

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/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. 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).

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

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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 2 p.m. 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.*



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



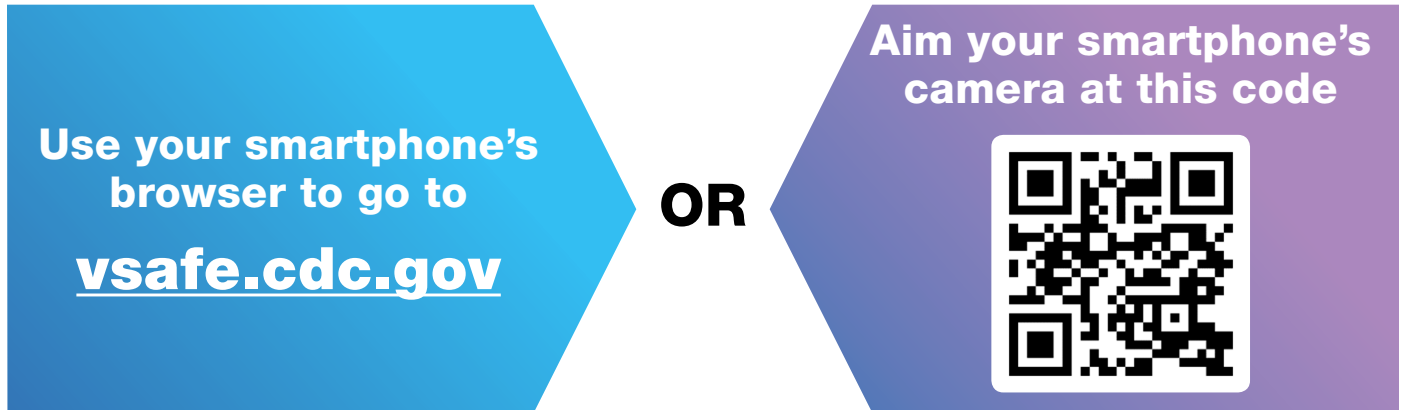
*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

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:



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 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 2 p.m. local time, **v-safe** will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., **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 2 p.m. 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



COVID-19 Vaccine

COVID-19 Vaccine FAQs for General Consumers

02/01/2021



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Ascension's Mission is a commitment to giving to "spiritually centered, holistic care" that "sustains and improves the health of individuals and communities." Receiving a vaccine is not only a way to care for yourself, but also a way to care for your families and community. These Frequently Asked Questions (FAQs) are part of our commitment to giving care, alleviating fears, and honoring each person with dignity and reverence.

General Consumer Facing COVID-19 Vaccine FAQs

You may have some questions about COVID-19 vaccinations. Here are some answers to some commonly asked questions. We also encourage you to talk with your doctor or provider, visit <https://healthcare.ascension.org/doctors> .

Where can I find information about Ascension's approach to the COVID-19 vaccine?

Ascension's COVID-19 Vaccine Resource Center site for patients can be found by clicking [here](#).

Ascension's COVID-19 COVID-19 site can be found by clicking [here](#).

Ascension's COVID-19 Vaccine Resource Center site for **associates** can be found by clicking [here](#).

How do I know the COVID-19 vaccine is safe?

All vaccines require extensive research, documentation and closely monitored clinical trials to determine effectiveness and safety before being submitted by pharmaceutical companies for approval. The U.S. Food and Drug Administration (FDA) is responsible to ensuring the safety, effectiveness and availability of vaccines available to the public to protect safety and identify any potential side effects.

If the FDA determines that a vaccine meets its safety and effectiveness standards, it can make these vaccines available for use in the United States by approval or Emergency Use Authorization (EUA).

How does an Emergency Use Authorization (EUA) differ from full FDA approval?

According to the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA) approval of a drug means that the agency has determined, based on substantial evidence, that the drug is effective for its intended use, and that the benefits of the drug outweigh its risks when used according to the product's approved labeling.

In the case of a public health emergency, the FDA may issue an Emergency Use Authorization (EUA) before the full approval process can be completed. For the COVID-19 vaccines under development for the prevention of COVID-19, the FDA will make an assessment on a case-by-case basis considering all of the scientific evidence available, including data from adequate and well conducted clinical trials, as well

as an assessment that the benefits of the vaccine outweigh the potential risks.

[Emergency Use Authorization for Vaccines to Prevent COVID-19](#)

How do COVID-19 vaccines work?

According to the CDC, COVID-19 vaccines help our bodies produce antibodies and develop immunity to the virus that causes COVID-19 without us having to get the illness. Additionally, the vaccine causes the body to produce “memory” lymphocytes that will remember how to fight that virus in the future.

It typically takes a few weeks for the body to produce antibodies and immunity after vaccination. Therefore, it is possible that a person could be infected with the virus that causes COVID-19 just before or just after vaccination and then get sick because the vaccine did not have enough time to provide protection.

The two vaccines submitted for Emergency Use Authorization (EUA) by the FDA (Pfizer and Moderna) use the same novel mRNA technology, injecting small pieces of genetic material that the body's cells use to produce a protein similar to the coronavirus. In response to this protein, the body then creates antibodies that are primed to fight off the virus.

Sometimes after vaccination, the process of producing antibodies and building immunity can cause symptoms, such as fever. These symptoms are normal and are a sign that the body is building immunity.

[Understanding How COVID-19 Vaccines Work](#)

If I tested positive and have recovered from COVID-19, do I still need the vaccination?

Data from clinical trials indicate that mRNA COVID-19 vaccines are safe in persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until the end of this period, if desired.

How many doses of the vaccine will I need, and do my two doses of the vaccine need to be from the same manufacturer?

According to the CDC, all but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the United States need two shots to be effective. **For vaccines that require two doses, both doses must be from the same manufacturer.**

The Pfizer BioNTech BNT162b2 vaccine requires **2 doses, 21 days apart**. For more information on the Pfizer vaccine, visit [Coronavirus COVID-19 Scientific Research and Resources](#)

The Moderna mRNA-1273 vaccine requires **2 doses, 28 days apart**. For more information on the Moderna vaccine, visit [Moderna's Work on a COVID-19 Vaccine Candidate](#)

Both doses of the vaccine need to be from the same manufacturer. You will receive patient fact sheets that will note which vaccine you received. We encourage you to communicate with your provider about the vaccine you received both when you schedule and when you receive your second dose. When you receive your first dose, you should receive documentation noting which vaccine you received. Keep that document and bring it with you for your second dose (if needed).

What are the risks of the vaccine?

The FDA's rigorous testing helps ensure that vaccines are safe and highly effective. However, all medications, including vaccines, carry a small risk of side effects. Most common side effects are identified in clinical trials before the vaccine is approved, but less-common side effects may not be detected until the medicines or vaccines are more widely available. That's why vaccines are continuously, carefully monitored for possible side effects even after they are licensed.

Does the flu vaccine cover COVID-19 too?

No. The flu vaccine is important to protect you from influenza, particularly during the current coronavirus pandemic, but it does not vaccinate you for COVID-19. Receiving both a flu vaccine and COVID-19 vaccine are important to stay healthy. The flu vaccine is important to protect you from influenza, particularly during the current coronavirus pandemic, but it does not vaccinate you for COVID-19. Receiving the COVID-19 vaccine will help protect you and prevent the spread of the coronavirus.

Will masks still be required within Ascension facilities?

We are committed to ensuring a safe, healthy environment for associates, patients and visitors at all Ascension facilities. Masks are currently required to ensure the safest possible experience, as well as frequent handwashing and social distancing. These safety behaviors will continue. We will continue to evaluate our mask requirement as the larger landscape evolves.

Will my second dose of the vaccine have to be exactly 21 or 28 days after my first does?

The second dose should be administered as close to the recommended interval as possible. Second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period should not be repeated. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID -19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose. There is currently limited data on the efficacy on mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series.

After receiving the vaccine, what side effects could I experience?

The most reported side effects were injection site pain and flu-like reactions which tended to last up to two days. More than 50% of adults under the age of 55 reported experiencing fatigue or headache, 33% reported having chills or muscle pain, and up to 16% reported having a fever with 2nd dose- but older adults were less likely to report experiencing those side effects. Those with existing allergies, anaphylaxis, or those who experience severe allergic reactions to other medications or food are more at risk to experience side effects. Many participants who received the vaccine reported feeling those side effects in the hours after they received the second dose, suggesting that people may need to plan to rest and/or take a day off work after receiving the second dose.

I received my first dose of vaccine, and I am not sure if I am experiencing side effects or if I have COVID-19?

Sometimes after vaccination, the process of building immunity can cause symptoms, such as fever, body ache, headache, and fatigue. These symptoms are normal and are a sign that the body is building immunity, [according to the CDC](#). While COVID-19 infection can cause these same symptoms, additional and more specific COVID-19 symptoms may include cough, shortness of breath, congestion/runny nose, and new loss of taste and smell. If side-effect symptoms worsen or do not subside within 72 hours of receiving the vaccine, contact your primary care physician. If you experience an adverse event, please contact your primary care physician as soon as possible.

How can I participate in the CDC's V-safe program and what is it?

According to the CDC, V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you get the COVID-19 vaccine. 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 get more information. And V-safe will remind you to get your second COVID-19 vaccine if you need one.

For instructions on how to register and use V-safe, view the link below:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

For frequently asked questions about V-safe, view the link below:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq.html>

For More information

Speak to your healthcare provider to learn more about the COVID-19 vaccine, or utilize our

Ascension Connect COVID-19 Hotlines

Market	Toll-Free Number
Ascension Connect Main Number	(833) 978-0649
Baltimore/Binghamton/DC	(833) 980-0692
Birmingham	(833) 980-0690
Florida & Gulf Coast	(833) 981-0712
Illinois (AMITA)	(224) 273-3900
Indiana	(833) 981-0733
Kansas and Oklahoma	(855) 782-1039
Michigan	(833) 981-0738
Tennessee	(833) 981-0626
Texas	(833) 919-1680
Wisconsin	(833) 981-0711

Other resources

CDC - [Coronavirus Disease 2019 \(COVID-19\) Vaccines](#)

FDA - [FDA COVID-19 Vaccine Information](#)

HHS Operation Warp Speed - [Fact Sheet: Explaining Operation Warp Speed](#)

FDA - [Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Recipients and Caregivers](#)

FDA - [Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine](#)

FDA - [Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization](#)

FDA - [Moderna COVID-19 Vaccine Fact Sheet for Recipients and Caregivers](#)

FDA - [Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine](#)

FDA - [Moderna COVID-19 Vaccine EUA Letter of Authorization](#)