COVID-19 Vaccination Education Janssen (Johnson & Johnson)

Thank you for your commitment to getting vaccinated. Included in this packet is the information that you need to know:

- Emergency Use Authorization of Janssen COVID-19 Vaccine by Johnson & Johnson.
- Next steps after receiving the COVID-19 Vaccine including symptom monitoring.
- Centers for Disease Control and Prevention Vaccine Safety (V-Safe) symptom reporting.

A Guide to Available Services for Enrolled Veterans

Minneapolis VA Health Care System (MVAHCS) is a teaching hospital providing a full range of patient care services with state-of-the-art technology, education, and research. Comprehensive health care is provided through primary care, tertiary care and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, extended care and 13 Community Based Outpatient Clinics (CBOC) across the region.

Choose VA

- ✓ VHA is the largest integrated health care system in the United States, providing care at 1,227 health care facilities, including 168 VA Medical Centers and 1,047 outpatient sites of care of varying complexity.
- ✓ As of 2016, VA Consolidated Mail Outpatient Pharmacy received the highest customer satisfaction among the nation's public and private mail-order pharmacies, according to a J.D. Power study. Nearly 5 million Veterans receive their prescriptions through VHA pharmacies.
- ✓ VA is the national leader in telehealth services. VA telehealth services are critical to expanding access to VA care in more than 45 clinical areas.

Services Available at the Minneapolis VA Health Care System

Audiology & ENT	Neurology & Neurosurgery	Primary Care
Cardiology	Nutrition	Prosthetics
Dental	Oncology/Cancer Care	Rehabilitation
Dermatology	Ophthalmology	Respiratory Services
General Surgery	Optometry	Telehealth Services
Home Care Services	Orthopedics	Thoracic Surgery
Hospice/Palliative Care	Orthotics	Urology
Mental Health Services	Pharmacy	Vascular Surgery
MOVE! Weight Management	Podiatry & Wound	Women's Health
Whole Health & Integrative Health Services		

IMPORTANT NUMBERS

Minneapolis VA Health Care System:
(612) 725-2000 • Toll Free: (866) 414-5058

Primary Care Call Center:
(612) 467-1100 • Toll Free: 1 (866) 414-5058

Enrollment:
1 (877) 222-VETS (8387)

Benefits:
1-800-827-1000

VA | U.S. Department of Veterans Affairs

For more information, please visit:
www.va.gov/minneapolis-health-care/
www.va.gov

Revised: July 2021

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

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

The Janssen COVID-19 Vaccine 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 Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.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. Common 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 JANSSEN COVID-19 VACCINE?

The Janssen 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 Janssen 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 JANSSEN COVID-19 VACCINE?

Tell the 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 JANSSEN COVID-19 VACCINE?

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

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

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

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

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

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

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

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

Severe Allergic Reactions

There is a remote chance that the Janssen 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 Janssen 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.

Blood Clots with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,

- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

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

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body
- Difficulty walking
- Difficulty with facial movements, including speaking, chewing, or swallowing
- Double vision or inability to move eyes
- Difficulty with bladder control or bowel function

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 "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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 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 JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen 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 JANSSEN 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 JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen 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 JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

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For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: Jul/08/2021

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

Barcode Date: 02/2021

NEXT STEPS after receiving the COVID-19 Vaccine

VA Side Effects and Adverse Events Reporting Fact Sheet

Whether you are an employee or a Veteran receiving the COVID-19 vaccine, you have taken an important step towards protecting yourself, your family and friends, and your communities from COVID-19.

Now that you have received the vaccine, what can you expect?

Vaccines protect us by stimulating the body's natural immune system to produce antibodies to fight a virus. This is called an immune response. Vaccines are a way to trigger the immune response to allow the body to protect against becoming infected and getting sick from illnesses like COVID-19.

Many people who receive the COVID-19 vaccine who experience a reaction have mild symptoms (listed in the table below). These usually go away on their own within a few days. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease.

Local symptoms at the injection site may include:	General symptoms (not at the injection site) may include:		
Pain – Discomfort	Chills	Muscle or Body Aches (myalgia)	Joint Pains (arthralgia)
Redness/Swelling/Itching	Fever	Fatigue or Tiredness	Allergic Reaction
	Headache	Nausea/Vomiting/Diarrhea	

It is important to know what side effects to expect and which ones should be reported to your healthcare team or when to seek immediate medical attention. ***Contact your health care provider if your symptoms make you unable to work, do daily activities, or if you feel that you need urgent care for any of these symptoms.*** This reporting is part of the Emergency Use Authorization (EUA) safety monitoring process required by the U. S. Food and Drug Administration (FDA). You can play an important role in this process.

If you experience a reaction to the vaccine, please use the table on the back of the sheet to record your symptoms and the day that you experienced them.

If you experience these symptoms ***and they have an impact on your daily routine***, please contact your provider and record your information in the table on the back of this sheet.

- If you are an employee and experience symptoms to the COVID-19 vaccine that impact daily activities, please contact your local Employee Occupational Health department at _____.
- If you are a Veteran and experience symptoms to the COVID-19 vaccine that impact daily activities, please contact your healthcare team at _____.
- If you are a non-Veteran, adolescent patient, or Veteran not eligible for general care at the VA and experience symptoms, please contact your primary care provider. In addition, please remember to share your CDC Vaccination Record card with your primary care provider or pediatrician (adolescents).

Janssen Vaccine Only: A very rare but serious side effect involving blood clots with low levels of platelets (blood cells that help your body stop bleeding) has occurred primarily among women aged 18-49 years following vaccination with the Janssen vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks following vaccination. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving the Janssen COVID-19 vaccine:

- Severe or persistent headaches or blurred vision
- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Easy bruising or tiny blood spots under the skin beyond the injection site

Moderna and Pfizer-BioNTech COVID-19 Vaccines Only: Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received these vaccines. In most of these people, symptoms frequently began within a few days following receipt of the second dose. The chance of having this occur is very rare and according to CDC, the benefits of the vaccine outweigh the risks. You should seek medical attention right away if you have any of the following symptoms after receiving the Moderna or Pfizer-BioNTech COVID-19 Vaccine:

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

There are vaccines that require two doses and one that requires one dose. If you receive a vaccine requiring two doses, it is important for you to return for the 2nd dose to maximize immunity from the vaccine to protect yourself, your family and friends, and your community.

☐ **You will be returning for a 2nd dose on**: _____. Please bring this sheet and your Vaccination Record card when you return for your next appointment.

☐ **You do not need to return for a second dose.**

COVID-19 Vaccine Monitoring Record

Current Vaccines and Required Doses				
Vaccine	**Pfizer BioNTech**	**Moderna**	**Janssen**	**Other**
Doses Required	2	2	1	
Days Apart	21 days (minimum)	28 days (minimum)		

Please see the tables on the previous page to review the descriptions of and differences between injection site symptoms and general symptoms.

	Dose 1		Dose 2* (Not required for Janssen)	
Day	Have you had any injection site symptoms? **Check if yes** (write which one)	Have you had any general symptoms? **Check if yes** (write which one)	Have you had any injection site symptoms? **Check if yes** (write which one)	Have you had any general symptoms? **Check if yes** (write which one)
1 (day of vaccination)	☐	☐	☐	☐
2	☐	☐	☐	☐
3	☐	☐	☐	☐
4	☐	☐	☐	☐
5	☐	☐	☐	☐
6	☐	☐	☐	☐
7	☐	☐	☐	☐
Week				
2 (up to 14 days after vaccination)	☐	☐	☐	☐
3 (up to 21 days)	☐	☐	☐	☐
4 (up to 28 days)	☐	☐	☐	☐
5 (up to 35 days)	☐	☐	☐	☐
6 (up to 42 days)	☐	☐	☐	☐

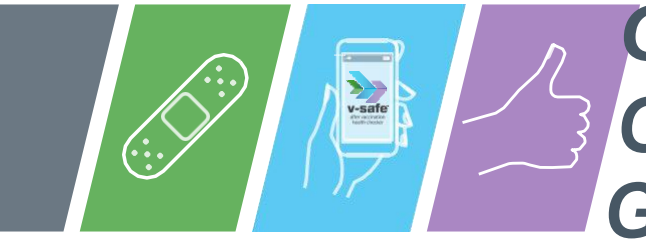
Other important events

Please contact your provider/clinic immediately if any of the following occur after you receive the vaccine:

- You are admitted to the hospital for any reason
- You receive a positive test for COVID-19
- If female, you become pregnant

Notes (any info needed to collect – temperature/date (if fever), medication taken, reported to doctor/clinic/ER, COVID-19 test)

July 2021



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.

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.*

v-safe℠

after vaccination

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. 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.

12/01/20

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:

Use your smartphone's browser to go to

vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

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