

WHAT YOU NEED TO KNOW ABOUT THE JOHNSON & JOHNSON (J&J)/JANSSEN VACCINE

What does the Emergency Use Authorization Mean?

Because COVID-19 is a public health emergency with the potential to affect national security and the health and security of people living in the U.S., the FDA may issue an emergency use authorization (EUA). In the US, the vaccine may not be approved for licensure until a larger number of vaccine recipients have been followed over a longer period of time (2 years or more).

The FDA gives an EUA only if experts determine that the study results show:

1. The vaccine is safe and potential side effects are reasonable and to be expected.
2. The vaccine is effective at reducing or preventing severe disease like COVID-19.
3. These vaccines have been shown to have acceptable safety profile in other disease areas including Ebola (already approved and rolled out), HIV, Malaria and RSV (ongoing clinical trials with no safety concerns to date).

A History of Using Ad26-based Vaccines

- The J&J/Janssen vaccine is based on the Ad26 vector platform.
- As of December 31, 2020, Ad26-based vaccines have been used to vaccinate over 193,000 participants in clinical studies and vaccination programs for a variety of diseases.
- An Ad26-based Ebola vaccine is licensed and being used in African countries.
- Ad26-based vaccines for RSV and HIV are being researched and no safety concerns have been identified to date.

Who was in the J&J/Janssen Ensemble COVID-19 vaccine study?

- Approximately 40,000 participants aged 18 years and older
- Geographic Distribution
 - 47% United States
 - 40% Central/South America: Argentina, Brazil, Chile, Colombia, Mexico, Peru
 - 13% South Africa
- 45% females
- Race (rounded to the nearest whole number):
 - 59% White
 - 19% Black or African American
 - 10% Indigenous (1% American Indian/Alaskan Native in the US)
 - 3% Asian
 - less than 1% Native Hawaiian/Pacific Islander
 - 6% Multiracial
 - 1% Unknown
- 45% Latin origin (14% Hispanic/Latino/a in the US)
- 20% aged 65 years old or older
- Enrollment of participants aged 18-40 was limited to approximately 20%
- About 41% reported underlying health conditions (known as comorbidities). The top were:
 - Obesity (29%)
 - High Blood Pressure (Hypertension) (10%)
 - Diabetes (8%)
 - HIV (3%)

This vaccine requires 1 dose to prevent COVID-19 disease, hospitalization, and death.

How Effective is the Vaccine?

Vaccine Efficacy in the J&J/Janssen Ensemble study is reported as how well the vaccine protects against moderate and severe COVID-19 disease. This is what that means:

Moderate COVID-19 = having a positive SARS-CoV-2 test and symptoms of COVID-19 (fever, increased heart rate, chills, cough, sore throat, etc.).

Severe COVID-19 = having a positive SARS-CoV-2 test; needing a ventilator or oxygen; having severe high blood pressure; having significant acute kidney, liver or nervous system dysfunction; admission to the intensive care unit; or death.

Overall, the Jansen COVID-19 vaccine:

- Prevented 66% of moderate to severe COVID-19 disease
- Prevented 85% of severe COVID-19 disease
- Prevented 95% of hospitalizations due to COVID-19 disease
- Prevented 100% of deaths due to COVID-19 disease
- Has similar efficacy across age, racial and ethnic groups

Because of the Viral variants, additional analyses were conducted in the US, Brazil, and South Africa.

US:

- 96% efficacy in preventing moderate to severe COVID-19 against the Washington strain (known as A.1) virus.

Brazil:

- Approximately 65% of COVID-19 cases that occurred in Brazil were found to be caused by the viral variant from Brazil (known as P.1).
- Vaccine efficacy in Brazil was similar to what was seen in the US.

South Africa:

- Approximately 95% of the COVID-19 cases that occurred in South Africa were due to the South Africa variant virus (known as B.1.351).
- Efficacy of 82% in preventing severe COVID-19 disease in South Africa
- Efficacy of 64% in preventing moderate to severe COVID-19 disease in South Africa
- All 7 deaths in the study occurred in the placebo group and were in South Africa. All of these participants had one or more pre-existing conditions (Obesity, Hypertension, Diabetes, Heart Failure, Asthma) which placed them at higher risk for severe COVID-19.

Is the J&J/Janssen Vaccine Safe?

YES! Independent experts who reviewed the safety data have concluded that the vaccine is safe.

- Researchers are still studying the long-term safety of this vaccine in ongoing studies.
- Most side effects happened within 7 days of vaccination.

The most common side effects were reported to be mild or moderate and lasted 1 to 2 days after vaccination:

- Injection site pain
- Headache
- Fatigue/Feeling tired
- Muscle Pain

Allergic Reactions:

- Hives were reported more often in the vaccine group compared to the placebo group, so there is a possible relationship to the vaccine.
- There have been cases of severe allergic reactions, including anaphylaxis, after receiving the J&J/Janssen COVID-19 vaccine. If you have a history of allergic reactions, consult a healthcare provider before getting vaccinated.

What we don't know:

- We do not know how long the vaccine protection lasts.
- We do not know if the vaccine can prevent coronavirus infection.
- We do not know whether a vaccinated person can transmit coronavirus to others.
- We do not know whether the vaccine will have an impact on long-term effects of COVID-19 disease in people who are infected after vaccination.
- We do not know if this vaccine is safe for the groups of people that were not enrolled in the Ensemble Study.
 - Children younger than 16 years of age
 - Pregnant and lactating individuals
 - People with weaker immune systems