FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE SPIKEVAX COVID-19 VACCINE MODERNA TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 6 YEARS OF AGE AND OLDER

You are being offered Spikevax COVID-19 Vaccine Moderna to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of Spikevax, which you may receive because there is currently a pandemic of COVID-19.

Spikevax is a vaccine and may prevent you from getting COVID-19. There is no Philippines Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about Spikevax. Talk to the vaccination provider if you have questions.

Spikevax may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit https://www.modernacovid19global.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include fever or chills, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

WHAT IS SPIKEVAX?
Spikevax is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of Spikevax to prevent COVID-19 in individuals 6 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET SPIKEVAX?
Tell your vaccination provider about all your medical conditions, including if you:
- have any allergies
- have a fever

- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET SPIKEVAX?
FDA has authorized the emergency use of Spikevax in individuals 6 years of age and older.

WHO SHOULD NOT GET SPIKEVAX?
You should not get Spikevax if you:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN SPIKEVAX?
Spikevax contains the following ingredients: messenger ribonucleic acid (mRNA), lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, and water for injection.

HOW IS SPIKEVAX GIVEN?
Spikevax will be given to you as an injection into the muscle in your upper arm.

The Spikevax vaccination series is a 2-dose series administered 28 days apart.
- Individuals 12 years of age and older – Spikevax 100 micrograms (0.5 mL) each dose
- Individuals 6 through 11 years of age – Spikevax 50 micrograms (0.25 mL) each dose

If you receive one dose of Spikevax, you should receive a second dose of the same vaccine 28 days later to complete the vaccination series.

For immunocompromised individuals 18 years of age and older, a third dose (0.5 mL) of Spikevax may be administered at least 28 days after the second dose.

A booster dose (0.25 mL) of Spikevax may be given at least 6 months after the second dose in individuals 18 years of age and older.

HAS SPIKEVAX BEEN USED BEFORE?
Spikevax is an unapproved vaccine. A total of 30,351 subjects were followed for a median of 92 days (range: 1-122) for the development of COVID-19 disease.

WHAT ARE THE BENEFITS OF SPIKEVAX?
In an ongoing clinical trial, Spikevax has been shown to prevent COVID-19 following 2 doses given 28 days apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF SPIKEVAX?
There is a remote chance that Spikevax could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose

of Spikevax. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.

Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported in a clinical trial with Spikevax include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), itchiness, and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, rash, and fever
- Rare side effects: temporary one-sided facial drooping and swelling of the face

Side effects that have been reported during post-authorization use of Spikevax include:

- Severe allergic reactions and hypersensitivity

These may not be all the possible side effects of Spikevax. Serious and unexpected side effects may occur. Spikevax is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, get urgent medical attention or go to the nearest hospital.

If you get any side effects, talk to your doctor, pharmacist or nurse.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to the FDA at (02) 8809 5596 or report online to https://www.fda.gov.ph/covid-19-vaccine-report-a-side-effect/.

WHAT IF I DECIDE NOT TO GET SPIKEVAX?

It is your choice to receive or not receive Spikevax. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES SPIKEVAX?

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE SPIKEVAX WITH OTHER VACCINES?

There is no information on the use of Spikevax with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL SPIKEVAX GIVE ME COVID-19?
No. Spikevax does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of Spikevax. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the COVID-19 Vaccine Moderna website https://www.modernacovid19global.com.

To access the most recent Fact Sheets, please scan the QR code provided below.

COVID-19 Vaccine Moderna website
https://www.modernacovid19global.com/

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit FDA at https://www.fda.gov.ph.
- Contact your local public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The Philippines FDA has made Spikevax COVID-19 Vaccine Moderna available under an emergency access mechanism called an EUA.

Spikevax has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for Spikevax is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked after which the product may no longer be used.

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Revised: 25 May 2022