



COVID Vaccination Patient Screening

Name: (Last)	(First)	(Middle Initial)	
Home Address:	City:	Zip:	Sex: M F
Age:			
Email:	Home Phone:	Birth date:	

SCREENING QUESTIONS

	YES	NO
1. Have you ever received a dose of COVID-19 Vaccine? if yes which product? <input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Johnson & Johnson- Janssen <input type="checkbox"/> Other_____	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you ever had an allergic reaction to: <ul style="list-style-type: none"> <input type="checkbox"/> Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures <input type="checkbox"/> Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids. <input type="checkbox"/> A previous dose of COVID-19 vaccine <input type="checkbox"/> 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. 	<input type="checkbox"/>	<input type="checkbox"/>
3. Are you feeling sick today?	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you have a bleeding disorder or are you taking a blood thinner?	<input type="checkbox"/>	<input type="checkbox"/>
6. Do you have dermal fillers?	<input type="checkbox"/>	<input type="checkbox"/>

I have made the decision to receive the COVID-19 Vaccine voluntarily and freely. I know I have the option to refuse this vaccine. I have received the COVID-19 Vaccine manufacturer fact sheet and have reviewed it. I understand the FDA has authorized the emergency use of this vaccine and it is not a fully licensed FDA vaccine. I have had the chance to ask questions and my questions were answered to my satisfaction. I understand the nature, alternatives, benefits, and risks of vaccination. I know that with all vaccines there is no promise that I will become immune or that I will not have side effects. The vaccine I am about to receive maybe a two-dose series, if so I understand I must return at the scheduled time to receive the second dose. I authorize the organization providing my vaccine to release information. I authorize release of all records to act on this request.

Disclosure of Records: I understand the organization providing my vaccine may be required to or may voluntarily disclose my vaccine-related health information to my primary care physician, health systems and hospitals, and state or federal registries or other public health authorities, for purposes of treatment, or health care operations. I also understand the organization providing my vaccine will use and disclose my health information as described in its Notice of Privacy Practices which I may receive upon request.

Signature (Patient or Legal Representative): _____ **Date:** ___/___/___

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.

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.

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 involving blood vessels in the brain, 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. Most people who developed these blood clots and low levels of platelets were 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

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

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?

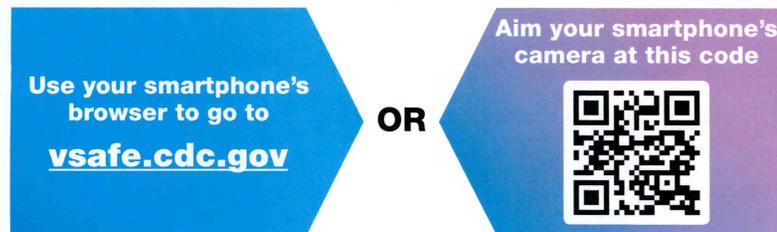
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

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

