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

Taiwan Centers for Disease Control, Ministry of Health and Welfare, Sept. 8, 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.

- **Suitable ages: This vaccine is approved in Taiwan for ages 12 and older.**
- **Dosage and administration interval: This vaccine requires two doses**. Based on the current domestic guidelines, the doses should be administered **at least four weeks (28 days) apart.**
- **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. **This COVID-19 vaccine should not be administered concomitantly with other vaccines. A minimum interval of seven days between this vaccine and influenza vaccines is recommended; furthermore, a minimum interval of 14 days between this 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.

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 personnel should 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.
   - Very rare cases of myocarditis and pericarditis have been observed following vaccination with BioNTech (BNT162b2) COVID-19 Vaccine. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. 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 listed below within the 28 days after vaccination should seek medical attention immediately:
     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 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 (https://www.cdc.gov.tw/- Category/Page/3-aXlTBq4ggn5Hg2dveHBg) via your child's health care provider or local health department.
   - 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 (https://www.cdc.gov.tw/- Category/Page/3-aXlTBq4ggn5Hg2dveHBg) via your child's health care provider or local health department.

4. 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.

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-phosphocholine (DSPC), Cholesterol, Potassium chloride, Potassium dihydrogen phosphate, Sodium chloride, 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[2]

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[2,3]

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.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf
3. 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

Taiwan CDC,
MOHW cares about you

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

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

Checklist	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?		

◆ Body temperature：_____℃

□ Vaccination recommended □ Vaccination not recommended. Reason(s):

_____

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

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

Sample

BioNTech (BNT162b2) COVID-19 Vaccine
Aftercare Sheet/Immunization Notice

A reminder to parents/guardians from your child’ s school, _____, in _____ City/County

On _____ yyyy/mm/dd, your child _____ (Grade: ___Class: ___ Roll Number: ___)

☐ **Received the BioNTech (BNT162b2) COVID-19 Vaccine**

Stamp of health department/contracted medical institution:

【After vaccination: What you need to know】

1. The most common side effects that occur after vaccination are **pain, redness, or 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**. The frequency of side effects decreases with inreasing age, and most reactions are mild and resolvedwithin a few days. Clinical trials show that side effects are **more common after the second dose compared to the first.**
2. Your child **may develop a fever (≥38°C) after vaccination. This usually goes away within 48 hours**. 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.
3. **Very rare cases of myocarditis and pericarditis have been observed following vaccination with BioNTech (BNT162b2) COVID-19 Vaccine.** These cases have **primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men.** Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. 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 listed below **within the 28 days** after vaccination should seek medical attention immediately:
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4. 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.
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.

☐ **Your child was not vaccinated with the BioNTech (BNT162b2) COVID-19 Vaccine. (Reason: _____)**

*Please register your child's willingness to receive this vaccine on the "COVID-19 government-funded vaccination appointment reservation system" within the time period announced by the CECC. Those who are eligible to schedule an appointment or receive a reminder via text message can schedule a vaccination appointment.

(Please return this slip to the school after your child receives a COVID-19 vaccine.)

City/county: _____ School: ___ Grade: ___ Class: ___ Roll number: ___

Student’ s name : _____ National ID/resident certificate/passport number:_____

Was vaccinated with the BioNTech (BNT162b2) COVID-19 vaccine on yyyy/mm/dd _____

Stamp of health department/contracted medical institution:

Adverse reactions and frequency rate in the 7 days after each dose, as observed during Phase III clinical trials[2]

Adverse reactions	Frequency	
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Uncommon(≥1/1,000 ~ <1/100)	Lymphadenopathy, Hypersensitivity reactions (e.g. rash, pruritus, urticariab, angioedemab), Insomnia, 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. The frequency category for urticaria and angioedema 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.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf
3. 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

Taiwan CDC, MOHW cares about you

_____Regards from your Department of Health

_____Department of Health Contact: _____

_____School Contact: _____