaccination.

d. Observed in the paediatric population (6 months to 5 years of age).

e. 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.

f. Most cases appeared to be non-serious and temporary in nature.

Reference

1. https://www.fda.gov.tw/TC/siteList.aspx?sid=11845

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）XBB.1.5 COVID-19 Vaccine (Age18 and above)

☐I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of **Moderna（Spikevax）XBB.1.5 COVID-19 Vaccine**, as well as the precautions to take. I consent to COVID19 vaccination after an evaluation by a physician.

◆Pre-vaccination 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)?		
Do you have a weakened immune system, for instance because you're on an immunosuppressive therapy?		
Are you currently pregnant?		
Body temperature: ° C		

Vaccine recipient's full name:_____

National ID/residence 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/residence certificate/passport number:_____

☐**I am the person being vaccinated.** ☐**Relationship to person given consent for immunization:**_____

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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：**_____

Prevaccination Checklist and Consent Form for Moderna（Spikevax）XBB.1.5 COVID-19 Vaccine (Age12-17)

1. I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of **Moderna（Spikevax）XBB.1.5 COVID-19 Vaccine**, as well as the precautions to take.
   - ☐ I consent to the vaccination of my child using **Moderna（Spikevax）XBB.1.5 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 name:_____

   Parent or guardian' s national ID/resident certificate/passport number: _____

◆ 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)?		
Do you have a weakened immune system, for instance because you're on an immunosuppressive therapy?		
Are you currently pregnant?		
Body temperature: ° C		

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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：**_____

Prevaccination Checklist and Consent Form for Moderna（Spikevax）XBB.1.5 COVID-19 Vaccine (Age5-11)

1. I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of **Moderna（Spikevax）XBB.1.5 COVID-19 Vaccine**, as well as the precautions to take.
   - ☐ I consent to the vaccination of my child using **Moderna（Spikevax）XBB.1.5 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 name:_____

   Parent or guardian' s national ID/resident certificate/passport number: _____

◆ 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)?		
Do you have a weakened immune system, for instance because you're on an immunosuppressive therapy?		
Body temperature: ° C		

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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：**_____

Prevaccination Checklist and Consent Form for Moderna（Spikevax）XBB.1.5 COVID-19 Vaccine （6 months through 4 years of age)

1. I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of **Moderna（Spikevax）XBB.1.5 COVID-19 Vaccine**, as well as the precautions to take.
   - ☐ I consent to the vaccination of my child using **Moderna（Spikevax）XBB.1.5 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 name:_____

   Parent or guardian' s national ID/resident certificate/passport number: _____

◆ 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)?		
Do you have a weakened immune system, for instance because you're on an immunosuppressive therapy?		
Body temperature: ° C		

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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：**_____