



Kidney Community  
Emergency Response



## FDA MedWatch

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4/15/2021

### Janssen COVID-19 Vaccine Frequently Asked Questions

[https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/janssen-covid-19-vaccine-frequently-asked-questions?utm\\_medium=email&utm\\_source=govdelivery#60783a6c7db35](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/janssen-covid-19-vaccine-frequently-asked-questions?utm_medium=email&utm_source=govdelivery#60783a6c7db35)

On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The EUA allows 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?**

**Why are the FDA and CDC recommending a pause in the use of the Janssen COVID-19 Vaccine? (added 4/14/2021)**

**If I received the Janssen COVID-19 Vaccine am I at risk for these adverse events? (added 4/14/2021)**

**What should health care providers look for in evaluating Janssen COVID-19 Vaccine recipients for these rare events? (added 4/14/2021)**

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

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

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

**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?**

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

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

**Can pregnant or breastfeeding women receive the vaccine?**

**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)?**

**What information is available about allergic reactions?**

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

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

**How will additional safety monitoring be conducted?**

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

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

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