Moderna (Spikevax) COVID-19 Vaccine Aftercare Sheet/Immunization Notice

Taiwan Centers for Disease Control, Ministry of Health and Welfare, Apr. 22, 2022

| | der to parents/guardians from your child's school,, in City/County yyyy/mm/dd, your child (Grade:Class: Roll Number:) |
|--------|---|
| | Received the Moderna (Spikevax) COVID-19 Vaccine 1st Dose 2nd Dose np of health department/contracted medical institution: |
| [A | fter 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 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 (≥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 mRNA 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 |
| 4. | (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-aXITBq4ggn5Hg2dveHBg) via your child's health care provider 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. |
| 6. | 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. |
| ır chi | ild was not vaccinated with the Moderna (Spikevax) COVID-19 Vaccine. (Reason:) |
| _ | (Please return this slip to the school after your child receives a COVID-19 va |
| ity/co | ounty: School: Grade: Class: Roll number: |

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

| | Frequency | | | |
|-------------------------------|------------------|------------------|------------------|--|
| Adverse reactions | Individuals aged | Individuals aged | Individuals aged | |
| | 18 and older | 12 to 17 | 6 to 11 | |
| Pain at injection site | 92% | 97% | 98.4% | |
| Fatigue | 70% | 75% | 73.1% | |
| Headache | 64.7% | 78% | 62.1% | |
| Muscle ache | 61.5% | 54% | 35.3% | |
| Chills | 45.4% | 49% | 34.6% | |
| Joint aches | 46.4% | 35% | 21.3% | |
| Nausea/Vomiting | 23% | 29% | 29.3% | |
| Axillary swelling/ Tenderness | 19.8% | 35% | 27.0% | |
| Fever (>38°C) | 15.5% | 14% | 25.7% | |
| Injection Site welling | 14.7% | 28% | 22.3% | |
| Redness | 10% | 26% | 24.0% | |

Adverse reactions from clinical trials and post-authorization experience in individuals aged 6 and up*

| Frequency Adverse reactions | | | | | |
|-----------------------------|---|--|--|--|--|
| Very common (≥1/10) | Lymphadenopathya; Pain or swelling at the injection site; fatigue; headache; muscle ache; chills; joint aches; pyrexia;; nausea; vomiting | | | | |
| Common (≥1/100~ <1/10) | Rash, hives, or rash at the injection site; delayed injection site reaction | | | | |
| Uncommon (≥1/1,000~ <1/100) | Dizziness, Itchiness at the injection site | | | | |
| Rare (≥1/10,000~<1/1,000) | Acute peripheral facial paralysis b, Hypoesthesia, Swelling of the face, | | | | |
| Very rare (<1/10,000) | Myocarditis, Pericarditis | | | | |
| Not known | Anaphylaxis, Hypersensitivity | | | | |

- a. Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site. Other lymph nodes (e.g., cervical, supraclavicular) were affected in some cases.
- b. Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the Spikevax group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
- c. There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination.

References

 $https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf$

| Regards from your Departr | Regards from your Department of Health | | |
|---------------------------|--|----------------------------------|--|
| Department of Health | Contact: | To Disease | |
| School | Contact: | Taiwan CDC, MOHW cares about you | |