BioNTech (BNT162b2) COVID-19 Vaccine Sheet

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BioNTech (BNT162b2) COVID-19 Vaccine is a 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%[1]. 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 and other vaccines could be administered at the same time on different arm or administered at any interval**.
  2. Vaccination should be postponed for individuals suffering from a fever or an acute moderate-to-severe illness.
  3. 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.)
  4. 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.
  5. 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 (≥38°C) after vaccination. This usually goes away within 48 hours**.
3. 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 recommend. Seek medical attention 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 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.
4. **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 40 and younger than in women or men in other age groups. In addition, some studies have preliminarily confirmed that a longer interval between the first dose and second dose may reduce the risk of myocarditis or pericarditis. In the UK and US, the recommended interval between the first and second dose has been changed to 8 weeks or 12 weeks for adolescents or young men under 40[3-4]. The recommended interval of a two-dose mRNA vaccine for adolescents and children aged 5 to 11 in Taiwan is in line with this new guidance.**
5. **After SARS-CoV-2 infection, there is the risk of 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 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.**
6. Results of VAERS surveillance show that the reporting rate of myocarditis or pericarditis after mRNA vaccination in Taiwan is similar to that observed by international vaccine safety surveillance. The U.S., Canada, Japan, and other countries have monitored the reporting rate of myocarditis or pericarditis among younger people after mRNA vaccination (Moderna or Pfizer-BioNTech) and found that such rare adverse events occurred more commonly after the second dose than the first dose. Some observational studies of post-marketing data[5] suggest that there may be an increased risk of myocarditis and pericarditis in males under 40 years of age following the second dose of the Moderna COVID-19 Vaccine relative to other authorized or approved mRNA COVID-19 vaccines. But the comparative analysis of the risk of myocarditis or pericarditis following vaccination with the Moderna vaccine and Pfizer-BioNTech vaccine has not yet yielded fully consistent results[6].

7. According to the US, Australia and Japan's safety monitoring data through March 2022, the reporting rates of myocarditis or pericarditis for adolescents after either dose of the primary series of mRNA (Moderna or BNT) vaccine were 0 to 18 (females) and 2.3 to 86 (males) cases per million doses administered; the reporting rates following the second dose were 0 to 26 (females) and 21.6 to 158 (males) cases per million[7-9].
8. According to the Taiwan' s Vaccine Adverse Event Reporting System updated as of April 20, 2022, the reporting rates of myocarditis or pericarditis in individuals aged 12-17 years after the first dose of the Pfizer-BioNTech were 14.1 (females) and 32.6 (males) cases per million doses administered; the reporting rates following the second dose were 16.1 (females) and 142.6 (males) cases per million doses administered. In addition, the reporting rates of myocarditis or pericarditis after the first dose for those aged 18-24 years in Taiwan were 6.8 (females) and 8.4 (males) cases per million doses administered; the reporting rates following the second dose were 11.0(females) and 32.3 (males) cases per million doses administered; the reporting rates following the booster dose were 5.7(females) and 14.6(males) cases per million doses administered. However, 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.
9. 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-aXlTBq4ggn5Hg2dveHBg) via your health care institution or local health department.
10. 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

Adverse reactions and frequency rate in the 7 days after primary series, as observed during Phase III clinical trials [10,11]

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 ache	38.3%	42.2%
Chills	31.9%	49.2%
Joint aches	23.6%	20.2%
Injection Site welling	10.5%	9.2%
Fever (>38°C)	14.2%	24.3%

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

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, redness at injection site
Uncommon (≥1/1,000~<1/100)	Lymphadenopathy[b], Hypersensitivity reactions (e.g. rash, pruritus, urticaria[c], angioedema[c]), Decreased appetite, Insomnia, Hyperhidrosis, Night sweats, Lethargy, Pain in extremity[d], Malaise, Injection site pruritus
Rare (≥1/10,000~<1/1,000)	Acute peripheral facial paralysis[e]
Very rare (<1/10,000)	Myocarditis[f], Pericarditis[f]
Not known	Anaphylaxis, Hypersensitivity, Paraesthesia[f], Hypoaesthesia[f], Erythema multiforme[f], Extensive swelling of vaccinated limb[f]; Facial swelling[g]

a. A higher frequency of pyrexia was observed after the second dose compared to the first dose.
b. A higher frequency of lymphadenopathy (2.8% vs. 0.4%) was observed in participants receiving a booster.
c. The frequency category for urticaria and angioedema was rare.
d. Refers to vaccinated arm.
e. 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.
f. Adverse reaction determined post-authorisation.
g. Facial swelling in vaccine recipients with a history of injection of dermatological fillers has been reported in the post-marketing phase.

Reference

1. https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf
2. https://www.who.int/news/item/27-10-2021-gacvs-statement-myocarditis-pericarditis-covid-19-mrna-vaccines-updated
3. https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a
4. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#recommendations
5. USFDA Moderna COVID-19 Vaccine Health Care Provider Fact Sheet(https://www.fda.gov/media/144637/download)
6. USFDA Review Memorandum Addendum to CBER' s review memorandum dated November 18,2021 entitled, "CBER Assessment of a booster dose of Moderna COVID-19 Vaccine (0.25 mL) administered following a primaryCOVID-19 immunization series in individuals 18 years of age and older"
7. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/02-COVID-Su-508.pdf
8. https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-05-05-2022
9. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/03-COVID-Klein-Shimabukuro-508.pdf
10. https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_29032022.pdf
11. https://www.fda.gov/media/153713/download
12. https://www.fda.gov/media/153714/download

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.

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.	Are you currently pregnant?		
5.	Body temperature： ℃		

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:** _____