

# Prevaccination Checklist for COVID-19 Vaccines



For vaccine recipients:

Patient Name \_\_\_\_\_

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today.

Age \_\_\_\_\_

**If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked.

If a question is not clear, please ask your healthcare provider to explain it.

Yes No Don't know

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
<ul style="list-style-type: none"> <li>If yes, which vaccine product did you receive?                               <input type="checkbox"/> Pfizer    <input type="checkbox"/> Moderna    <input type="checkbox"/> Janssen (Johnson &amp; Johnson)    <input type="checkbox"/> Another product _____                         </li> </ul>			
3. Have you ever had an allergic reaction to:			
(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
<ul style="list-style-type: none"> <li>A component of a COVID-19 vaccine including either of the following:                             <ul style="list-style-type: none"> <li><input type="radio"/> Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures</li> <li><input type="radio"/> Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids.</li> </ul> </li> <li>A previous dose of COVID-19 vaccine.</li> <li>A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but it is not known which component elicited the immediate reaction.</li> </ul>			
4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication?			
(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, or any vaccine or injectable medication? This would include food, pet, venom, environmental, or oral medication allergies.			
6. Have you received any vaccine in the last 14 days?			
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
8. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
9. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
10. Do you have a bleeding disorder or are you taking a blood thinner?			
11. Are you pregnant or breastfeeding?			
12. Do you have dermal fillers?			

Form reviewed by \_\_\_\_\_

Date \_\_\_\_\_

**This page was intentionally left blank.**

# COVID-19 Mass Vaccination Form

## For documentation in RPMS EHR

Use of form is not necessary if documenting vaccine in RPMS EHR at point of service

Use of form is optional based on determined local workflow

### Section I: PATIENT or PATIENT REPRESENTATIVE to complete this section

<b>Date:</b>	<b>Last Name (Print):</b>	<b>First Name (Print):</b>	<b>Middle Name (Print):</b>
<b>Date of Birth:</b>	<b>Chart Number (if known):</b>	<b>Allergies/Adverse Drug Reactions:</b>	<input type="checkbox"/> NONE
<b>COVID dose:</b> <input type="checkbox"/> 1 <sup>st</sup> dose <input type="checkbox"/> 2 <sup>nd</sup> dose	<b>If 2<sup>nd</sup> dose:</b> Date of 1 <sup>st</sup> dose:	<b>If 2<sup>nd</sup> vaccine dose, manufacturer of 1<sup>st</sup> dose:</b> <input type="checkbox"/> Moderna <input type="checkbox"/> AstraZeneca <input type="checkbox"/> Novavax <input type="checkbox"/> Pfizer <input type="checkbox"/> Johnson&Johnson <input type="checkbox"/> Sanofi Pasteur <input type="checkbox"/> Other:	<b>If 2<sup>nd</sup> dose, note if there were any unexpected reactions to 1<sup>st</sup> dose:</b>

### Section II: To Be Completed By HEALTHCARE PROFESSIONAL Administering Vaccine

Patient meets requirement for COVID-19 immunization per CDC and ACIP recommendations/guidelines?

Yes  No

COVID-19 Vaccine Screening Questionnaire reviewed and vaccination administration deemed appropriate?

Yes  No

<b>COVID-19 Vaccine Manufacturer:</b> <input type="checkbox"/> Moderna <input type="checkbox"/> AstraZeneca <input type="checkbox"/> Novavax <input type="checkbox"/> Pfizer <input checked="" type="checkbox"/> Johnson&Johnson <input type="checkbox"/> Sanofi Pasteur <input type="checkbox"/> Other:	<b>Lot Number:</b>	<b>Injection volume:</b> <input type="checkbox"/> 0.3mL <input type="checkbox"/> 0.5mL
---	--------------------	---

<b>Immunization site:</b> <input type="checkbox"/> Right Deltoid <input type="checkbox"/> Right Thigh (peds) <input type="checkbox"/> Left Deltoid <input type="checkbox"/> Left Thigh (peds)	<b>Vaccine Information Statement (VIS) or Emergency Use Authorization (EUA) Fact Sheet Date:</b>	<b>Administration time:</b>
---	--	-----------------------------

Administration notes:

<input type="checkbox"/> Vaccine literature provided	Education duration (minutes): _____
<input type="checkbox"/> Information given on benefits, side effects, post immunization care	Education duration (minutes): _____
<input type="checkbox"/> Provided information on following the required schedule for vaccinations	Education duration (minutes): _____
<b>Level of Understanding:</b> <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor	<b>Readiness to Learn:</b> <input type="checkbox"/> Receptive
<b>Comments:</b>	<input type="checkbox"/> Other:

<b>Assessment after injection:</b> <input type="checkbox"/> Patient left before assessment completed <input type="checkbox"/> Patient assessed after 15 minutes <input type="checkbox"/> No reaction noted	<b>Return Date (if applicable):</b> <input type="checkbox"/> COVID vaccination documentation completed in EHR
---	--

\_\_\_\_\_  
Signature and Title of Vaccinator

\_\_\_\_\_  
Date

## **Instructions for Completing COVID-19 Mass Vaccination Form for documentation in RPMS EHR**

### **Purpose of form:**

1. Capture patient vaccine information during mass vaccination events, off-site vaccination events, or during other times when it is not feasible to capture vaccination at the point of service
2. Use of form is not necessary if vaccine administration is captured in RPMS EHR at the point of service

### **Form instructions:**

1. Print legibly in all fields using dark permanent ink
2. Section I, to be completed by PATIENT or PATIENT REPRESENTATIVE
3. Section II, to be completed by HEALTHCARE PROFESSIONAL who administers vaccine
4. Information from form is to be electronically recorded in RPMS EHR

## 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](http://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- $\beta$ -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.

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.

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.

## **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.

<b>e-mail</b>	<b>Fax number</b>	<b>Telephone numbers</b>
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](http://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
	<a href="http://www.janssencovid19vaccine.com">www.janssencovid19vaccine.com</a>	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>.

**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](http://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



© 2021 Janssen Pharmaceutical Companies

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

Revised: Feb/27/2021



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

Barcode Date: 02/2021



# 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.



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](https://vsafe.cdc.gov)

OR

Aim your smartphone's camera at this code

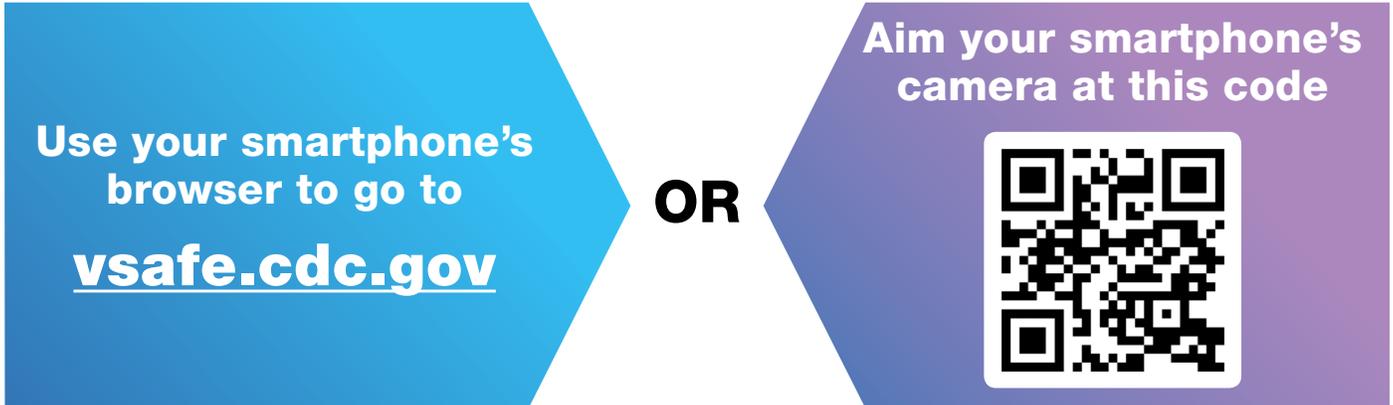


## How to register and use v-safe

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:



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](https://www.cdc.gov/vsafe)

