

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT  
MODERNA COVID-19 VACCINE, BIVALENT  
WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT  
CORONAVIRUS DISEASE 2019 (COVID-19)**

You or your child is being offered the Moderna COVID-19 Vaccine, Bivalent to prevent coronavirus disease 2019 (COVID-19) which is caused by the virus SARS-CoV-2. This fact sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, Bivalent which you or your child may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make the Moderna COVID-19 Vaccine, Bivalent available during the COVID-19 pandemic (for more details about an EUA please see “**What is an Emergency Use Authorization?**” at the end of this document). The Moderna COVID-19 Vaccine, Bivalent is not an FDA-approved vaccine in the United States. Read this Fact Sheet for information about the Moderna COVID-19 Vaccine, Bivalent.

**WHAT IS COVID-19?**

COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close 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 leading to death. 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.

**WHAT IS MODERNA COVID-19 VACCINE, BIVALENT?**

Moderna COVID-19 Vaccine, Bivalent is a vaccine for use in individuals 6 months of age and older to prevent COVID-19.<sup>1</sup> The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, Bivalent under an EUA.

The Moderna COVID-19 Vaccine, Bivalent may not protect everyone.

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<sup>1</sup> Moderna COVID-19 Vaccine, Bivalent encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

## **WHAT SHOULD YOU MENTION TO THE VACCINATION PROVIDER BEFORE YOU OR YOUR CHILD GET MODERNA COVID-19 VACCINE, BIVALENT?**

Tell the vaccination provider about all your or your child's medical conditions, including if you or your child:

- 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 or your child's 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

## **HOW IS THE VACCINE GIVEN?**

Moderna COVID-19 Vaccine, Bivalent is given as an injection into the muscle.

### **Individuals 6 months through 5 years of age:**

- **Unvaccinated individuals:** Two doses of Moderna COVID-19 Vaccine, Bivalent are administered. The second dose is administered 1 month after the first.
- **Individuals who have received one dose of Moderna COVID-19 Vaccine:<sup>2</sup>** A single dose of Moderna COVID-19 Vaccine, Bivalent is administered 1 month after the dose of Moderna COVID-19 Vaccine.
- **Individuals who have received two doses of Moderna COVID-19 Vaccine:** A single dose of Moderna COVID-19 Vaccine, Bivalent is administered at least 2 months after the last dose of Moderna COVID-19 Vaccine.

### **Individuals 6 years of age and older:**

- **Unvaccinated individuals:** A single dose of Moderna COVID-19 Vaccine, Bivalent.
- **Individuals who have received one or more doses of any monovalent COVID-19 vaccine:<sup>3</sup>** A single dose of Moderna COVID-19 Vaccine, Bivalent is administered at least 2 months after any monovalent COVID-19 vaccine.
- **Individuals 65 years of age and older who have received one dose of a bivalent COVID-19 vaccine:** A dose of Moderna COVID-19 Vaccine, Bivalent may be administered at least 4 months after the dose of the bivalent COVID-19 vaccine.

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<sup>2</sup> Moderna COVID-19 Vaccine, a monovalent vaccine, encodes the spike protein of only the Original SARS-CoV-2.

<sup>3</sup> Monovalent refers to any COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

### **Immunocompromised individuals 6 months of age and older:**

- For immunocompromised individuals 6 months through 5 years of age who have received two doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), a single additional dose of Moderna COVID-19 Vaccine, Bivalent may be administered at least 1 month following the most recent dose of Moderna COVID-19 Vaccine, Bivalent; additional doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
- For immunocompromised individuals 6 years of age and older, a single additional age-appropriate dose of Moderna COVID-19 Vaccine, Bivalent may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional age-appropriate doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

### **WHO SHOULD NOT GET MODERNA COVID-19 VACCINE, BIVALENT?**

A person should not get Moderna COVID-19 Vaccine, Bivalent if they had:

- a severe allergic reaction after a previous dose of Moderna COVID-19 Vaccine<sup>4</sup> Moderna COVID-19 Vaccine, Bivalent, or SPIKEVAX (COVID-19 Vaccine, mRNA).<sup>5</sup>
- a severe allergic reaction to any ingredient in these vaccines.

### **WHAT ARE THE INGREDIENTS IN THIS VACCINE?**

Moderna COVID-19 Vaccine, Bivalent contains 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.

### **HAS THIS VACCINE BEEN USED BEFORE?**

Millions of individuals 6 months of age and older have received Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) under EUA.

In addition, millions of individuals 6 months of age and older have received the monovalent Moderna COVID-19 Vaccine under EUA. In clinical trials, approximately 5,000 individuals 6 months through 5 years of age, 4,000 individuals 6 years through 11 years of age, and 30,000 individuals 12 years of age and older have received at least 1 dose of Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine, Bivalent is made in the same way as the 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.

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<sup>4</sup> Moderna COVID-19 Vaccine, a monovalent vaccine, encodes the spike protein of only the Original SARS-CoV-2.

<sup>5</sup> SPIKEVAX (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by ModernaTX, Inc. SPIKEVAX encodes the spike protein of only the Original SARS-CoV-2.

## **WHAT ARE THE BENEFITS OF MODERNA COVID-19 VACCINE, BIVALENT?**

FDA has authorized Moderna COVID-19 Vaccine, Bivalent to provide protection against COVID-19.

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

## **WHAT ARE THE RISKS OF MODERNA COVID-19 VACCINE, BIVALENT?**

There is a remote chance that the vaccine 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, the vaccination provider may ask you or your child to stay at the place where you or your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the 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 Moderna COVID-19 Vaccine, Bivalent, Moderna COVID-19 Vaccine, or SPIKEVAX, 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 vaccination. The chance of having this occur is very low. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine:

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

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in clinical trials with Moderna COVID-19 Vaccine, Bivalent or Moderna COVID-19 Vaccine include:

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

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

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- 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. Serious and unexpected side effects may occur. The possible side effects are still being studied.

### **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you or your child experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your or your child's healthcare provider if you or your child 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 "Moderna COVID-19 Vaccine, Bivalent EUA" 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 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](http://www.cdc.gov/vsafe).

### **WHAT IF I DECIDE NOT TO GET OR NOT TO HAVE MY CHILD GET MODERNA COVID-19 VACCINE, BIVALENT?**

Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide not to receive, or for your child not to receive, this vaccine, it will not change the standard medical care.

### **ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE, BIVALENT?**

Other vaccines to prevent COVID-19 may be available under EUA, including bivalent vaccines that contain an Omicron component of SARS-CoV-2. SPIKEVAX (COVID-19 Vaccine, mRNA) and COMIRNATY (COVID-19 Vaccine, mRNA) are FDA-approved monovalent COVID-19 vaccines.

## **CAN I OR MY CHILD RECEIVE MODERNA COVID-19 VACCINE, BIVALENT AT THE SAME TIME AS OTHER VACCINES?**

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

## **WHAT IF I AM, OR MY CHILD IS, IMMUNOCOMPROMISED?**

Immunocompromised individuals 6 months of age and older may receive one or more additional doses of Moderna COVID-19 Vaccine, Bivalent (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, you or your child should continue to maintain physical precautions to help prevent COVID-19. Your close contacts should be vaccinated as appropriate.

## **WHAT ABOUT PREGNANCY OR BREASTFEEDING?**

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

## **WILL THIS VACCINE GIVE ME OR MY CHILD COVID-19?**

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


## **KEEP THE VACCINATION CARD**

When you, or your child, receive the first COVID-19 vaccine, you will get a vaccination card. Remember to bring the card if you receive additional doses.

## **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.

<b>Moderna COVID-19 Vaccine website</b>	<b>Telephone number</b>
<a href="https://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a> 	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 VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your or your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. 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 THIS COVID-19 VACCINE?**

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 this vaccine. 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/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

**WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The FDA has made Moderna COVID-19 Vaccine, Bivalent available under an emergency access mechanism called an EUA. 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 under EUA during the COVID-19 pandemic.

The 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](http://www.modernatx.com/patents)  
Revised: Apr/17/2023



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

GDTI: 0886983000592