

COVID VACCINATION INFORMATION SHEETS

DIRECTIONS

- I. The first set of sheets are for YOUR INFORMATION
 - Please read carefully so it will allow you to make a fully informed decision about taking the COVID vaccine

BLANK Sheet

- II. Please complete the first sheet behind the BLANK Sheet down to the signature and "For Clinic Use Only" area
DO NOT complete the SIGNATURE line or this "Clinic only" Area. This will be done at the clinic
- III. The last sheet should not be completed UNTIL just before you come to the clinic for your vaccination.

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF
THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019
(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER**

You are being offered the Moderna COVID-19 Vaccine 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 the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine 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.

WHAT IS THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine 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 the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 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 THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of 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 THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine 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 THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine 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, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

Side effects that have been reported with the Moderna COVID-19 Vaccine 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, and fever

There is a remote chance that the Moderna COVID-19 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 of the Moderna COVID-19 Vaccine. 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

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

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 "Moderna COVID-19 Vaccine 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 new 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 THE MODERNA COVID-19 VACCINE?

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?

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 THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

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

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?

No. The Moderna COVID-19 Vaccine 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 the Moderna COVID-19 Vaccine. 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/emergencv-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencv-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. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

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/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The 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.

The Moderna COVID-19 Vaccine 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 the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

©2020 ModernaTX, Inc. All rights reserved.

Patent(s): www.modernatx.com/patents

Revised: 12/2020



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

Barcode Date: 12/2020



Reporting Reactions or Side Effects to the COVID -19 Vaccine

Reactions Experienced after receiving a vaccine can be mild, moderate, or severe.

Please report any symptoms or reactions you experience after receiving the COVID -19 vaccine so that they can be entered into the Vaccine Adverse Event Reporting System (VAERS).

This system is used to monitor the safety of vaccines. You can report reactions or symptoms to VAERS:

1. online at <https://vaers.hhs.gov/index>
2. By phone at 1-800-822-7967
3. Call the Alabama Department of Public Health at 1-800-270-7268 and ask to speak with a nurse and they will submit a report to VAERS
4. V – safe (a smartphone-based tool) ask for a handout if you choose to use this reporting method

Common reactions or symptoms that may be experienced but not limited to, are; pain, redness and swelling at the injection site, fever, tiredness, headache, chills, vomiting, diarrhea, new or worsened muscle pain, joint pain, and swollen lymph nodes.

12/15/2020



**Get vaccinated.
Get your smartphone.
Get started with v-safe.**

What is v-safe?

v-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.



v-safeSM
after vaccination
health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your
smartphone's browser at
vsafe.cdc.gov

OR

Aim your smartphone's
camera at this code



How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the **v-safe** website using one of the two options below:



OR



2. Read the instructions. Click **Get Started**.
 3. Enter your name, mobile number, and other requested information. Click **Register**.
 4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
 5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
 6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
 7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
 8. **Congrats! You're all set!** If you complete your registration before 2pm local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2pm, **v-safe** will start your initial health check-in immediately after you register—just follow the instructions.
- You will receive a reminder text message from **v-safe** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit www.cdc.gov/vsafe



BLANK PAGE

**THESE ARE HEALTH DEPT.
FORMS**

**Persons getting vaccine from
other providers will use 'their'
forms.**



Alabama Department of Public Health COVID -19 Vaccine Administration Form PATIENT INFORMATION

Last Name		First Name		M.I.	Gender
Last 4 Digits of Social Security Number		Date of Birth		Age	Race
Street Address			Phone		
City	County		State	Zip	

PARENT / LEGAL GUARDIAN INFORMATION FOR DEPENDENTS

Last Name		First Name		Relationship to Patient <input type="checkbox"/> Parent <input type="checkbox"/> Legal Guardian <input type="checkbox"/> Other _____	
Street Address if Different			City	State	Zip
Phone		Emergency Contact			

INSURANCE INFORMATION

Insurance Provider (check one): <input type="checkbox"/> United Healthcare <input type="checkbox"/> SEIB <input type="checkbox"/> PEEHIP <input type="checkbox"/> LGB <input type="checkbox"/> Humana <input type="checkbox"/> Medicare <input type="checkbox"/> BCBS <input type="checkbox"/> Medicaid <input type="checkbox"/> Uninsured					
Group Number _____			Effective Date of Policy _____		Insurance Policy Number, Medicaid, or Medicare Number
Card Subscriber Name	Last	First	Subscriber Date of Birth	Relationship to Patient <input type="checkbox"/> Self <input type="checkbox"/> Parent <input type="checkbox"/> Legal Guardian <input type="checkbox"/> Spouse <input type="checkbox"/> Other _____	

VACCINATION AND HEALTH-RELATED INFORMATION

Has the patient ever received a COVID - 19 vaccination? If yes, date given _____ Manufacturer _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the patient have long-term health problems with: •immunocompromised condition or taking a medicine that affects your immune system •Heart Disease • Lung Disease • Asthma • Kidney or Liver Disease • Metabolic Disease, such as Diabetes • Bleeding disorder or take a blood thinner	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has the patient had life threatening reaction to any injectable medication, a COVID -19 vaccine, or to a vaccine component (examples: eggs, thimerosal, gelatin, neomycin, phenol, or bovine protein)? Yes, list _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
For Women: Are you pregnant or considering becoming pregnant in the next three months, or currently nursing?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has the patient had a seizure or any other brain or other nervous system problem (i.e. Guillain-Barré Syndrome after receiving a vaccine)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I have read the Emergency Use Authorization (EUA) Fact Sheet or the VIS about the COVID - 19 virus and vaccine. I understand the benefits and risks of the COVID -19 vaccine. I give permission for the above named patient to receive the vaccine indicated. I authorize billing insurance for the vaccine administration fee for the vaccine provided. I have also received notice of my privacy rights, and I have been given or offered a copy of the Alabama Department of Public Health "Notice of Privacy Practices." I understand this information is available upon request, as well as available for review at the time of vaccination.

Signature or person to receive the vaccine or authorized representative or Legal Guardian:

X-----Date-----

(FOR CLINIC USE ONLY)

Date Vaccine and EUA/VIS Given	Type and Date of VIS or EUA Fact Sheet	Clinical Site	County Code	NCES #	
Vaccine Given: <input type="checkbox"/> Moderna 1st dose <input type="checkbox"/> Admin Code 0011A		<input type="checkbox"/> Moderna 2nd dose <input type="checkbox"/> Admin Code 0012A		CPT code 91301	
Site Location:	Manufacturer	Lot Number	NDC #	Site of Injection LA RA	Route IM
Nurse Signature				Date	

SCREENING GUIDANCE PRIOR TO PROVIDING COVID – 19 VACCINATION

Prior to the administration of a COVID -19 vaccination screen the individual for COVID -19 or any other acute illness:

1. Have you been exposed to anyone with COVID – 19, or tested positive, for COVID -19, within the last 14 days?
 - No – vaccine not deferred
 - Yes – defer vaccine until quarantine or isolation period has ended

Do you have one of the following symptoms? If yes, defer vaccine until resolved or COVID -19 ruled out.

- Cough, new onset, unrelated to known chronic conditions
- Shortness of breath, new onset unrelated to known chronic conditions

2. Have you experienced at least two of the following symptoms in the past 24 hours? If yes, vaccine should be deferred until recovery from acute illness, or symptoms resolved.

- Fever - Temperature_____ A temperature of 99° or above, regardless of other symptoms, the vaccine should be deferred until the fever is resolved without the use of fever reducing medications
- Chills
- Repeated shaking with chills
- Muscle pain
- Headache
- Sore throat
- New loss of taste or smell

If yes, vaccine should be deferred until recovery from acute illness, or symptoms resolved.

3. Have you received another vaccine within the past 14 days?

- No – vaccine not deferred
- Yes – vaccine should be deferred until there has been a minimum interval of 14 days before or after administration with any other vaccine

4. Have you been diagnosed with COVID -19 and been treated with monoclonal antibodies or convalescent plasma within the last 90 days?

- No – vaccine not deferred
- Yes – vaccine should be deferred for at least 90 days to avoid interference of the treatment with vaccine – induced immune responses

5. Have you had a severe reaction (e.g., anaphylaxis) to any component of the Moderna COVID – 19 vaccine?

- No - vaccine not deferred
- Yes – contraindication to receiving the vaccine. Do not administer the vaccine

The Moderna COVID-19 Vaccine 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, and sucrose.

6. Do you meet criteria to receive the COVID -19 vaccine based on the current or one of the past phases of the COVID – 19 Vaccination Allocation Plan? If an individual provides information take their word.

Current Phase of Allocation Plan _____ * See attached COVID – 19 Vaccination Allocation Plan

- No - vaccine deferred. Based on information provided make individual aware of which phase they will be eligible for
- Yes – Vaccine not deferred