

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

20210915

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 1st Dose 2nd Dose

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 increasing age, and most reactions are mild and resolved within 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 ($\geq 38^{\circ}\text{C}$) 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: 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/tv/Category/Page/3-aXITBq4ggn5Hg2dveHBg>) 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.

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 1st Dose 2nd Dose 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 ¹

| 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 ^{1,2}

| Frequency | Adverse reactions |
|--|---|
| 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 |
| Uncommon ($\geq 1/1,000 \sim < 1/100$) | Lymphadenopathy, Hypersensitivity reactions (e.g. rash, pruritus, urticaria ^b , angioedema ^b), 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.² During short-term follow-up, the majority of patients recovered after medical treatment.

References:

1. https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

2. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biotech-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: _____