Janssen COVID-19 Vaccine Frequently Asked Questions

On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19 (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The EUA allows Janssen COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine) to be distributed in the U.S for use in individuals 18 years of age and older.

What data did the FDA review when deciding to authorize Janssen COVID-19 Vaccine for emergency use?

Janssen COVID-19 Vaccine is authorized to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. It is administered as a single-dose.

The FDA evaluated and analyzed the safety and effectiveness data from clinical trials conducted in over 40,000 thousand study participants and manufacturing information submitted by Janssen Biotech, Inc. The FDA has determined that the totality of the available data provides clear evidence that Janssen COVID-19 Vaccine may be effective in preventing COVID-19. The data also show that that the known and potential benefits outweigh the known and potential risks of the vaccine's use in millions of people 18 years of age and older, including healthy individuals.

How well does Janssen COVID-19 Vaccine prevent COVID-19?

The effectiveness data to support the EUA include an analysis of 39,321 participants in the ongoing randomized, placebo-controlled study being conducted in South Africa, certain countries in South America, Mexico, and the U.S. who did not have evidence of SARS-CoV-2 infection prior to receiving the vaccine. Among these participants, 19,630 received the vaccine and 19,691 received placebo. Overall, among these clinical trial participants, the vaccine was approximately 67% effective in preventing moderate to severe/critical COVID-19 disease occurring at least 14 days after vaccination and 66% effective in preventing moderate to severe/critical disease at least 28 days after vaccination.

Additionally, the vaccine was approximately 77% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination.

For the vaccine and placebo groups, respectively, there were 116 and 348 COVID-19 cases that occurred at least 14 days after vaccination, and 66 and 193 cases that occurred at least 28 days after vaccination. Starting 14 days after vaccination, there were 14 severe/critical cases in the vaccinated group versus 60 severe/critical cases in the placebo group, and starting 28 days after vaccination, there were 5 severe/critical cases in the vaccine group versus 34 severe/critical cases in the placebo group.

Is there information about the effectiveness of Janssen COVID-19 according to the geographic regions where the study was conducted?

Information is available for the United States, South Africa, and Brazil. A subgroup analysis was conducted for these countries. Following are the results of this analysis:

- **United States:** the vaccine was 74.4% effective and 72% effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days and 28 days after vaccination, respectively.
- **South Africa:** the vaccine was 52.0% effective and 64.0% effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days and 28 days after vaccination, respectively.
- **Brazil:** the vaccine was 66.2% effective and 68.1% effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days and 28 days after vaccination, respectively.

What information is available about the SARS-CoV-2 strains that caused the cases of COVID-19 in study participants during the clinical trial?

Efficacy of the Janssen COVID-19 vaccine demonstrated in the clinical trial reflected protection against several emerging SARS-CoV-2 variants of concern, including the Wuhan-H1 variant D614G (predominant in the United States), the B.1.351 variant (predominant in South Africa), and a P.2 variant (predominant in Brazil).

Is it possible to make comparisons about the effectiveness among the three COVID-19 vaccines that the FDA has authorized for emergency use to date?

No. The only way to accurately compare the effectiveness of medical products, such as vaccines or drugs, is by direct comparison in head-to-head clinical trials, which did not occur for these vaccines. Furthermore, the clinical trials for these vaccines occurred in different geographic regions and at different points in time with varying incidence of COVID-19. All of the COVID-19 vaccines that the FDA has authorized for emergency use are at least 50% more effective than placebo in preventing COVID-19, consistent with FDA recommendations provided in our October 2020 guidance document, *Emergency Use Authorization for Vaccines to Prevent COVID-19* (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19). A vaccine with at least 50% efficacy would have a significant impact on disease, both at the individual and societal level.

Did clinical trial participation include members of racial or ethnic groups at greater risk from COVID-19?

Yes. Overall, 45.3% of participants in the clinical trials identify as Hispanic/Latino, 19.4% Black or African American, 9.5% American Indian or Alaska Native, 3.3% Asian, 0.2% Native Hawaiian or other Pacific Islander, and 5.6% Multiracial.

The demographic characteristics were similar among participants who received Janssen COVID-19 Vaccine and those who received placebo.

What safety information did the FDA evaluate to authorize Janssen COVID-19 Vaccine for emergency use?

The available safety data to support the EUA include an analysis of 43,783 participants enrolled in an ongoing randomized, placebo-controlled study being conducted in South Africa, certain countries in South America, Mexico, and the U.S. These participants, 21,895 of whom received the vaccine and 21,888 of whom received saline placebo, were followed for a median duration of eight weeks after vaccination. The most commonly reported side effects were pain at the injection site, headache, fatigue, muscle aches and nausea. Most of these side effects were mild to moderate in severity and lasted 1-2 days.

Can pregnant or breastfeeding women receive the vaccine?

While there have been no specific studies in these groups, there is no contraindication to receipt of the vaccine for pregnant or breastfeeding women. Pregnant or breastfeeding women should discuss their options with their healthcare providers.

Can Janssen COVID-19 Vaccine be administered to individuals over 60 years of age who have health conditions (e.g., obesity, high blood pressure, diabetes)?

Yes. The FDA has determined that the totality of the available data provides clear evidence that Janssen COVID-19 Vaccine may be effective in preventing COVID-19. The data also show that that the known and potential benefits outweigh the known and potential risks of the vaccine. Among these participants in the vaccine group of the clinical trial, there were no COVID-19-related deaths and no COVID-19 cases requiring medical intervention occurring 28 days or more after vaccination.

What information is available about allergic reactions?

In the study that evaluated safety in 43,783 participants (21,895 of whom received the vaccine and 21,888 of whom received saline placebo), hives was reported in five vaccine recipients and 1 placebo recipient in the 7 days following vaccination. In this study, there has been one report of severe hypersensitivity reaction, not classified as anaphylaxis, beginning two days following vaccination with Janssen COVID-19 Vaccine. The event was serious and likely related to vaccination.

In another ongoing clinical study in South Africa, one case of anaphylaxis has been reported following administration of the vaccine.

The Fact Sheet for Healthcare Providers Administering Vaccine and the Prescribing Information (/media/146304/download) include the following information, and the same general information is also included in the COVID-19 Vaccine Fact Sheets for Healthcare Providers Administering Vaccine and the Prescribing Information for the other authorized COVID-19 vaccines:

CONTRAINDICATION
Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of the Janssen COVID-19 Vaccine or any component of the Janssen COVID-19 Vaccine (see Full EUA Prescribing Information).

WARNINGS
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

This information is also consistent with the Prescribing Information for all vaccines intended to prevent infectious diseases.

The Fact Sheet for Healthcare Providers Administering Vaccine and the Prescribing Information (/media/146304/download) direct the reader to the Centers for Disease Control and Prevention's guidelines for monitoring for allergic reactions following vaccination.

In addition to reported allergic reactions, is information available about other less common adverse events, including serious adverse events?

Serious adverse events and other adverse events of interest, while uncommon, represented medical events that occur in the general population at similar frequency as observed in the study.

A serious adverse event of severe pain in the injected arm that began immediately after vaccination and that was ongoing 74 days following vaccination was reported in one vaccine recipient. A serious adverse event of severe generalized weakness, fever, and headache, with onset on the day following vaccination and resolution three days following vaccination was reported in one vaccine recipient. These serious adverse events are likely related to the vaccine.

Numerical imbalances, with more events in vaccine than placebo recipients, were observed for the following serious and non-serious adverse events of interest in individuals receiving the vaccine or placebo, respectively:

- **Thromboembolic events:**
  - *Deep vein thrombosis:* 6 events (2 serious) in vaccine recipients versus 2 events (1 serious) in placebo recipients
  - *Pulmonary embolism:* 4 events (3 serious) in vaccine recipients versus 1 event (serious) in placebo recipients
  - *Transverse sinus thrombosis:* 1 event (serious) in vaccine recipients versus 0 in placebo recipients
- **Seizures:**
  4 events (1 serious) in vaccine recipients versus 1 event (0 serious) in placebo recipients
- **Tinnitus** (ringing in one or both ears):
  6 events (0 serious) in vaccine recipients versus 0 in placebo recipients

For these events, a causal relationship with the Janssen COVID-19 vaccine cannot be determined. The assessment of causality was confounded by the presence of underlying medical conditions that may have predisposed individuals to these events.

What side effects (adverse events) must be reported to the FDA by vaccination providers and Janssen Biotech, Inc?

It is mandatory for Janssen Biotech, Inc. and vaccination providers to report the following to the Vaccine Adverse Event Reporting System (VAERS) (https://vaers.hhs.gov/) for Janssen COVID-19 Vaccine:

- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome (MIS)
- Cases of COVID-19 that result in hospitalization or death

It is also mandatory for vaccination providers to report all vaccine administration errors, whether or not associated with an adverse event, to VAERS for which they become aware, and for Janssen Biotech, Inc. to include a summary and analysis of all identified vaccine administration errors in monthly safety reports submitted to the FDA.

How will additional safety monitoring be conducted?

Janssen Biotech, Inc. has submitted a pharmacovigilance plan to the FDA to monitor the safety of Janssen COVID-19 Vaccine. The pharmacovigilance plan includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials. The pharmacovigilance plan also includes other activities aimed at monitoring the safety of the vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

In addition, the FDA, CDC, and other federal partners are using robust systems and data sources to conduct ongoing safety monitoring for COVID-19 vaccines authorized under an EUA. There are multiple, complementary systems in place with validated analytic methods that can rapidly detect signals for possible vaccine safety problems. The U.S. government – in partnership with health systems, academic centers, and private sector partners –are using multiple existing vaccine safety monitoring systems to monitor COVID-19 vaccines in the post-authorization period. Some of these systems are VAERS, the Vaccine Safety Datalink (VSD), the Biologics Effectiveness and Safety (BEST) Initiative, and Medicare claims data.

Can people who have already had COVID-19 get the vaccine?

While relatively few confirmed COVID-19 cases occurred overall among participants with evidence of infection prior to vaccination, limited data suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and may benefit from vaccination. Furthermore, available data suggest that the safety profile of the vaccine in previously infected individuals is just as favorable as in previously uninfected individuals.

How will additional data on the effectiveness of the vaccine be obtained?

Additional data on vaccine effectiveness will be generated from further follow-up of participants in clinical studies already underway before the EUA was issued, plus studies conducted by the manufacturer or by the U.S. government evaluating effectiveness of the vaccine as used under the EUA.

Can the Janssen COVID-19 Vaccine be used to complete a vaccination series initiated with another COVID-19 Vaccine?

No, there are no data available to support this scenario.