Janssen COVID-19 Vaccine Frequently Asked Questions


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?