



March 2, 2021

****Emergency Use Authorization****
Janssen COVID-19 Vaccine (Ad26.COV2.S)

Vaccine Platform & Mechanism of Action¹: Non-replicating human adenovirus type 26 (Ad26) viral vector; Viral vector vaccines consist of a recombinant virus (the viral vector), often attenuated to reduce pathogenicity, in which genes encoding viral antigens have been cloned using recombinant DNA techniques. Non-replicating vector vaccines initially enter cells and produce the vaccine antigen, but no new virus particles are formed.

Current Status²: On February 27, 2021, the U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) for emergency use of the Janssen COVID-19 vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older. It is not approved for any indication.

Availability³:

The Janssen COVID-19 vaccine is compatible with standard vaccine distribution channels and will be shipped using the same cold chain technologies used to transport medicines. On February 27, 2021, the manufacturer began shipping vaccine and expects to deliver enough single-shot vaccines by the end of March to enable the full vaccination of more than 20 million people in the U.S. The manufacturer plans to deliver 100 million single-shot vaccines to the U.S. during the first half of 2021. The U.S. government will manage allocation and distribution of the vaccine in the U.S. This will be prioritized according to the populations identified by the CDC's Advisory Committee on Immunization Practices guidelines.

Recommended Administration & Storage⁴:

The Janssen COVID-19 vaccine is a suspension for intramuscular injection administered as a **single dose** (0.5 mL), supplied in a multi-dose vial. Each vial contains 5 doses, does not contain a preservative, and requires no reconstitution. There are no data available on use of this vaccine to complete a vaccination series initiated with another COVID-19 vaccine.

Store unpunctured multi-dose vials of vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen. Unpunctured vials may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Record the date and time of first use on the vaccine vial label. Discard the vial if vaccine is not used within these timeframes.

Efficacy^{2,4}:

Study COV3001 (NCT04505722), aka "ENSEMBLE", is an ongoing randomized, double-blind, placebo-controlled Phase 3 study of >43,000 participants designed to assess the efficacy, safety, and immunogenicity of a single dose of Ad26.COV2.S for prevention of COVID-19 in adults aged 18 years and older. Randomization was stratified by age (18-59 years, 60 years and older). The study was conducted in 8 countries on 3 continents: Argentina, Brazil, Chile, Columbia, Mexico, Peru, the U.S, and South Africa. American Indian/Alaskan Natives (*from the U.S. only*) represented <<1% of study participants (n=175).

Co-primary endpoints for efficacy were first occurrence of moderate to severe/critical COVID-19 with onset of symptoms at least 14 days and at least 28 days after vaccination. The median length of follow up for efficacy in the study was 8 weeks post-vaccination. Vaccine efficacy for the endpoints was 66.9% at least 14 days after vaccination (95% CI: 59.0; 73.4) and 66.1% at least 28 days after vaccination (95% CI: 55.0; 74.8). Similar vaccine efficacy was demonstrated by age, comorbidities status, sex, race, and ethnicity.

Of note, regional subgroup analyses reported that vaccine efficacy endpoints in U.S. participants at 14 days and 28 days after vaccination were 74.4% (95% CI: 65.9, 81.6) and 72.0% (95% CI: 58.2, 81.7), respectively.

Safety & Adverse Vaccine Events (AVEs)⁴: FDA's review of available safety data from participants 18 years of age and older, who were followed for 8 weeks after receiving the vaccine or placebo, did not identify specific safety concerns that would preclude issuance of an EUA. The most common adverse reactions reported in the ENSEMBLE trial following vaccine administration include injection site pain (48%), headache (39%), fatigue (38%), myalgia (33%), and nausea (14%). In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following the administration of the vaccine. Serious adverse events, excluding those related to confirmed COVID-19, were reported by 0.4% (n=83) of individuals who received Janssen COVID-19 vaccine and 0.4% (n=96) of individuals who received placebo.

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

- Deep vein thrombosis: 6 events (2 serious; 5 within 28 days of vaccination) vs. 2 events placebo
- Pulmonary embolism: 4 events (3 serious; 2 within 28 days of vaccination) vs. 1 event placebo
- Transverse sinus thrombosis: 1 event (serious and within 28 days of vaccination) vs. 0 placebo
- Seizures: 4 events (1 serious; 4 within 28 days of vaccination) vs. 1 event placebo
- Tinnitus: 6 events (0 serious; 6 within 28 days of vaccination) vs. 0 placebo

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.

CDC Advisory Committee on Immunization Practices (ACIP)⁵: On February 28, 2021, the ACIP voted to recommend the Janssen COVID-19 vaccine for use in the U.S. The ACIP states that offering the Janssen COVID-19 vaccine is an effective implementation strategy that (1) allows for jurisdictional flexibility, (2) supports rapid vaccination and increases in population immunity, (3) does not single out any group and (4) allows individuals to be vaccinated with the earliest vaccine available.

Additionally, the ACIP states no preference for any of the 3 authorized vaccines and reports that the Janssen Phase III trial results are not comparable with mRNA vaccines based on various issues (differing variants, calendar time, geography, etc.). The ACIP also reports strong protection from the Janssen COVID-19 vaccine against severe COVID-19 infection evidenced by its 93% vaccine efficacy against hospitalizations (2 cases in vaccinated vs. 29 in placebo) and no COVID-associated deaths in vaccinated participants vs. 7 in placebo.

Mandatory Requirements for Vaccine Administration^{2,4}:

1. Administer only to individuals 18 years of age and older
2. Communicate to the individual receiving the vaccine (or caregiver), information consistent with the "[Fact Sheet for Recipients and Caregivers](#)" prior to receiving the Janssen COVID-19 Vaccine
3. Report the following to the CDC's Vaccine Adverse Event Reporting System (VAERS), and please include the letters "IHS" in item/field #26.
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events* (irrespective of attribution to vaccination),
 - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
 - cases of COVID-19 that result in hospitalization or death
4. Respond to FDA requests for information about vaccine administration errors, adverse events, cases of MIS, and cases of COVID-19 that result in hospitalization or death following vaccine administration

*More information is available on the FDA website: [Janssen COVID-19 Vaccine Frequently Asked Questions](#)

References:

1. Van Riel D, de Wit E. [Next-generation vaccine platforms for COVID-19](#). *Nature Materials*. 2020; 19:810-812.
2. U.S. Food and Drug Administration. [Letter of Authorization](#). Janssen COVID-19 Vaccine. February 27, 2021.
3. Johnson & Johnson, Inc. [Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic](#). Accessed March 1, 2021.
4. U.S. Food and Drug Administration. Fact Sheet for Health Care Providers. [Emergency Use Authorization of Janssen COVID-19 vaccine](#).
5. CDC Advisory Committee on Immunization Practices. ACIP COVID-19 Vaccines Work Group. [Implementation considerations for COVID-19 vaccines](#). ACIP Emergency Meeting, March 1, 2021.