

BioNTech (BNT162b2) COVID-19 Vaccine Sheet

Taiwan Centers for Disease Control, Ministry of Health and Welfare, Sept. 14, 2021

BioNTech (BNT162b2) COVID-19 Vaccine

BioNTech (BNT162b2) COVID-19 Vaccine is an messenger RNA (mRNA) vaccine that encodes the SARS-CoV-2 virus spike(S) protein, and is used to prevent COVID-19. This vaccine has received an emergency use authorization from the World Health Organization, the European Union, and countries including Taiwan. It is suitable for use on individuals aged 12 and older, and two doses are required for protection. Clinical trial results show that for adolescents at least 16 years old and adults, this vaccine is about 94% effective at preventing symptomatic COVID-19 infection at least seven days after the second dose. For adolescents aged 12 to 15 years old, the vaccine's efficacy in preventing symptomatic infection is nearly 100%*. The protective effect of the vaccine varies depending on the age and physical condition of its recipients. 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 hypersensitivity to any of the vaccine components, or who had a severe allergic reaction to the previous 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 seven days between this COVID-19 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 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 anticoagulant 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, which usually go away within several days. Other possible reactions include fatigue, headache, muscle ache, chills, joint pain, nausea, and an elevated body temperature. Most reactions are mild and disappear within a few days. **It is common to develop a fever ($\geq 38^{\circ}\text{C}$) after vaccination. This usually goes away within 48 hours.**
3. According to post-marketing surveillance worldwide, **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. 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 (such as acute and persistent chest pain, shortness of breath, or palpitations) should seek medical attention immediately.**
4. **If a fever persists for more than 48 hours or you experience severe allergic reactions 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-aXITBq4ggn5Hg2dveHBg>) via your health care institution 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
Very common ($\geq 1/10$)	Headache, diarrhea, arthralgia, myalgia, injection site pain, fatigue, chills, fever ^a , injection site swelling
Common ($\geq 1/100 \sim < 1/10$)	Nausea, vomiting, redness at injection site
Uncommon ($\geq 1/1,000 \sim < 1/100$)	Lymphadenopathy, hypersensitivity reactions (e.g. rash, pruritus, urticaria ^b , angioedema ^b), pain in extremity ^c , malaise, injection site pruritus
Rare ($\geq 1/10,000 \sim < 1/1,000$)	Acute peripheral facial paralysis ^d
Not known	Anaphylaxis, myocarditis ^e , pericarditis ^e

a. Fever is more common after the second dose.

b. For urticaria and angioedema, the frequency rate was Rare.

c. Refers to the vaccinated arm.

d. During the clinical trial safety follow-up period dating to Nov. 14, 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COVID-19 mRNA Vaccine group. Reaction onset occurred on Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. There were no cases of acute peripheral facial paralysis (or palsy) in the placebo group.

e. These adverse reactions were determined post-authorization. According to the U.S. FDA's post-marketing surveillance data (dated Aug. 23, 2021), the risk of myocarditis and pericarditis is higher among males under 40 years of age than among females and older males. It's been observed that the risk is higher in adolescents 12 through 17 years of age. During short-term follow-up, the majority of patients recovered after medical treatment.

References:

*https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1



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Prevaccination Checklist and Consent Form for BioNTech (BNT162b2) COVID-19 Vaccine

I have read the COVID-19 vaccine information sheet carefully. I understand the protective efficacy, side effects, and contraindications of BioNTech (BNT162b2) COVID-19 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
1. Have you ever had a severe allergic reaction to a vaccine or an injectable medication?		
2. Are you currently experiencing physical discomfort (such as a fever of 38°C and above, vomiting, or difficulty breathing)?		
3. Do you have a weakened immune system, for instance, because you're on an immunosuppressive therapy?		
4. Have you had a vaccine injected in the last seven days?		
5. Are you currently pregnant?		
6. 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): _____

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