BioNTech (BNT162b2) COVID-19 Vaccine Information Sheet for Student Immunization

Taiwan Centers for Disease Control, Ministry of Health and Welfare, Dec. 1, 2021

Dear parents/guardians:

Our school is working with a medical team contracted by the local health department to offer COVID- 19 vaccination to your child. It's our responsibility to notify you of this program and to obtain your consent for vaccinating your child at school. Please read the following information, fill in the consent form, and have your child return it to the school. Thank you for your support and cooperation.

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. This vaccine has received an emergency use authorization in markets including the United States, the European Union, and Taiwan.

◆ **Age indication: This vaccine is approved in Taiwan for ages 12 and older.**

◆ **Dosage and administration interval: This vaccine requires two doses of primary series. The Advisory Committee on Immunization Practices (ACIP) of the Ministry of Health and Welfare in Taiwan recommends administering 2-dose primary series separated by at least four weeks (28 days).** Because an extended vaccine interval may boost immune response, and due to the safety concerns about myocarditis/pericarditis seen among adolescents in the U.K., Canada, and European Union, **it is recommended that adolescents 12-17 years old wait at least 12 weeks for their second dose.**

◆ **Safety and protective efficacy:**

- This vaccine does not contain replication-competent SARS-CoV-2 viral particles and cannot cause the recipient to become infected with COVID-19.
- 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%.[1] The protective effect of the vaccine varies depending on the age and physical condition of its recipients.

Before vaccination: contraindications and precautions

◆ **Contraindications to vaccination: This vaccine must not be given to individuals with a history of hypersensitivity to any of the vaccine components, or who had a severe allergic reaction to 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. At present, there is insufficient data to recommend the routine use of COVID-19 vaccines on pregnant women. Pregnant women at high risk of exposure to SARS-CoV-2 should weigh the risks and benefits of inoculation with their doctor before receiving the vaccine.
6. mRNA COVID-19 vaccines can be administered to people with a history of chronic cardiovascular conditions, including coronary artery disease, myocardial infarction, stable heart failure, arrhythmias, rheumatic heart disease (RHD), Kawasaki Disease, most congenital heart disease, cardiomyopathy, or cardiac transplant, and in people with implantable cardiac devices. No specific precautions are recommended for people in these groups. There is no current data suggesting that compared to the general population, people with a history of cardiovascular disease have a higher risk of developing myocarditis or pericarditis after receiving mRNA vaccines.
7. Prior to vaccination, people with a history of the following conditions are advised to consult a cardiologist or an infectious diseases specialist about the best timing of vaccination and whether any additional precautions are recommended: heart inflammation (such as myocarditis, pericarditis, and endocarditis), acute rheumatic fever, dilated cardiomyopathy (only pertains to patients 12 to 29 years old), complex or severe forms of congenital heart defect (including single ventricle anomaly with Fontan circulation), acute decompensated heart failure, and heart transplantation.
8. The Ministry of Health and Welfare's Taiwan Centers for Disease Control, experts from the Ministry of Health and Welfare's ACIP, and the Taiwan Society of Pediatric Cardiology jointly developed the "Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines" in September 2021, to provide clinical considerations and other 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 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. Fainting after vaccination

Fainting is usually triggered by pain or anxiety. Sometimes people faint after vaccination, **especially adolescents.** Symptoms like vertigo and nausea **typically occur during or immediately after injection (within five minutes).** During mass vaccination, there is occasionally the collective occurrence of post-vaccination fainting in recipients. This phenomenon is categorized as a mass psychogenic illness. Scientific evidence shows that fainting is due to the vaccination process but not to the vaccines themselves. Vaccine recipients are advised **to not get vaccinated on an empty stomach, to avoid longer waiting times at vaccination sites, and to relax while waiting in line by listening to music, watching videos, or talking. Recipients should be in a seated position when receiving a vaccine and during the post-vaccination observation period, to prevent falls and injuries if fainting occurs. Recipients who faint after vaccination should be monitored by medical personnel until regaining consciousness, and should be asked to sit or lie down in the observation area and provided emotional support by medical personnel. If a recipient does not recover immediately, medical personnelshould provide further care and inquire about the patient's medical history.**

3. Possible side effects after vaccination

- 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, elevated body temperature, chills, joint pain, and nausea.** The frequency of experiencing these side

effects decreases with increasing age, and most reactions are mild and disappear within a few days. Clinical trials show that side effects are **more common after the second dose compared to the first. 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 both the World Health Organization's Global Advisory Committee on Vaccine Safety (GACVS)[2] and Taiwan's ACIP, the prognosis for such cases of myocarditis and pericarditis is mainly favorable. Cases mostly occur within 14 days after vaccination. They occur more commonly after the second dose than the first, and more commonly in males aged 30 and younger than in women or men in other age groups. Although the long-term outcomes are unknown and still under investigation, cases are extremely rare. **Seek medical attention for your child immediately if symptoms of myocarditis or pericarditis occur within 28 days after vaccination. These symptoms include chest pain, pressure, or 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 child's 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.
- **After SARS-CoV-2 infection, there might be risk for severe COVID-19 symptoms or the complication of myocarditis. During a pandemic, this risk must be considered alongside the extremely low likelihood of developing myocarditis or pericarditis after vaccination. Due to the COVID-19 pandemic and the threat of mutant strains, a second dose of the BioNTech (BNT162b2) COVID-19 Vaccine is approved for adolescents who had no severe adverse reactions to the first dose. Only the individual can decide whether to take the second dose, based on a physician's assessment and objective factors, such as underlying medical conditions, risk factors for severe illness, proximity of residence to infection hotspots, and the need to enter infection hotspots. Your child can choose to be vaccinated at school or at a medical institution.**
- **The U.S., Australia, Japan, and other countries have monitored the incidence of myocarditis and pericarditis among adolescents after mRNA vaccination (with Moderna or BNT). According to their safety monitoring data[3-5] as of early November 2021, the reporting rate for female adolescents after the first dose or all doses was 0.4 to 14 cases per million doses administered, while the rate for male adolescents was 2.4 to 67 per million. After the second dose, the reporting rate for female adolescents was 1.0 to 26 cases per million, while the rate for male adolescents was 2.9 to 108 per million. According to data on Taiwan's Vaccine Adverse Event Reporting System as of Nov. 24, 2021, the rate was 7.35 cases per million for females and 32.49 cases per million for males, showing an increased incidence for males. Safety monitoring data may differ between countries due to variations in when vaccines were rolled out, the robustness of passive surveillance systems for vaccine safety, public willingness to report adverse reactions, case definitions, and case review. 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.**
- **If a fever persists for more than 48 hours or your child experiences 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 child s 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 (VAERS) via your child s health care provider or local health department: https://www.cdc.gov.tw/Category/Page/3-aXlTBq4ggn5Hg2dveHBg (https://www.cdc.gov.tw/- Catego- ry/Page/3-aXlTBq4ggn5Hg2dveHBg)

4. 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.

5. After vaccination, a **COVID-19 Vaccination Record will be issued. Please keep this card in a safe place.** This card must be presented at the second-shot appointment. Once it is filled in with information about both vaccine doses, the card can be used as proof of vaccination.
6. **Other ingredients in this vaccine:** ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)1,2-Distearoyl-sn-glycero-3-phos- phocho-line (DSPC), Cholesterol, Potassium chloride, Potassium dihydrogen phosphate, Sodium chlori de, Disodium phosphate dihydrate, Sucrose, Water for injections.

Adverse reactions and frequency rate in the 7 days after each dose, as observed during Phase III clinical trials [6]

Adverse reactions	Frequency	
	Individuals aged 16 and older	Individuals aged 12 to 15
Pain at injection site	84.1%	90.5%
Fatigue	62.9%	77.5%
Headache	55.1%	75.5%
Muscle pain	38.3%	42.2%
Chills	31.9%	49.2%
Joint pain	23.6%	20.2%
Fever (>38°C)	14.2%	24.3%

Adverse reactions from clinical trials and post-authorization experience in individuals aged 12 and up [6,7]

Frequency	Adverse reactions
Very common (≥1/10)	Headache, Diarrhea, Arthralgia, Myalgia, Injection site pain, Fatigue, Chills, Fever [a], injection site swelling
Common (≥1/100 ~ <1/10)	Nausea, Vomiting
Uncommon (≥1/1,000 ~ <1/100)	Lymphadenopathy, Hypersensitivity reactions (e.g. rash, pruritus, urticaria [b], angioedema [b]), Pain in extremity [c], Malaise, Injection site pruritus
Rare (<1/1000)	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. Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COVID -19 mRNA Vaccine group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
e. This adverse reaction was determined post-authorization. According to the U.S. FDA's Postmarketing data (dated Aug. 23, 2021), increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age.3 During short-term follow-up, the majority of patients recovered after medical treatment.

References:

1. https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1
2. https://www.who.int/news/item/27-10-2021-gacvs-statement-myocarditis-pericarditis-covid-19-mrna-vaccines-updated
3. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf
4. https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-25-11-2021
5. https://www.mhlw.go.jp/content/10601000/000844075.pdf
6. https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf
7. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty > Fact Sheet for Healthcare Providers Administering Vaccine

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

City/county: _____ **School name:** _____

☐ 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 ☐ I do not consent to the vaccination of my child using **BioNTech (BNT162b2) COVID-19 Vaccine.**

◆ Vaccination location (please select one)

☐ Your child's school ☐ Local health department/contracted medical institution

Student's name：_____ (Grade: _____ Class: _____ Roll Number: _____)

Student's national ID/resident certificate/passport number: _____

Student's date of birth (yyyy/mm/dd): _____

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
1.Have you ever had a severe allergic reaction or serious adverse events following vaccines or medication given by injection?		
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?		

◆ Body temperature: _____ °C

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

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

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