VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS

ABOUT SPIKEVAX (COVID-19 VACCINE, mRNA), MODERNA COVID-19 VACCINE, AND MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

SPIKEVAX (COVID-19 VACCINE, mRNA) AND MODERNA COVID-19 VACCINE FOR 12 YEARS OF AGE AND OLDER

MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) FOR 18 YEARS OF AGE AND OLDER

You are being offered either SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, or Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Moderna COVID-19 Vaccine, Bivalent, to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Moderna COVID-19 Vaccine for use in individuals 12 years of age and older and the authorized Moderna COVID-19 Vaccine, Bivalent for use in individuals 18 years of age and older, and also includes information about the FDA-licensed vaccine, SPIKEVAX (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older.[1]

The FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and the Moderna COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older can be used interchangeably, when used according to their respective instructions for use.[2]

[1] You may receive this Vaccine Information Fact Sheet even if your child is 11 years old. Children who will turn from 11 years to 12 years of age between doses in the primary series may receive, for any dose in the primary series, either: (1) the Moderna COVID-19 Vaccine authorized for use in individuals 6 years through 11 years of age; or (2) Moderna COVID-19 Vaccine authorized for use in individuals 12 years of age and older; or (3) SPIKEVAX (COVID-19 Vaccine, mRNA).

[2] FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and one presentation of the EUA-authorized Moderna COVID-19 Vaccine (supplied in vials with red caps and labels with a light blue border) can be used interchangeably for the primary series for individuals 12 years of age and older without presenting any safety or effectiveness concerns.

SPIKEVAX (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by ModernaTX, Inc. It is approved as a two-dose series for prevention of COVID-19 in individuals 18 years of age and older. It is also authorized under EUA to provide:

- **a two-dose primary series to individuals 12 years through 17 years of age; and**
- **a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.**

The Moderna COVID-19 Vaccine has received EUA from FDA to provide:

- **a two-dose primary series to individuals 12 years of age and older; and**
- **a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.**

Moderna COVID-19 Vaccine, Bivalent has received EUA from FDA to provide either:

- **a single booster dose to individuals 18 years of age and older at least 2 months after completion of primary vaccination with any authorized or approved monovalent[3] COVID-19 vaccine; or**
- **a single booster dose to individuals 18 years of age and older at least 2 months after receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, and Moderna COVID-19 Vaccine, Bivalent, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, and Moderna COVID-19 Vaccine, Bivalent may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

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; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

[3] Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

HOW ARE SPIKEVAX (COVID-19 VACCINE, mRNA) MODERNA COVID-19 VACCINE, AND MODERNA COVID-19 VACCINE, BIVALENT RELATED?

SPIKEVAX (COVID-19 Vaccine, mRNA) and Moderna COVID-19 Vaccine can be used interchangeably.[4] Moderna COVID-19 Vaccine, Bivalent is made in the same way as SPIKEVAX and Moderna COVID-19 Vaccine, but it also contains an Omicron component to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2.

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 ANY OF THESE VACCINES?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- 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
- have ever fainted in association with an injection

WHO SHOULD NOT GET SPIKEVAX (COVID-19 VACCINE, mRNA), MODERNA COVID-19 VACCINE, OR MODERNA COVID-19 VACCINE, BIVALENT?

You should not get any of these vaccines if you:

- had a severe allergic reaction after a previous dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or Moderna COVID-19 Vaccine
- had a severe allergic reaction to any ingredient in these vaccines

WHAT ARE THE INGREDIENTS IN THESE VACCINES?

SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, and Moderna COVID-19 Vaccine, Bivalent contain the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

HOW ARE THESE VACCINES GIVEN?

SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, or Moderna COVID-

[4] FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and one presentation of the EUA-authorized Moderna COVID-19 Vaccine (supplied in vials with red caps and labels with a light blue border) can be used interchangeably for the primary series for individuals 12 years of age and older without presenting any safety or effectiveness concerns.

19 Vaccine, Bivalent will be given to you as an injection into the muscle.

Primary Series: SPIKEVAX (COVID-19 Vaccine, mRNA) and Moderna COVID-19 Vaccine are administered as a two-dose series, 1 month apart. A third primary series dose may be administered at least 1 month after the second dose to individuals with certain kinds of immunocompromise.

Booster Dose: Moderna COVID-19 Vaccine, Bivalent is administered as a single booster dose at least 2 months after:

- completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine; or
- receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

HAVE THESE VACCINES BEEN USED BEFORE?
In clinical trials, approximately 30,000 individuals 12 years of age and older have received at least 1 dose of Moderna COVID-19 Vaccine. Millions of individuals have received Moderna COVID-19 Vaccine under EUA since December 18, 2020.

In a clinical trial, approximately 400 individuals received 1 dose of a bivalent vaccine that differs from the Moderna COVID-19 Vaccine, Bivalent in that it contains a different Omicron component.

WHAT ARE THE BENEFITS OF THESE VACCINES?
SPIKEVAX (COVID-19 Vaccine, mRNA) and Moderna COVID-19 Vaccine have been shown to prevent COVID-19. FDA has authorized Moderna COVID-19 Vaccine, Bivalent to provide better protection against COVID-19 caused by the Omicron variant of SARS-CoV-2.

The duration of protection against COVID-19 is currently unknown.

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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received SPIKEVAX (COVID-19 Vaccine, mRNA) or Moderna COVID-19 Vaccine, more commonly in adult males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this

occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in clinical trials with these vaccines include:

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

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

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects of these vaccines. Serious and unexpected side effects may occur. The possible side effects of these vaccines are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

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 **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include either "SPIKEVAX (COVID-19 Vaccine, mRNA)", "Moderna COVID-19 Vaccine EUA," or "Moderna COVID-19 Vaccine, Bivalent EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET SPIKEVAX (COVID-19 VACCINE, mRNA), MODERNA COVID-19 VACCINE, OR MODERNA COVID-19 VACCINE, BIVALENT?
Under the EUA, it is your choice to receive or not receive any of these vaccines. Should you

decide not to receive any of these vaccines, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES SPIKEVAX (COVID-19 VACCINE, mRNA), MODERNA COVID-19 VACCINE, OR MODERNA COVID-19 VACCINE, BIVALENT?

For primary vaccination, another choice for preventing COVID-19 is COMIRNATY (COVID-19 Vaccine, mRNA), an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under EUA, including bivalent vaccines that contain an Omicron component of SARS-CoV-2.

CAN I RECEIVE SPIKEVAX (COVID-19 VACCINE, mRNA), MODERNA COVID-19 VACCINE, OR MODERNA COVID-19 VACCINE, BIVALENT AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, or Moderna COVID-19 Vaccine, Bivalent at the same time as other vaccines. If you are considering receiving SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, or Moderna COVID-19 Vaccine, Bivalent with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?

If you are immunocompromised, you may receive a third primary series dose of Moderna COVID-19 Vaccine or SPIKEVAX (COVID-19 Vaccine, mRNA). Individuals 18 years of age and older may receive a booster dose with Moderna COVID-19 Vaccine, Bivalent. Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. Your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

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

WILL THESE VACCINES GIVE ME COVID-19?

No. These vaccines do not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive your first COVID-19 vaccine, you will get a vaccination card. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

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

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose of the primary series. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THESE COVID-19 VACCINES?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including these vaccines. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An EUA is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA

is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA approved 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.

An EUA 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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Patent(s): www.modernatx.com/patents
Revised: Aug/31/2022

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: 0886983000349