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

Taiwan Centers for Disease Control, Ministry of Health and Welfare, May 3, 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. 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.	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) and Taiwan's ACIP recommend. 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).
4.	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. 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	Id 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 vacc
ity/co	unty: School: Grade: Class: Roll number:
tuden	t's name:National ID/resident certificate/passport number:
	ccinated with the Moderna (Spikevax) COVID-19 vaccine 1st Dose 2nd Dose on yyyy/mm/dd

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:

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

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