COVID-19 Vaccine, Viral Vector (Janssen) (Systemic)

Recombinant, replication-incompetent, viral vector (i.e., adenovirus serotype 26 [Ad26] vector) vaccine used to stimulate active immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Class: 80:12 • Vaccines (AHFS primary)

Brands*:

**also available generically*

Special Alerts:

National Alert Network (NAN) Alert Regarding Influenza and COVID-19 Vaccine Mix-ups: On October 15, 2021, the National Alert Network (NAN) issued an alert to make vaccine providers aware of reports of accidental mix-ups between the influenza (flu) and COVID-19 vaccines. The alert is based on 16 cases reported to the Institute for Safe Medication Practices (ISMP) error reporting programs. Most of the reports ISMP has received involve administration of one of the COVID-19 vaccines instead of an influenza vaccine; in 3 cases, patients received an influenza vaccine instead of a COVID-19 vaccine. Because most of the errors were reported by consumers, details about the contributing factors were not provided in many cases. However, possible contributing factors include increased demand for vaccination services, the ability to administer the flu and COVID-19 vaccines during the same visit, syringes located next to each other, unlabeled syringes, distractions, and staffing shortages. The alert provides recommendations for preventing such vaccine mix-ups. For additional information, consult the NAN alert at https://www.ismp.org/sites/default/files/attachments/2021-10/NAN-20211015.pdf.

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Uses

Prevention of Coronavirus Disease 2019 (COVID-19)

- Being investigated and used for prevention of COVID-19† caused by SARS-CoV-2.
- Although efficacy and safety not definitely established, the COVID-19 vaccine (Janssen), also known as the Johnson & Johnson COVID-19 vaccine is available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals ≥18 years of age.
- The EUA authorizes use as a single-dose primary vaccination regimen† in individuals ≥18 years of age, as a single homologous booster dose† in individuals who have completed primary vaccination with this vaccine in individuals ≥18 years of age, or as a single heterologous booster dose† in individuals ≥18 years of age who have completed primary vaccination with another authorized or approved COVID-19 vaccine.
- On February 27, 2021, FDA issued an EUA that permits use of the Janssen COVID-19 vaccine in individuals ≥18 years of age. The EUA was amended and reissued multiple times since then as the scope of authorization changed. For the most current version, consult the Janssen COVID-19 vaccine EUA letter of authorization at https://www.fda.gov/media/146303/download.
- The EUA includes certain mandatory requirements such as providing the recipient or caregiver with information consistent with the EUA fact sheet.
- Consult the Janssen COVID-19 vaccine EUA fact sheet for healthcare providers (https://www.fda.gov/media/146304/download), and EUA fact sheet for recipients and caregivers (https://www.fda.gov/media/146305/download) for additional information.
- Consult the CDC's Advisory Committee on Immunization Practices (ACIP) interim recommendations and clinical considerations for use of COVID-19 vaccines, including dosage and administration, specific populations and situations, and cautionary information.
- There currently are 3 different COVID-19 vaccines available for use in the US, including 2 mRNA vaccines (Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine) and a viral-vectored vaccine (Janssen COVID-19 vaccine). COVID-19 vaccination is currently recommended for individuals ≥5 years of age in the US for prevention of COVID-19; however, the age groups approved or authorized to receive vaccination vary by vaccine product. In most situations, ACIP states that the mRNA vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination because of the risks associated with the Janssen vaccine; however, the Janssen COVID-19 vaccine may be offered in certain situations.

Dosage and Administration

General

Pretreatment Screening

- Screen all individuals for contraindications and precautions to vaccination.

Patient Monitoring

- *Monitor all individuals who receive a COVID-19 vaccine for immediate adverse reactions according to CDC (ACIP) guidelines.* ACIP states that the following individuals should be observed for 30 minutes after receiving the vaccine: those with a history of immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapy; those with a contraindication to a different type of COVID-19 vaccine; those with a history of a non-severe, immediate allergic reaction to a previous dose of COVID-19 vaccine; and those with a history of anaphylaxis due to any cause. All other individuals should be observed for 15 minutes. A longer period of observation may be indicated for some individuals based on clinical concern (e.g., vaccine recipient develops pruritus and swelling at the injection site during the observation period).
- Instruct vaccine recipients to seek immediate medical care if they develop signs or symptoms of an allergic reaction after the observation period is complete. (See Hypersensitivity Reactions under Cautions.)

Premedication and Prophylaxis

- Antipyretics or analgesics (e.g., acetaminophen, nonsteroidal anti-inflammatory agents) may be taken for the treatment of postvaccination local or systemic symptoms, if medically appropriate. However, routine premedication for the purpose of preventing postvaccination symptoms in individuals receiving a COVID-19 vaccine is *not* currently recommended because information regarding possible impact on antibody response to the vaccine is not available at this time.
- Premedication with antihistamines prior to vaccination to prevent allergic reactions is *not* recommended; antihistamines do not prevent anaphylaxis and may mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)

Dispensing and Administration Precautions

- Appropriate medications and supplies for managing immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of COVID-19 vaccines. Healthcare personnel who are trained and qualified to recognize signs and symptoms of anaphylaxis and administer IM epinephrine should be available at vaccination sites at all times. Vaccination locations that anticipate vaccinating large numbers of people (e.g., mass vaccination clinics) should plan adequate staffing and supplies (including epinephrine) for assessment and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)
- Syncope (vasovagal or vasodepressor reaction; fainting) may occur following administration of parenteral vaccines; such reactions usually occur within 15 minutes following vaccine administration and are reported most frequently in adolescents and young adults. Take appropriate measures to decrease the risk of injury if the vaccine recipient becomes weak or dizzy or loses consciousness (e.g., instruct the vaccine recipient to sit or lie down during and for 15 minutes after vaccination). If syncope occurs, observe the individual until symptoms resolve.

Other General Considerations

- At the time of vaccine administration, provide the vaccine recipient or their caregiver with a vaccination record card that documents the name of vaccine and date when the vaccine was given.
- Provide vaccine recipients or their caregiver with information on CDC's v-safe program, a voluntary smartphone-based tool that uses text messaging and web surveys to monitor for adverse effects in individuals who have received a COVID-19 vaccine. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

- Prior to vaccination, counsel vaccine recipient or their caregiver about local and systemic adverse effects that may occur following vaccination.
- Individuals who receive COVID-19 vaccines should follow current CDC guidance to protect themselves and others. This may include wearing a mask in certain settings with substantial or high levels of viral transmission; following application federal, state, local, tribal, or territorial laws, rules, and regulations; and following CDC travel guidance and any applicable local business or workplace guidance. (See Limitations of Vaccine Effectiveness under Cautions.)

Administration

IM Administration

Administer *only* by IM injection into the deltoid.

The Janssen COVID-19 vaccine is supplied as a suspension in multiple-dose vials.

Although the vaccine is *initially* stored frozen by the manufacturer, it is shipped and stored refrigerated at a temperature of 2–8°C. Do *not* refreeze the vaccine. (See Storage under Stability.)

Do not dilute the Janssen COVID-19 vaccine.

Swirl vials of vaccine gently in an upright position for 10 seconds before withdrawing a dose; do *not* shake.

The Janssen COVID-19 vaccine should appear as a colorless to slightly yellow, clear to very opalescent suspension; do *not* use if it is discolored or contains particulates.

To administer a dose, withdraw 0.5 mL of Janssen COVID-19 vaccine from the vial using aseptic technique and an appropriate syringe and needle and administer immediately.

Each multiple-dose vial of Janssen COVID-19 vaccine provides five 0.5-mL doses. Because the vaccine does not contain preservatives, it is critical that any vaccine remaining in the vial that does not constitute a full 0.5-mL dose should be discarded and *not* pooled with vaccine from other vials to obtain a dose.

Dosage

For primary vaccination or booster doses, the Janssen COVID-19 vaccine is administered as a single 0.5-mL dose. Each 0.5-mL dose contains 5×10^{10} virus particles of recombinant, replication-incompetent Ad26.

A single dose of the Janssen COVID-19 vaccine is considered a complete primary vaccination series.

Individuals are considered fully vaccinated against COVID-19 if ≥2 weeks have elapsed since they received a single dose of the Janssen COVID-19 vaccine.

ACIP states that, in limited, *exceptional* situations when an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the vaccination series with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), may consider giving a single dose of the Janssen COVID-19 vaccine at least 28 days after the dose of mRNA COVID-19 vaccine. In such exceptional circumstances, the individual should be considered to have received valid, single-dose vaccination with the Janssen COVID-19 vaccine (not a mixed vaccination series).

Adults

Primary Vaccination

IM: For the prevention of COVID-19†, a single 0.5-mL dose of the Janssen COVID-19 vaccine is administered as primary vaccination.

Booster Doses

IM: FDA EUA permits a single homologous booster dose† of 0.5 mL at least 2 months (8 weeks) after completion of the primary vaccine series in individuals ≥18 years of age.

FDA EUA permits administration of a single heterologous booster dose† of 0.5 mL of the Janssen COVID-19 vaccine following completion of primary vaccination with another authorized or approved COVID-19 vaccine in individuals ≥18 years of age. When a heterologous vaccine product is used for the booster dose, the dosing interval is the same as that authorized for a booster dose of the vaccine product used for primary vaccination.

Cautions

Contraindications

- Known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including polysorbate. (See Actions.)
- History of thrombosis with thrombocytopenia syndrome (TTS) following receipt of the Janssen COVID-19 vaccine or another adenovirus-vectored COVID-19 vaccine (e.g., AstraZeneca COVID-19 vaccine, which is not authorized for use in the US).

Warnings/Precautions

Sensitivity Reactions

Hypersensitivity Reactions

At the time of FDA's safety analysis of data for the EUA, urticaria (nonserious) was reported within 7 days following administration in 5 individuals who received COVID-19 vaccine (Janssen) and 1 individual who received placebo.

A serious adverse hypersensitivity event considered likely related to the vaccine was reported; consisted of urticaria beginning 2 days following vaccination and angioedema of the lips beginning 4 days following vaccination without respiratory distress.

Severe allergic reactions, including anaphylaxis, have been reported in clinical studies following administration of the Janssen COVID-19 vaccine.

If a hypersensitivity reaction occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Because anaphylactic reactions have been reported rarely following administration of COVID-19 vaccines, ACIP issued interim guidance with contraindications and precautions for use of COVID-19 vaccines pending further investigation.

History of polysorbate allergy: ACIP considers this a **contraindication** to vaccination with Janssen COVID-19 vaccine. Consider use of an mRNA COVID-19 vaccine (Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) in such individuals. However, polysorbates are structurally related to polyethylene glycol (PEG), an ingredient in mRNA COVID-19 vaccines, and there is potential for cross-reactive hypersensitivity with PEG. Therefore, consider consultation with an allergist-immunologist to help determine if an individual with polysorbate allergy can safely receive an mRNA COVID-19 vaccine.

Known contraindication to vaccination with mRNA COVID-19 vaccines (including known PEG allergy): ACIP considers this a **precaution** to vaccination with Janssen COVID-19 vaccine; may consider use of the Janssen COVID-19 vaccine in such individuals. However, because of potential cross-reactive hypersensitivity between mRNA COVID-19 vaccines and Janssen COVID-19 vaccine (including PEG and polysorbate 80, respectively), consider consultation with an allergist-immunologist to help determine if the individual can safely receive the Janssen COVID-19 vaccine. If a decision is made to administer the Janssen COVID-19 vaccine to individuals with a contraindication to mRNA COVID-19 vaccines, administer the vaccine *only* in an appropriate setting under supervision of a healthcare provider experienced in management of severe allergic reactions.

History of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., IM, IV, or sub-Q vaccines or therapies): ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination. ACIP states that history of allergic reaction to sub-Q immunotherapy for allergies (i.e., allergy shots) is **not** a precaution or contraindication to vaccination.

History of immediate allergic reaction to a vaccine or injectable therapy that contains multiple components (one of which is a vaccine component), but it is not known which component elicited the reaction: ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination.

History of allergic reactions (including severe allergic reactions) not related to COVID-19 vaccines or other vaccines or injectable therapies: ACIP states that allergic reactions to food, pets, insects, venom, or environmental allergies and allergic reactions to oral medications (including the oral equivalents of injectable medications) are **not** a contraindication or precaution to COVID-19 vaccination. Latex allergy is **not** a contraindication or precaution since vial stoppers of COVID-19 vaccines are not made with natural rubber latex. Allergies to eggs or gelatin are **not** a contraindication or precaution since COVID-19 vaccines do not contain eggs or gelatin.

If a precaution for COVID-19 vaccination is identified, ACIP recommends performing a risk assessment to help decide whether the individual should be vaccinated.

ACIP states to observe the following individuals for 30 minutes after vaccination: those with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy, those with a contraindication to a different type of COVID-19 vaccine, those with a history of a non-severe, immediate allergic reaction to a previous dose of COVID-19 vaccine, and those with a history of anaphylaxis due to any cause not considered a contraindication; observe all other individuals for 15 minutes. Instruct vaccine recipients to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination site.

Appropriate medications and supplies to assess and manage immediate allergic reactions (e.g. epinephrine) *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. Early recognition of clinical signs and symptoms of anaphylaxis is important since such reactions require immediate treatment. Immediately treat individuals with suspected anaphylaxis with IM epinephrine.

ACIP interim guidance regarding preparation for and management of anaphylaxis at COVID-19 vaccination sites are available at the CDC website at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html and https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

When confronted with a complex COVID-19 vaccine safety question concerning an individual patient that is not readily addressed by ACIP guidance, US healthcare personnel or health departments can request a clinical consultation from the Clinical Immunization Safety

Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html).

Thrombotic Events

At the time of FDA's safety analysis for the EUA, there had been 6 reports of deep-vein thrombosis in individuals who received the Janssen COVID-19 vaccine and 2 such events in placebo recipients. In addition, there were 4 reports of pulmonary embolism in vaccine recipients versus 1 report in placebo recipients, and 1 report of transverse sinus thrombosis in vaccine recipients versus none in placebo recipients. A causal relationship between these thromboembolic events and the vaccine was not established based on the phase 3 trial data. However, post-authorization experience supports a causal relationship between the vaccine and transverse sinus thrombosis with thrombocytopenia.

Thrombosis with Thrombocytopenia

Thrombosis in an unusual location (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery or vein) occurring with new-onset thrombocytopenia (also known as thrombosis with thrombocytopenia syndrome [TTS]) and with onset of symptoms approximately 1–2 weeks after vaccination reported rarely in recipients of the Janssen COVID-19 vaccine during post-authorization surveillance.

In response to reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia in a few recipients of the Janssen COVID-19 vaccine, FDA and CDC temporarily paused use of the vaccine in the US out of an abundance of caution. The temporary pause was lifted 10 days later after completion of a thorough safety review.

After extensive data evaluation and analyses of risks and benefits of vaccination with the Janssen COVID-19 vaccine, FDA and CDC determined that known and potential benefits of the vaccine outweigh its known and potential risks in adults ≥18 years of age. At the time of CDC's safety data analysis (April 21, 2021), a total of 15 cases of TTS had been reported and confirmed, including 3 fatalities. These post-authorization cases all occurred in females 18–59 years of age, symptom onset was 6–15 days after vaccination (median 8 days), and clinical course shared features with autoimmune heparin-induced thrombocytopenia. At the time of CDC's safety analysis, highest rates of TTS per vaccine doses administered were in women <50 years of age.

On December 14, 2021, FDA authorized revisions to the Janssen COVID-19 vaccine fact sheet for healthcare providers. A contraindication was added for individuals with a history of TTS following receipt of Janssen COVID-19 vaccine or another adenovirus-vectored COVID-19 vaccine. Cases of TTS have been reported across a wide age range of adults ≥18 years of age; females between 30–49 years have the highest reporting rate (approximately 1 case/100,000 doses administered). Overall, approximately 15% of TTS cases have been fatal.

FDA and CDC are continuing to closely monitor reports of TTS in recipients of the Janssen COVID-19 vaccine. Current evidence supports a causal relationship between TTS and the Janssen COVID-19 vaccine. Specific risk factors are still under investigation. Do not administer the Janssen COVID-19 vaccine to any individual who developed TTS following receipt of the Janssen COVID-19 vaccine or any other adenovirus-vectored COVID-19 vaccine.

ACIP states that women 18–50 years of age should be informed about the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (Moderna COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine).

ACIP advises that individuals who have a history of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia such as HIT should receive a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine.

Healthcare providers should be alert to and maintain a high index of suspicion for signs and symptoms of TTS (e.g., severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae, new or easy bruising) occurring approximately 1–2 weeks after vaccination in individuals who have received the Janssen COVID-19 vaccine.

When managing thrombotic events and thrombocytopenia in patients who recently received the Janssen COVID-19 vaccine, avoid use of heparin and its derivatives (may be harmful); consider use of other anticoagulants and high-dose immune globulin IV (IGIV). Consultation with hematology specialists strongly recommended.

Information regarding diagnosis and management of suspected cases of TTS is provided in the CDC Health Alert Network (HAN) notification at https://emergency.cdc.gov/han/2021/han00442.asp and is available from the American Society of Hematology (ASH) at https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia.

Instruct vaccine recipients to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurologic symptoms (including severe or persistent headaches or blurred vision), easy bruising, or a diffuse rash consisting of petechiae (pinpoint-like spots) beyond the vaccination site within a few weeks after receiving the Janssen COVID-19 vaccine. These symptoms are distinct from commonly reported adverse effects that may be experienced in the first few days following vaccination (e.g., headache, fatigue, muscle aches, nausea) that usually are mild to moderate in severity and last 1–2 days.

If TTS occurs following vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Immune Thrombocytopenia

Increased risk of immune thrombocytopenia (ITP) reported during the 42 days following vaccination.

Individuals with a history of ITP should discuss this risk with their healthcare provider and the potential need for platelet monitoring following vaccination with the Janssen COVID-19 Vaccine.

Guillain-Barré Syndrome

An increased risk of Guillain-Barré syndrome (GBS) following use of the Janssen COVID-19 vaccine has been suggested; the increased risk period is during the 42 days following vaccination. Males 50–64 years of age appear to be at highest risk.

Instruct vaccine recipients to seek immediate medical attention if they develop worsening weakness or tingling sensations or difficulty with walking, facial movements (e.g., speaking, chewing or swallowing), vision (e.g.,, double vision or inability to move eyes) or bladder control/bowel function.

If GBS occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Other Adverse Events

Other adverse effects with a numerical imbalance between vaccine recipients and placebo recipients included 4 reports of seizures in vaccine recipients (1 serious; 4 within 28 days of vaccination) versus 1 seizure event in placebo recipients and 6 reports of tinnitus in vaccine recipients (not serious; all 6 within 28 days, including 3 events within 2 days) versus none in placebo recipients. A causal relationship between these events and the vaccine could not be established.

Concomitant Illness

Base decision to administer or delay vaccination in an individual with a current or recent febrile illness on the severity of symptoms and etiology of the illness.

ACIP states that a moderate or severe acute illness is a precaution for administration of vaccines and recommends that a risk assessment be performed with potential deferral of vaccination. Deferring vaccination until an individual has recovered avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.

Individuals with Current SARS-CoV-2 Infection

ACIP recommends deferring COVID-19 vaccination in individuals with known *current* SARS-CoV-2 infection until they have recovered from the acute illness (if symptomatic) and until criteria for discontinuance of isolation have been met.

Individuals with Prior SARS-CoV-2 Infection

Available data suggest that COVID-19 vaccines can be given safely to individuals with evidence of prior SARS-CoV-2 infection.

Individuals with a History of Multisystem Inflammatory Syndrome

Data not available to date regarding safety and efficacy of COVID-19 vaccines in adults or children with a history of multisystem inflammatory syndrome (MIS-A or MIS-C, respectively). ACIP recommends weighing theoretical concerns of dysregulated immune response to SARS-CoV-2 against the known risks of COVID-19 following reinfection and the benefits of protection following COVID-19 vaccination.

ACIP states that individuals with a history of MIS-A or MIS-C may choose to be vaccinated.

If MIS-A or MIS-C associated with a confirmed SARS-CoV-2 infection develops after receipt of a COVID-19 vaccine, consider referral to a specialist in infectious diseases, rheumatology, or cardiology. Healthcare providers can also request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html).

If MIS-A or MIS-C occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Individuals with Underlying Medical Conditions

ACIP states that individuals with altered immunocompetence or certain underlying medical conditions may receive COVID-19 vaccine if they have no contraindications to vaccination. ACIP does not state a preference for any specific COVID-19 vaccine in such individuals. Current FDA-approved or FDA-authorized COVID-19 vaccines are not live vaccines, so they may be safely administered to immunocompromised individuals.

US healthcare personnel and health departments can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) if they have concerns about vaccinating individuals with certain underlying medical conditions.

Individuals with Altered Immunocompetence

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy (see Specific Drugs under Interactions), may have diminished immune responses to vaccines, including the Janssen COVID-19 vaccine.

Counsel such individuals about the unknown safety profile and effectiveness of COVID-19 vaccines in immunocompromised populations and the potential for reduced immune responses and need to continue following all current guidelines to protect themselves from COVID-19.

An additional primary dose of an mRNA COVID-19 vaccine is recommended in moderately or severely immunocompromised individuals. Janssen COVID-19 vaccine is not authorized for use as an additional primary dose; immunocompromised individuals who received the single primary vaccination of the Janssen COVID-19 vaccine should not receive an additional primary dose but should receive a booster. A single booster dose with any FDA authorized or approved mRNA COVID-19 vaccine is recommended in moderately or severely immunocompromised individuals ≥18 years of age who received the single dose primary vaccination with the Janssen COVID-19 vaccine.

Individuals with Autoimmune Conditions

ACIP states that individuals with autoimmune conditions may receive any authorized COVID-19 vaccine, unless they have a contraindication to vaccination.

Individuals with a History of Thrombosis or Risk Factors for Thrombosis

ACIP advises that individuals who have a history of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia such as HIT should receive a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine. The Janssen COVID-19 vaccine is contraindicated in any individual who developed TTS following the Janssen COVID-19 vaccine or any other adenovirus-vectored COVID-19 vaccine. (See Thrombosis with Thrombocytopenia under Cautions.)

Experts believe that individuals with risk factors for venous thromboembolism (VTE) or history of other types of thrombosis (including CVST) not associated with thrombocytopenia are unlikely to be at increased risk for TTS.

ACIP states that administration of anticoagulants or aspirin prior to vaccination with the Janssen COVID-19 vaccine is not recommended. (See Specific Drugs under Interactions.)

Individuals with Liver Disease

American Association for the Study of Liver Diseases (AASLD) released a consensus statement regarding use of COVID-19 vaccines in individuals with chronic liver disease or a liver transplant. These experts state vaccination against COVID-19 is strongly recommended because of increased risk of morbidity and mortality in adults with chronic liver disease, especially those with cirrhosis.

Consult AASLD consensus statement for additional guidance on use of COVID-19 vaccines in individuals with chronic liver disease.

Individuals with a History of Guillain-Barré Syndrome

ACIP states that individuals with a history of Guillain-Barré syndrome (GBS) may receive COVID-19 vaccination, unless they have a contraindication to the vaccine. A history of GBS is not usually considered a contraindication or precaution to vaccination.

Individuals with a History of Bell's Palsy

Although a causal relationship not established, several cases of Bell's palsy have been reported in COVID-19 vaccine clinical trials.

ACIP states that, in the absence of a causal relationship between COVID-19 vaccines and Bell's palsy, individuals with a history of Bell's palsy may receive COVID-19 vaccination, unless they have a contraindication to the vaccine.

If Bell's palsy occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Individuals with Increased Bleeding Risk

Advise individuals who have bleeding disorders or are receiving anticoagulant therapy about the risk of hematoma from IM injections.

ACIP states that IM vaccines may be given to individuals who have bleeding disorders if a clinician familiar with the patient's bleeding risk determines that the preparation can be administered IM with reasonable safety. In these cases, use a fine needle (23 gauge or smaller) to administer the vaccine and apply firm pressure to the injection site (without rubbing) for ≥2 minutes. In individuals receiving therapy for hemophilia, schedule IM vaccines for administration shortly after a dose of such therapy.

Individuals receiving anticoagulation therapy presumably have the same bleeding risk as those with clotting factor disorders and should follow the same guidelines for IM administration. If possible, schedule IM vaccines prior to use of an anticoagulant so that the patient's risk of bleeding is not increased by the drug's therapeutic action.

Individuals Vaccinated Outside the US

Some individuals in the US may have previously received vaccination against COVID-19 in another country using a vaccine not authorized by FDA and/or not listed for emergency use by WHO. ACIP provides guidance on COVID-19 vaccination in such patients.

Limitations of Vaccine Effectiveness

May not protect all vaccine recipients against COVID-19. The risk of SARs-CoV-2 infection cannot be fully eliminated in fully vaccinated individuals while there is continued widespread community transmission of COVID-19.

Use of COVID-19 vaccines for outbreak management or for postexposure prophylaxis to prevent SARS-CoV-2 infection is unlikely to be effective and is not currently recommended. ACIP states that, because the median incubation period of SARS-CoV-2 infection is 4–5 days, it is unlikely that a dose of a COVID-19 vaccine would provide an adequate immune response within the incubation period for effective postexposure prophylaxis.

The FDA-approved or FDA-authorized COVID-19 vaccines are both efficacious and effective against symptomatic SARS-CoV-2 infection, including severe forms of disease. A substantial amount of data is available that has evaluated the effectiveness of COVID-19 vaccines in real world conditions.

High vaccine efficacy against symptomatic COVID-19 and other evidence suggests that transmission risk is substantially reduced after vaccination. Vaccination against COVID-19 has substantially reduced the burden of disease in the US through prevention of serious disease in vaccinated individuals and interruption of chains of transmission.

Based on unknown duration of vaccine-induced protection and unknown efficacy against emerging SARS-CoV-2 variants, counsel individuals who receive COVID-19 vaccination and are considered fully vaccinated to follow current guidance to protect themselves and others. This may include wearing a mask and physically distancing in certain settings and venues if required by federal, state, local, tribal, or territorial laws, rules, and regulations and following CDC travel guidance and any applicable workplace or school guidance. CDC issued interim public health recommendations for individuals who are fully vaccinated against COVID-19; consult these recommendations (available at the CDC website at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html) for information on precautionary measures that fully vaccinated individuals should take in certain social situations and/or following exposure to someone with suspected or confirmed COVID-19.

Duration of Immunity

Duration of protection against SARS-CoV-2 infection following vaccination with a single dose of the Janssen COVID-19 vaccine not fully evaluated. The immunogenicity of COVID-19 vaccines has been demonstrated through 6 to 8 months after completion of the primary vaccine series. However, waning antibody levels and reduced neutralization of variants has been documented. Compared to mRNA COVID-19 vaccines, the Janssen COVID-19 vaccine produces lower neutralizing titers 2–3 months after primary vaccination.

Improper Storage and Handling

Improper storage or handling of vaccines may reduce or destroy vaccine potency resulting in inadequate or no immune response in vaccine recipients. Inspect all vaccines on delivery and monitor during storage to ensure that recommended storage temperatures are maintained.

The Janssen COVID-19 vaccine must be shipped, stored, and handled under specific conditions at all times, according to specifications in the EUA fact sheet for healthcare providers and guidance from the manufacturer and CDC. Do not administer vaccine that has been mishandled or has not been stored at the recommended temperatures.

Contact the manufacturer at 800-565-4008 for guidance if there are concerns about mishandling or defective or damaged vaccine.

EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting

Safety and efficacy not established.

Some data available regarding adverse effects associated with use of the vaccine. Additional adverse effects, some of which may be serious, may become apparent with more widespread use.

Monitor all vaccine recipients for immediate adverse reactions according to CDC (ACIP) guidelines.

Provide vaccine recipients or their caregivers with information on, and encourage participation in, CDC's voluntary smartphone-based tool (v-safe) that uses text messaging and web surveys to check in with individuals who have received a COVID-19 vaccine to identify potential adverse effects.Information on v-safe is available at https://www.cdc.gov/vsafe.

It is mandatory that vaccination providers administering the Janssen COVID-19 vaccine report all vaccine administration errors (even if not associated with an adverse event) and serious adverse events (irrespective of attribution to vaccination) that occur following vaccination and also report all cases of multisystem inflammatory syndrome (MIS) and COVID-19 that result in hospitalization or death in vaccine recipients to VAERS. Can complete and submit VAERS reports online at https://vaers.hhs.gov/reportevent.html or by faxing to 877-721-0366; include the words "Janssen COVID-19 Vaccine EUA" in description section of the report. Obtain information on submitting a VAERS report by calling 800-822-7967 or emailing info@vaers.org. To the extent feasible, also provide a copy of the VAERS form to the manufacturer (Janssen) at JNJvaccineAE@its.jnj.com (email), 215-293-9955 (fax), or 800-565-4008 (phone).

Consult FDA fact sheet for the Janssen COVID-19 vaccine available at the FDA website and at http://www.janssencovid19vaccine.com for requirements and instructions regarding reporting of adverse reactions and vaccination errors.

Specific Populations

Pregnancy

Data insufficient to date regarding use of the Janssen COVID-19 vaccine in pregnant women to inform vaccine-associated risks during pregnancy. A developmental toxicity study in female rabbits did not reveal evidence of vaccine-related adverse effects on female fertility, embryofetal development, or postnatal development.

Observational data suggest that, while the absolute risk is low, pregnant women with COVID-19 are at increased risk of severe illness, including illness resulting in admission to an intensive care unit (ICU), mechanical ventilation, extracorporeal membrane oxygenation (ECMO), or death. Additionally, such women are at increased risk of preterm birth and may be at an increased risk of adverse pregnancy complications or outcomes, such as preeclampsia, coagulopathy, and stillbirth.

Although data are limited regarding safety of the Janssen COVID-19 vaccine during pregnancy, a different adenovirus-vectored vaccine (i.e., Ebola virus vaccine not available in the US) has been used in a large-scale vaccination trial that included pregnant women who were vaccinated during any trimester and no adverse pregnancy-related outcomes, including infant outcomes, were identified that were determined to be related to the vaccine. The Janssen COVID-19 vaccine contains a replication-incompetent adenovirus viral vector and cannot cause SARS-CoV-2 infection in the pregnant woman or her fetus.

FDA states that pregnancy is not a contraindication for use of the Janssen COVID-19 vaccine; pregnant women should discuss their options with their healthcare providers.

ACIP and ACOG state that pregnant and postpartum women <50 years of age should be informed about the rare risk of TTS after receipt of the Janssen COVID-19 vaccine (see Thrombosis with Thrombocytopenia under Cautions) and the availability of other FDA-authorized COVID-19 vaccines (Moderna COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine). ACOG states that women who choose not to receive the Janssen COVID-19 vaccine should be strongly encouraged to receive a different FDA-authorized COVID-19 vaccine.

ACOG recommends that pregnant women be vaccinated against COVID-19. When recommending the COVID-19 vaccine to pregnant women, ACOG suggests that clinicians review available data on risks and benefits of vaccination, including risks of not getting vaccinated, in the context of the individual patient's current health status and risk of exposure (e.g., possibility for exposure at work or home) and possibility for exposing high-risk household members. In addition, take into account the individual patient's values and perceived risk of various outcomes; autonomous decision-making should be respected and supported.

ACIP and ACOG state that a conversation between the pregnant woman and her clinical team may assist with decisions regarding use of COVID-19 vaccines available under an EUA. When making a decision, pregnant women and their healthcare providers should consider the level of COVID-19 transmission in the community, the individual's personal risk of contracting COVID-19, the increased risk of severe COVID-19 in the pregnant woman and potential risks to the fetus, the known and potential benefits of vaccination, efficacy of the vaccine, adverse effects of the vaccine, and limited but growing data about use of the vaccine during pregnancy.

Adverse effects similar to those reported in non-pregnant individuals can occur following COVID-19 vaccination in pregnant women. Advise pregnant women who experience fever following COVID-19 vaccination to take acetaminophen; may also offer acetaminophen as an option for pregnant women experiencing other postvaccination symptoms.

Defer administration of other vaccines (e.g., diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed [DTaP], influenza vaccine) in pregnant women for 14 days after COVID-19 vaccination. (See Vaccines under Interactions.) ACOG states do not withhold Rh_o(D) immune globulin when indicated in an individual who is planning to receive or recently received a COVID-19 vaccine. (See Specific Drugs under Interactions.)

Pregnancy exposure registry established to monitor pregnancy outcomes in women exposed to the Janssen COVID-19 vaccine during pregnancy. Encourage women who are vaccinated with the Janssen COVID-19 vaccine during pregnancy to enroll in the registry at https://c-viper.pregistry.com.

Encourage women who receive a COVID-19 vaccine during pregnancy and those who become pregnant within 30 days after receiving a COVID-19 vaccine to participate in CDC's v-safe program. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Females and Males of Reproductive Capacity

Routine pregnancy testing *not* recommended before receiving a COVID-19 vaccine.

ACIP states that vaccination against COVID-19 is recommended for women currently trying to get pregnant and those who might become pregnant in the future. Women trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination.

There is no evidence that any COVID-19 vaccines affect current or future fertility. Because the Janssen COVID-19 vaccine contains a replication-incompetent adenoviral vector that cannot cause infection or alter the DNA of vaccine recipients, it cannot cause infertility. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility.

Lactation

Not known whether the Janssen COVID-19 vaccine administered to a woman who is breast-feeding has any effects on the breast-fed infant or milk production.

FDA states breast-feeding is not a contraindication for use of the Janssen COVID-19 vaccine; women who are breast-feeding should discuss their options with their healthcare providers.

ACIP states that FDA-authorized COVID-19 vaccines administered to breast-feeding women cannot cause SARS-CoV-2 infection in women or their infants; therefore, breast-feeding women can receive COVID-19 vaccination. ACIP states that lactating women <50 years of age should be informed about the rare risk of TTS after receipt of the Janssen COVID-19 vaccine (see Thrombosis with Thrombocytopenia under Cautions) and the availability of other FDA-authorized COVID-19 vaccines (Moderna COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine).

ACOG recommends that lactating women be vaccinated against COVID-19. ACOG also states that theoretical concerns regarding the safety of vaccinating lactating women do not outweigh the potential benefits of receiving the vaccine and there is no need to avoid breast-feeding or to discontinue breast-feeding in those who receive a COVID-19 vaccine.

Pediatric Use

Safety and efficacy of the Janssen COVID-19 vaccine not assessed in individuals <18 years of age.

FDA EUA permits use of the Janssen COVID-19 vaccine *only* in individuals ≥18 years of age.

Geriatric Use

Individuals ≥65 years of age included in clinical trials evaluating the Janssen COVID-19 vaccine, and data from such individuals contribute to overall assessment of safety and efficacy of the vaccine.

At the time of FDA's safety and efficacy analysis of data from the ongoing phase 3 trial for the EUA, 19.5% of participants were ≥65 years of age and 3.7% were ≥75 years of age. No overall differences in safety or efficacy observed between those ≥65 years of age and younger adults.

Common Adverse Effects

Primary vaccination: Local adverse effects include injection site pain (48.6%), erythema (7.3%), and swelling (5.3%). Onset usually within first 1–2 days after vaccination with median duration of 2 days. However, local adverse effects reported to last >7 days in some vaccine recipients. Systemic adverse effects include headache (38.9%), fatigue (38.2%), myalgia (33.2%), nausea (14.2%), and fever (9%).

Booster dose: Local adverse effects in individuals 18–55 years of age include injection site pain (59.6%) and erythema (1.1%). Local adverse effects reported in vaccine recipients ≥65 years of age include injection site pain (20.8%). Systemic adverse effects reported in vaccine recipients 18–55 years of age include headache (41.6%), fatigue (51.7%), myalgia (36%), nausea (10.1%), and fever (5.6%). Systemic adverse effects reported in vaccine recipients ≥65 years of age included headache (27.1%), fatigue (33.3%), myalgia (10.4%), and nausea (2.1%).

Interactions

Vaccines

Data not available to date to assess concomitant administration of COVID-19 vaccines, including the Janssen COVID-19 vaccine, with other vaccines.

Although ACIP previously recommended giving COVID-19 vaccines alone, with a minimum interval of 14 days before or after administration of any other vaccines, these experts currently state that COVID-19 vaccines and other vaccines may be administered without regard to timing, including on the same day or within 14 days of each other.

Extensive experience with non-COVID-19 vaccines demonstrated that immunogenicity and adverse event profiles are generally similar whether vaccines are administered concomitantly or alone. However, it is not known whether reactogenicity of COVID-19 vaccines is increased when administered concomitantly with other vaccines, including those known to be more reactogenic (e.g., adjuvanted vaccines, live vaccines). Base decisions to administer a COVID-19 vaccine concomitantly with other vaccine(s) on whether routine immunizations with the other vaccines have been delayed or missed, the individual's risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and reactogenicity profiles of the vaccines.

If a COVID-19 vaccine is administered concomitantly with other vaccines, give each parenteral vaccine at a different injection site and, if possible, separate injection sites by ≥1 inch. ACIP states that, although >1 vaccine can be given IM into the deltoid muscle in adolescents and adults, give COVID-19 vaccines and vaccines likely to cause a local reaction (e.g., tetanus toxoid-containing vaccines, adjuvanted vaccines) in different limbs, if possible.

Specific Drugs

Drug	Interaction	Comments
Anticoagulants and aspirin		Administration of an anticoagulant or aspirin not recommended prior to vaccination Do not need to discontinue or alter dosage of anticoagulants or aspirin prior to COVID-19 vaccination

		in individuals receiving the drugs routinely
Antiviral agents	Antiviral agents given at any interval before or after COVID-19 vaccination unlikely to impair development of vaccine-induced protective antibody responses	
COVID-19 convalescent plasma	Limited data are available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine	To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥90 days after such antibody therapy if received for treatment and ≥30 days if received for post-exposure prophylaxis based on estimated half-life of SARS-CoV-2 antibody therapies and evidence suggesting reinfection uncommon in first 90 days after initial infection If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of SARS-CoV-2 antibody therapies, or timing of such treatment
Hormonal contraceptives (estrogen-progestin oral contraceptive, transdermal system, or vaginal ring)	Although certain hormonal contraceptives may increase overall general risk of thrombosis, experts believe such contraceptives do not make individuals more susceptible to TTS after receipt of the Janssen COVID-19 vaccine	Discontinuance or change in hormonal contraceptive methods not needed in women who have received or plan to receive the Janssen COVID-19 vaccine
Immune globulin and antibody therapies *not* specific for SARS-CoV-2 (e.g., immune globulin IV [IGIV], Rh_o[D] immune globulin)		May give COVID-19 vaccine concurrently with or at any interval before or after immune globulin or antibody therapies *not* specific for SARS-CoV-2
Immunosuppressive agents (e.g., cancer chemotherapy, corticosteroids, radiation)	Possible decreased or suboptimal antibody responses to vaccines, including the Janssen COVID-19 vaccine Data insufficient to date to inform optimal timing of COVID-19 vaccination for individuals planning to receive immunosuppressive therapies	ACIP states that individuals receiving immunosuppressive therapy may receive COVID-19 vaccine if they have no contraindications to vaccination Based on general best practices for vaccination of immunocompromised individuals, ACIP states COVID-19 vaccination should ideally be completed ≥2 weeks before initiation of immunosuppressive therapies; if this is not possible, individuals on immunosuppressive therapy can still receive COVID-19 vaccination; consider individual's risks related to their underlying condition if making decisions to delay immunosuppressive therapy to complete COVID-19 vaccination Corticosteroids given topically or by local injection (e.g., intra-articular, intrabursal, or tendon injection): COVID-19 vaccines may be administered without regard to timing of corticosteroid administration
SARS-CoV-2-specific monoclonal antibodies (bamlanivimab and etesevimab, casirivimab and imdevimab)	Data not available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine	To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥90 days after such antibody therapy if received for treatment and ≥30 days if received for post-exposure prophylaxis based on estimated half-life of SARS-CoV-2 antibody therapies and evidence suggesting reinfection uncommon in first 90 days after initial infection If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of SARS-CoV-2 antibody therapies, or timing of such treatment

Stability

Storage

Parenteral

Suspension, for IM Use

Supplied as a suspension in multiple-dose vials that are *initially* stored frozen by the manufacturer and are then shipped at a temperature of 2–8°C.

After receipt, store multiple-dose vials of the vaccine in a refrigerator at 2–8°C, protect from light, and do *not* freeze.

If the vaccine is still frozen upon receipt, thaw in a refrigerator at 2–8°C. If the vaccine needs to be used immediately, may thaw appropriate number of vials at room temperature (up to 25°C). If thawing at room temperature is necessary, a carton of 10 vials will take approximately 2 hours to thaw and an individual vial will take approximately 1 hour to thaw. Do *not* refreeze thawed vaccine.

Consult EUA fact sheet for healthcare providers for the Janssen COVID-19 vaccine and information provided by CDC and the manufacturer for information on storage, handling, and

stability of the vaccine. Storage and handling information contained in the EUA fact sheet for healthcare providers supersedes storage and handling information on vaccine vials and carton labels.

After removal from refrigeration, may store unused (i.e., unpunctured) vials for up to 12 hours at room temperature (9–25°C).

After withdrawing first dose of vaccine from a multiple-dose vial, vial may be held in a refrigerator (2–8°C) for up to 6 hours or at room temperature (up to 25°C) for up to 2 hours and *must* be discarded if not used within these times after first vial entry.

Expiration dates are not marked on vials and cartons of the Janssen COVID-19 vaccine. Scan the QR code on the vial or carton to reach an online resource that provides the expiration date based on the lot number printed on the packaging. Alternatively, obtain expiration dates by entering the lot number at the manufacturer's website at https://vaxcheck.jnj. Because it is possible that expiration dates may be extended as more stability data become available, contact the manufacturer prior to discarding vaccine to determine if the expiration date has been extended.

Actions

- Viral vector vaccine composed of a recombinant, replication-incompetent, human adenovirus type 26 (Ad26) vector encoding the SARS-CoV-2 spike (S) protein in a stabilized conformation.
- Following IM injection, the Ad26 vector in the vaccine enters human cells and expresses the S antigen of SARS-CoV-2 (without virus propagation). The S antigen elicits an immune response to provide protection against SARS-CoV-2 infection.
- Data from clinical trial in healthy adults ≥18 years of age indicate that a single dose of Janssen COVID-19 vaccine containing 5×10^{10} virus particles (i.e., recombinant Ad26) elicited SARS-CoV-2 neutralizing antibody when tested against wild-type virus and a SARS-CoV-2 S-binding antibody response (detected by day 15 after the dose and increased by day 57). The vaccine dose elicited cellular responses in study participants consistent with a Th-1 phenotype. A second dose of the vaccine given 56 days after the first dose resulted in increased naturalizing antibody titers.
- COVID-19 vaccine (Janssen) available for use under the FDA EUA is provided as a suspension in multiple-dose vials. Each 0.5-mL dose of COVID-19 vaccine (Janssen) contains 5×10^{10} virus particles (i.e., recombinant Ad26). Each dose also contains citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate 80, and sodium chloride and may contain residual amounts of host cell proteins and/or host cell DNA.
- Does not contain preservatives; vial stoppers are not made with natural rubber latex.

Advice to Patients

- Prior to administration of COVID-19 vaccine (Janssen), the vaccine recipient or their caregiver must be provided with information consistent with the Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age or Older and given a copy of the fact sheet or directed to the manufacturer's website at http://www.janssencovid19vaccine.com to obtain the fact sheet.
- Give the vaccine recipient or their caregiver a vaccination card that provides the name of the vaccine (Janssen COVID-19 vaccine) and the date the vaccine was administered.
- Provide the vaccine recipient or their caregiver with information on, and encourage participation in, CDC's voluntary smartphone-based tool (v-safe) that uses text messaging and web surveys to check in with individuals who have received a COVID-19 vaccine to identify potential adverse effects; live telephone follow-up is provided if a medically important health impact is reported. Information on v-safe is available at https://www.cdc.gov/vsafe.
- Inform vaccine recipients or their caregivers that FDA authorized the emergency use of the Janssen COVID-19 vaccine, which is an investigational vaccine that has not received FDA approval, for use in individuals ≥18 years of age. Advise them that an ongoing clinical trial has shown that a single dose of the vaccine can prevent COVID-19; however, the duration of protection following vaccination is unknown and the vaccine may not protect everyone who receives it.
- Provide vaccine recipients or their caregivers with information on available alternative vaccines and the risks and benefits of those alternatives.
- Inform vaccine recipients or their caregivers about the significant known and potential risks and benefits of the Janssen COVID-19 vaccine, and the extent to which such risks and benefits are unknown. Inform them that local adverse effects (injection site pain, swelling, redness) and systemic adverse effects (headache, fatigue, muscle aches, nausea, fever) have been reported in recipients of the Janssen COVID-19 vaccine.
- Importance of vaccine recipient informing the vaccination provider of any allergies or fever. Advise vaccine recipients or their caregivers that there is a remote chance that the vaccine could cause a severe allergic reaction and such reactions would usually occur within a few minutes to 1 hour after receiving the vaccine dose and may include difficulty breathing, swelling of the face and throat, fast heartbeat, bad rash all over the body, and dizziness and weakness.
- Inform vaccine recipients or their caregivers that blood clots involving blood vessels in the brain, abdomen, and legs along with low platelet counts have occurred rarely in individuals who received the Janssen COVID-19 vaccine and that symptoms began approximately 1–2 weeks following vaccination. While these events have been reported in a wide range of ages, reports of blood clots with low levels of platelets have been highest among women between 30–49 years of age (about 1 case/100,000 doses given). Cases have been fatal in about 1 out of every 7 cases. Advise vaccine recipients or their caregivers to immediately seek medical attention if shortness of breath, chest pain, leg swelling, persistent abdominal pain, severe or persistent headaches or blurred vision, easy bruising, or tiny blood spots under the skin at sites beyond the vaccine injection site occur following vaccination with the Janssen COVID-19 vaccine. Advise patients that they should not receive the Janssen COVID-19 vaccine if they previously developed a blood clot with low platelet counts following the Janssen COVID-19 vaccine or the AstraZeneca COVID-19 vaccine (not authorized in the US).
- Inform vaccine recipients or their caregivers that cases of Guillain-Barré syndrome have occurred in some individuals who received the Janssen COVID-19 vaccine; symptoms typically begin within 42 days following receipt of the vaccine. Advise vaccine recipients or their caregivers to immediately seek medical attention if any of these symptoms develop following vaccination: weakness or tingling sensations (especially in arms or legs) that is worsening and spreading to other parts of the body; difficulty walking; difficulty with facial movements (speaking, chewing, or swallowing); double vision or inability to move eyes; or difficulty with bladder control or bowel function.
- Importance of vaccine recipient informing the vaccination provider if they previously received any other COVID-19 vaccine, have any medical conditions (e.g., bleeding disorders, immunocompromising diseases), or are receiving anticoagulants or immunosuppressive therapy.
- Importance of women informing clinicians if they are or plan to become pregnant or plan to breast-feed.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

COVID-19 vaccine (Janssen) is not commercially available. Allocation of the vaccine for use under the EUA is being directed by the US government. The vaccine will be supplied directly from the manufacturer or authorized US distributor(s) and distributed to emergency response stakeholders as directed by the US government, including the CDC and/or other designee.

COVID-19 Vaccine, Viral Vector (Janssen)

Parenteral

Suspension, for IM use

5×10^{10} virus particles (recombinant Adenovirus type 26) per 0.5-mL dose

Janssen COVID-19 Vaccine, Janssen

† Use is not currently included in the labeling approved by the US Food and Drug Administration.