Novavax (Nuvaxovid) XFG COVID-19 Vaccine Information Sheet

Taiwan Centers for Disease Control,
Ministry of Health and Welfare, July 7, 2026

Novavax (Nuvaxovid) XFG COVID-19 Vaccine

Novavax (Nuvaxovid) XFG COVID-19 vaccine is a **protein subunit vaccine containing the SARS-CoV-2 (Omicron XFG) spike protein and adjuvanted with Matrix-M.** This vaccine is available to individuals aged 12 years 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 years and older; indigenous people aged 55 years and older; 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; staff in preschools, kindergartens, and childcare institutions; home-based childcare providers (nannies); parents or primary caregivers of infants under 6 months of age; children aged 6 months to under 6 years who have never received a COVID-19 vaccine; and adults aged 50–64 without high-risk conditions.**

◆ Number of doses, intervals and dosage

Individuals aged 12 years and older in the vaccination program should receive **one dose (0.5 mL)**, regardless of their COVID-19 vaccination history. For those who have previously received the COVID-19 vaccine, **the dose should be administered at least 12 weeks (84 days) after the previous COVID-19 vaccination**.

※Adults aged 65 years and older, indigenous people aged 55 years and older, and individuals aged 6 months and older who are immunodeficient or immunocompromised are recommended to receive an additional dose of COVID-19 vaccine at least 6 months (180 days) after vaccination. Immunodeficient or immunocompromised individuals include cancer patients currently receiving or who have received immunosuppressive therapy within the past year, organ transplant recipients / hematopoietic stem cell transplant recipients, individuals with moderate to severe primary immunodeficiency, patients undergoing dialysis, persons living with HIV infection, individuals currently receiving highly immunosuppressive medications, those who have received chemotherapy or radiotherapy within the past 6 months, and other individuals assessed by a physician as immunodeficient or immunocompromised.

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 this vaccine.

◆ 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.**

2. Vaccination should be postponed for individuals suffering from a fever or an acute moderate-to-severe illness.

3. There is limited experience with the use of Nuvaxovid in pregnant women. Animal testing does not indicate direct or indirect harmful effects of the vaccine on pregnancy, embryo/foetal development, parturition, or post-natal development. Clinical observational data show 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. It is currently unknown whether Nuvaxovid XFG is excreted in breast milk. No effects on the breastfed newborns/infants are anticipated since the systemic exposure of the breastfeeding woman to Nuvaxovid XFG is negligible. Women can continue to breastfeed after receiving a COVID-19 vaccine.

5. There is an increased risk of myocarditis and pericarditis following vaccination with Nuvaxovid. Available data suggest that the clinical course of myocarditis and pericarditis following vaccination is the same as that of cases unrelated to vaccination. Based on the available data, it is currently not possible to estimate the risk of myocarditis or pericarditis following administration of the Nuvaxovid XFG 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 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. The most common side effects that occur after vaccination are pain, redness, and swelling at the injection site. Applying a cold compress as appropriate is recommended. Do not rub or scratch the injection site. Adverse reactions (as shown in the table below) are typically mild to moderate in severity with a median duration of 2 days or less for local events and 1 day or less for systemic events.

3. **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.**

4. Vaccination reduces the chance of contracting COVID-19 and the likelihood of severe complications and death. However, infections with SARS-CoV-2 are 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 after vaccination, based on clinical trial results [1]

Dose and age / Adverse reactions	Nuvaxovid (Original) primary series		Nuvaxovid (Original) booster dose		Nuvaxovid (Omicron BA.5) booster dose
	12-17 years old	18 years and older	12-17 years old	18 years and older	18 years and older
Injection site tenderness	71%	75%	72%	73%	>50%
Injection site pain	67%	62%	64%	61%	>30%
Fatigue	54%	53%	66%	52%	>30%
Myalgia	57%	51%	62%	51%	>20%
Headache	63%	50%	68%	45%	>20%
Malaise	43%	41%	47%	40%	>10%
Arthralgia	19%	24%	-	26%	-
Nausea / Vomiting	23%	15%	26%	-	-
Pyrexia	17%	-	-	-	-

Adverse reactions from Nuvaxovid clinical trials and post-marketing experience in individuals aged 12 years and older [1]

Frequency	Adverse reactions
Very common (≥1/10)	Headache; Nausea or vomiting [a]; Myalgia [a]; Arthralgia [a]; Injection site tenderness [a]; Injection site pain [a]; Fatigue [a]; Malaise [a,b]
Common (≥1/100 ~ <1/10)	Injection site redness [a,c]; Injection site swelling [a]; Pyrexia [e]; Pain in extremity
Uncommon (≥1/1,000 ~ <1/100)	Lymphadenopathy; Hypertension [d]; Rash; Erythema; Pruritus; Urticaria; Injection site pruritus; Chills
Rare (≥1/10,000 ~ <1/1,000)	Injection site warmth
Not known (cannot be estimated from the available data)	Anaphylaxis; Paraesthesia; Hypoaesthesia; Myocarditis; Pericarditis

a. Higher frequencies of these events were observed after the second dose.
b. This term also included events reported as influenza-like illness.
c. This term includes both injection site redness and injection site erythema (common).
d. Hypertension was not reported in adolescents aged 12 through 17 years in the clinical study.
e. Pyrexia was observed more frequently in adolescents aged 12 through 17 years compared to adults, with the frequency being very common after the second dose in adolescents.

Reference

1. **https://mcp.fda.gov.tw/**

Prevaccination Checklist and Consent Form for Novavax (Nuvaxovid) XFG COVID-19 Vaccine (Aged 12 to 17 years)

Taiwan Centers for Disease Control,
Ministry of Health and Welfare, July 7, 2026

1. I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of **Novavax (Nuvaxovid) XFG 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 **Novavax (Nuvaxovid) XFG 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 Checklist**

Checklist	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 COVID-19 vaccine dose?		
【For individuals planning to receive an additional dose of the COVID-19 vaccine】Has it been at least 6 months (180 days) since your previous seasonal 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:** _____

Prevaccination Checklist and Consent Form for Novavax (Nuvaxovid) XFG COVID-19 Vaccine (Institutional Residents)

Taiwan Centers for Disease Control,
Ministry of Health and Welfare, July 7, 2026

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 **Novavax (Nuvaxovid) XFG 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 **Novavax (Nuvaxovid) XFG 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 Checklist**

Checklist	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 COVID-19 vaccine dose?		
【For individuals planning to receive an additional dose of the COVID-19 vaccine】Has it been at least 6 months (180 days) since your previous seasonal 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:** _____