COVID-19 Vaccine, Viral Vector (Janssen [Johnson and Johnson])

Other Name(s): Adenoviral vector COVID-19 vaccine , Adenovirus 26 vector COVID-19 vaccine, Ad26.COV2.S, COVID-19 Vaccine, Johnson and Johnson

IMPORTANT WARNING: The Janssen (Johnson and Johnson) coronavirus disease 2019 (COVID-19) vaccine is currently being studied to prevent coronavirus disease 2019 caused by the SARS-CoV-2 virus.

Information from clinical trials is available at this time to support the use of Janssen (Johnson and Johnson) COVID-19 vaccine to prevent COVID-19. In clinical trials, approximately 21,895 individuals 18 years of age and older have received the Janssen (Johnson and Johnson) COVID-19 vaccine. Millions of people have received the vaccine under EUA since February 27, 2021.

Janssen (Johnson and Johnson) COVID-19 vaccine has not undergone the standard review to be approved by the FDA for use. However, the FDA has also approved an EUA for the Janssen (Johnson and Johnson) COVID-19 vaccine to allow:

- **a single primary dose to people 18 years and older.**
- **a single booster dose at least 2 months after the first dose of the Janssen (Johnson and Johnson) COVID-19 vaccine for people 18 years and older.**
- **a single booster dose to people 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine.**

Talk to your doctor about the risks and benefits of receiving this medication.

What is COVID-19?

COVID-19 disease 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 (lung) 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, chills, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, runny nose, nausea, vomiting, or diarrhea.

How is the Janssen (Johnson and Johnson) COVID-19 vaccine given?

The Janssen (Johnson and Johnson) COVID-19 vaccine will be given to you as an injection into the muscle. The Janssen (Johnson and Johnson) COVID-19 vaccine vaccination is given as a one-time dose.

The FDA has also approved an EUA for the Janssen (Johnson and Johnson) COVID-19 vaccine to allow:

- a **single booster dose** at least two months after completion of the primary vaccination of Janssen (Johnson and Johnson) COVID-19 vaccine.
- a **single booster dose** to people 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster.

What should you tell the person who is giving the vaccine?

Tell your vaccine provider about all of your medical conditions, including if you:

- have any allergies.
- have a fever.
- have had a blood clot along with a low number of platelets (cells that help the blood to clot) after receiving the Janssen (Johnson & Johnson) or AstraZeneca (not currently approved in the US) COVID-19 vaccines.
- have a bleeding disorder or are on a blood thinner such as warfarin (Coumadin, Jantoven).
- are immunocompromised (weakened immune system) 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.
- have ever fainted in association with an injection.
- have had a serious allergic reaction to any ingredient in this vaccine.

What are the benefits of the Janssen (Johnson and Johnson) vaccine?

In an ongoing clinical trial, the Janssen (Johnson and Johnson) COVID-19 vaccine has been shown to prevent COVID-19 after a single dose. How long you are protected against COVID-19 is currently unknown.

What are the risks of the Janssen (Johnson and Johnson) vaccine?

Side effects that have been reported with the Janssen (Johnson and Johnson) COVID-19 vaccine include:

- injection site pain, swelling, and redness
- headache, feeling very tired, muscle aches, nausea, and fever
- swollen lymph nodes
- unusual feeling in the skin, such as tingling or a crawling feeling or decreased feeling or sensitivity
- ongoing ringing in the ears
- diarrhea, vomiting

There is a remote chance that the Janssen (Johnson and Johnson) 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 (Johnson and Johnson) COVID-19 vaccine.

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 to stop bleeding), have occurred in some people who have received the Janssen (Johnson and Johnson) COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks after 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 very rare. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen (Johnson and Johnson) COVID-19 Vaccine:

- shortness of breath
- chest pain
- leg swelling
- ongoing abdominal pain
- severe or ongoing headaches or blurred vision
- easy bruising or tiny blood spots under the skin beyond the site of the injection

GuillainBarré syndrome (a nervous system 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 (Johnson and Johnson) COVID-19 vaccine. In most of these people, symptoms began within 42 days (6 weeks) after receiving the Janssen (Johnson and Johnson) 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
- problems with facial movements, including speaking, chewing, or swallowing
- double vision or inability to move your eyes
- problems with bladder control or bowel function

These may not be all the possible side effects of the Janssen (Johnson and Johnson) COVID-19 vaccine. Serious and unexpected side effects may occur. Janssen (Johnson and Johnson) 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 1-800-565-4008 or JNJvaccineAE@its.jnj.com.
- 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: http://www.cdc.gov/vsafe.

Will the Janssen (Johnson and Johnson) vaccine give me COVID-19?

No. The Janssen (Johnson and Johnson) COVID-19 vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

Keep your vaccination card

When you get your dose, you will get a vaccination card. Remember to bring your card when you return for additional doses.

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 can I learn more?

- Ask the vaccination provider.
- Visit CDC at https://bit.ly/3vyvtNB.
- Visit FDA at https://bit.ly/3qI0njF.
- Contact your local or state public health department.

Can I be charged an administration fee for receiving 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 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 year from the date of receiving the vaccine. To learn more about this program, visit http://www.hrsa.gov/cicp/ or call 1-855-266-2427.

The American Society of Health-System Pharmacists, Inc. represents that this information about the Janssen (Johnson and Johnson) COVID-19 vaccine was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are cautioned that the Janssen (Johnson and Johnson) COVID-19 vaccine is not an approved vaccine for coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, but rather, is being investigated for and is currently available under an FDA emergency use authorization (EUA) to prevent COVID-19 in certain adults. The American Society of Health-System Pharmacists, Inc. makes no representations or warranties, express or implied, including, but not limited to, any implied warranty of merchantability and/or fitness for a particular purpose, with respect to the information, and specifically disclaims all such warranties. Readers of the information about the Janssen (Johnson and Johnson) COVID-19 vaccine are advised that ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of this information. Readers are advised that decisions regarding drug therapy are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and the information contained in this information is provided for informational purposes only. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. This information about the Janssen (Johnson and Johnson) COVID-19 vaccine is not to be considered individual patient advice. Because of the changing nature of drug information, you are advised to consult with your physician or pharmacist about specific clinical use of any and all medications.