

Janssen Scientific Affairs, LLC

1125 Trenton-Harbourton Road
PO Box 200
Titusville, NJ 08560
800.526.7736 tel
609.730.3138 fax



November 15, 2022

Brent Fuller
445 Hand Ct
Hampstead, MD 21074
USA

Dear Mr. Fuller,

Thank you for contacting the Medical Information Center. The enclosed information has been supplied in response to your unsolicited request.

Response(s):

- Janssen COVID-19 Vaccine - What are the risks of the Janssen COVID-19 Vaccine?
- Janssen COVID-19 Vaccine - Can you provide me with medical advice?

Information contained in this response is not intended as an endorsement of any usage of this product outside of the Fact Sheet. Janssen COVID-19 Vaccine is not approved by the Food and Drug Administration (FDA) and has been authorized by the FDA in the United States for emergency use only. For information on ongoing clinical trials for our products, please visit www.clinicaltrials.gov.

If you would like additional information or to report a possible adverse event or product quality complaint, please contact the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736).

Sincerely,





Marchelle A Robinson

Marchelle Robinson, RPh
Medical Information Specialist
Janssen Scientific Affairs, LLC

Inquiry #:03438973

Enclosure(s)/Electronic Link(s):

Need Help? If you have any additional questions, please contact us via:

 1-800-JANSSEN Monday - Friday, 9 am - 8 pm EST	 24x7 Access to Medical Information www.janssenmd.com
 Email Medical Information	 Locate Medical Science Liaison www.janssenmsl.com

To report a possible adverse event or product quality complaint, please call the Medical Information Center immediately, at 1-800-JANSSEN (1-800-526-7736).

Janssen COVID-19 Vaccine

What Are the Risks of the Janssen COVID-19 Vaccine?

SUMMARY

- The Janssen COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized by the FDA through an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and in individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine as: a single dose primary vaccination; a single booster dose after completing primary vaccination with the Janssen COVID-19 Vaccine; a single booster dose after completing primary vaccination with a different authorized or approved COVID-19 vaccine.
- Talk to the vaccination provider if you have questions. 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 Food and Drug Administration (FDA)/Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or call Janssen Biotech, Inc. at 1-800-565-4008 (United States [US] Toll Free). Please read the Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers available at www.JanssenCOVID19vaccine.com.^{1, 2}

Who should NOT get the Janssen COVID-19 Vaccine?

You should not get the Janssen COVID-19 Vaccine if you²:

- Had a severe allergic reaction after a previous dose of this vaccine
- Had a severe allergic reaction to any ingredient of this vaccine
 - The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl- β -cyclodextrin (HBCD), polysorbate-80, sodium chloride.
- Had a blood clot along with a low level of platelets (blood cells that help your body stop bleeding) following the Janssen COVID-19 Vaccine or following AstraZeneca's Coronavirus Disease 2019 (COVID-19) vaccine (not authorized or approved in the US)

What are the risks of the Janssen COVID-19 Vaccine?

Side effects that have been reported with the Janssen COVID-19 Vaccine include²:

- Injection site reactions: pain, redness of the skin and swelling
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever
- Swollen lymph nodes
- Blood clots
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- Persistent ringing in the ears (tinnitus)
- Diarrhea, vomiting

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 include²:

- 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 after vaccination. Blood clots with low levels of platelets following the Janssen COVID-19 Vaccine have been reported in males and females, across a wide age range of individuals 18 years and older; reporting has been highest in females ages 30 through 49 years (about 8 cases for every 1,000,000 vaccine doses administered), and about 1 out of every 7 cases has been fatal. You should seek medical attention right away if you have any of the following symptoms after receiving the Janssen COVID-19 Vaccine²:

- 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

Immune Thrombocytopenia (ITP)

Immune Thrombocytopenia (ITP) is a disorder that can cause easy or excessive bruising and bleeding due to very low levels of platelets. ITP 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. If you have ever had a diagnosis of ITP, talk to your vaccination provider before you get the Janssen COVID-19 Vaccine. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine²:

- Easy or excessive bruising or tiny blood spots under the skin beyond the site of the injection
- Unusual or excessive bleeding

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 Vaccine²:

- 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

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 (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.²

ADDITIONAL INFORMATION

How can I learn more?

- Ask your 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.²

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the Fact Sheet for Recipients and Caregivers. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full Fact Sheet for Recipients and Caregivers for the Janssen COVID-19 Vaccine.²

REFERENCES

1. United States Food and Drug Administration. Janssen COVID-19 Vaccine. FDA Emergency Use Authorization Letter. Available from: <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-EUA.pdf>.
2. Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers. Janssen Biotech, Inc. <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-Recipient-fact-sheet.pdf>.

Janssen COVID-19 Vaccine
Can you provide me with medical advice?

CAN YOU PROVIDE ME WITH MEDICAL ADVICE?

We are not able to provide you with medical advice. Only your healthcare provider can do that. Each person has a unique medical history that is best interpreted by his or her treating healthcare provider. Because the risks and benefits of any prescription medications or vaccine must be evaluated in relation to this history, your healthcare provider is the person most qualified to determine the appropriate treatment for you and to discuss your questions and concerns. Our policy strives to maintain the integrity of this healthcare provider-patient relationship.