COVID-19 Vaccine (Adenovirus Vector) (Lexi-Drugs)

Special Alerts

COVID-19 Vaccine (Adenovirus Vector): Health Canada Update Regarding Use of AstraZeneca, Covishield, and Janssen COVID-19 May 2021

Health Canada has reviewed the risk of thrombosis in combination with thrombocytopenia with the use of the AstraZeneca COVID-19 vaccine, Covishield COVID-19 vaccine, and the Janssen COVID-19 Vaccine and has concluded that a link is possible. The risk of these events is very rare, and the overall benefits of the vaccine in protecting Canadians from COVID-19 continue to outweigh the potential risks. Health Canada did not identify risk factors, such as age or gender, for these rare events and is not restricting the use of the vaccine at this time. Health Canada has worked with the manufacturers of the AstraZeneca COVID-19 vaccine, Covishield vaccine, and the Janssen vaccine to update the Canadian product monographs for these products to include new safety information about these events.

Further information may be found at https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00265 and https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00266.

COVID-19 Vaccine (Adenovirus Vector): Pause On Johnson & Johnson's Janssen COVID-19 Vaccine Lifted April 2021

Following a thorough safety review, the CDC and FDA have determined that the recommended pause regarding the use of the Janssen COVID-19 vaccine (adenovirus vector) in the US should be lifted and use of the vaccine should resume.

Further information may be found at:

https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough?utm_medium=email&utm_source=govdelivery

COVID-19 Vaccine (Adenovirus Vector): Canadian National Advisory Committee on Immunization (NACI) AstraZeneca COVID-19 Vaccine Recommendations March 2021

The Canadian National Advisory Committee on Immunization (NACI) has recommended that the AstraZeneca COVID-19 vaccine not be used in adults younger than 55 years at this time while the safety signal of vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) following vaccination is investigated further. Rare cases of serious thromboembolic events, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been reported in Europe following post-licensure use of the AstraZeneca COVID-19 vaccine. Cases have been reported primarily in women younger than 55 years and most commonly between 4 and 16 days after receipt of the vaccine. The exact mechanism by which the AstraZeneca vaccine triggers VIPIT is still under investigation. At this time, no other risk factors have consistently been identified in patients who develop VIPIT. This adverse event has not been identified following receipt of mRNA COVID-19 vaccines to date.

Further information may be found at https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-recommended-use-astrazeneca-covid-19-vaccine-younger-adults.html.

COVID-19 Vaccine (Adenovirus Vector): Health Canada Authorizes Use of AstraZeneca Vaccine, Covishield, and Johnson & Johnson's Janssen Vaccine Under Interim Order Updated March 2021

Health Canada has authorized the use of AstraZeneca's COVID-19 Vaccine and Covishield COVID-19 Vaccine (adenovirus vector) via an interim order. The AstraZeneca COVID-19 vaccine and Covishield (manufactured by Serum Institute of India under license from AstraZeneca) are ChAdOx1-S recombinant vaccines developed by the University of Oxford and AstraZeneca. Health Canada has reviewed the manufacturing information for these vaccines and found them to be comparable. Additionally, Health Canada has authorized the use of Janssen's COVID-19 vaccine (adenovirus vector) via an interim order. The interim order was issued to Janssen Pharmaceutical Companies of Johnson & Johnson.

Further information may be found at:

Interim Orders:

AstraZeneca and Covishield Vaccines: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/astrazeneca/authorization.html

Janssen Vaccine: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/janssen.html

Product Monographs:

AstraZeneca Vaccine: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf

Covishield: https://covid-vaccine.canada.ca/info/pdf/covishield-pm-en.pdf

Janssen Vaccine: https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf

Regulatory Decision Summaries:

AstraZeneca Vaccine: https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00772

Covishield: https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00773

Janssen Vaccine: https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00779

NACI: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-key-populations-early-covid-19-immunization.html

COVID-19 Vaccine (Adenovirus Vector): FDA Issues Emergency Use Authorization to Johnson & Johnson's Janssen COVID-19 Vaccine February 2021

The FDA has issued an emergency use authorization (EUA) for the Janssen COVID-19 Vaccine (adenovirus vector) for the prevention of COVID-19 in persons ≥18 years of age. The EUA was issued to

Janssen Biotech Inc, a Janssen Pharmaceutical Company of Johnson & Johnson. While the safety and effectiveness of this investigational agent for use in the prevention of COVID-19 continues to be evaluated, the vaccine was shown in clinical trials to prevent symptomatic COVID-19 occurring at least 14 days after a single dose; no significant safety concerns were identified.

Health care provider fact sheet: https://www.fda.gov/media/146304/download

Patient fact sheet: https://www.fda.gov/media/146305/download

Further information may be found at the following links, by scanning the QR code on the fact sheet or vaccine vial label, or by calling 1-800-565-4008:

Emergency Use Authorization letter: https://www.fda.gov/media/146303/download

FDA: https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine

Janssen vaccine website: https://www.janssencovid19vaccine.com

CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html

CDC V-safe: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Pronunciation

Vm

P

(KO vid nine teen vak SEEN ad e noh VYE rus vek tor)

Brand Names: US

Janssen COVID-19 Vaccine

Brand Names: Canada

AstraZeneca COVID-19 Vaccine; Covishield; Janssen COVID-19 Vaccine

Pharmacologic Category

Vaccine; Vaccine, Adenovirus Vector

Dosing: Adult

COVID-19 prevention:

Janssen COVID-19 Vaccine: IM: 0.5 mL as a single dose (FDA 2021; Janssen Canadian product monograph).

Interchangeability: The safety and efficacy of administering the Janssen COVID-19 Adenovirus Vector Vaccine after an mRNA vaccine has not been established. However, the CDC states that in limited, exceptional situations where a patient's first dose was an mRNA vaccine and they are unable to complete the series with the same or different mRNA vaccine (eg, due to a contraindication), then a

single dose of the Janssen vaccine may be considered at a minimum interval of 28 days from the mRNA vaccine dose. If a non-FDA COVID-19 vaccine has been administered, allow a minimum interval of 28 days between a non-FDA authorized vaccine and an FDA-authorized vaccine (CDC 2021a).

AstraZeneca COVID-19 Vaccine/Covishield [Canadian products]: IM: 0.5 mL per dose for 2 doses administered 28 to 84 days (4 to 12 weeks) apart; may use either the AstraZeneca COVID-19 Vaccine or Covishield vaccine to complete the series (AstraZeneca Canadian product monograph; Covishield Canadian product monograph). **Note:** The World Health Organization recommends an interval of 56 to 84 days (8 to 12 weeks) between doses due to increased efficacy and immunogenicity observed with a longer dose interval. If the second dose is inadvertently administered early (<28 days after the first dose), then dose does not need to be repeated (WHO 2021).

Premedication: The CDC does not recommend routine prophylactic administration of antihistamines, antipyretic/analgesic medications (eg, acetaminophen, nonsteroidal anti-inflammatory drugs), or aspirin/anticoagulants for the purpose of preventing postvaccination symptoms. Antihistamines may mask cutaneous symptoms of anaphylaxis, which could delay the diagnosis and management of the reaction. The impact of antipyretic/analgesic medications on antibody response is unknown. Antipyretic/analgesic medications may be taken **after** vaccination for the treatment of postvaccination local/systemic symptoms (if medically appropriate) (CDC 2021a).

Dosing recommendations for deviation in dose preparation or administration: If dose volume was too high, do **not** repeat dose. If dose volume was too low but more than half of the dose was administered, do **not** repeat the dose. If less than half the dose or the amount is unknown, repeat the dose in the opposite arm (CDC 2021a).

* See Dosage and Administration in AHFS Essentials for additional information.

Dosing: Geriatric

Refer to adult dosing.

Dosing: Renal Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Hepatic Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Pediatric

COVID-19 prevention:

Janssen vaccine: Adolescents ≥18 years: IM: 0.5 mL as a single dose (FDA 2021; Janssen Canadian product monograph).

Interchangeability: The safety and efficacy of administering the COVID-19 adenovirus vector vaccine by Janssen after an mRNA vaccine has not been established. However, the CDC states that in limited, exceptional situations where a patient's first dose was an mRNA vaccine and they are unable to complete the series with the same or different mRNA vaccine (eg, due to a contraindication), then a single dose of the Janssen vaccine may be considered (if age appropriate) at a minimum interval of 28

days from the mRNA vaccine dose. If a non-FDA COVID-19 vaccine has been administered, allow a minimum interval of 28 days between a non-FDA authorized vaccine and an FDA-authorized vaccine (CDC 2021a).

AstraZeneca vaccine/Covishield [Canadian products]: Adolescents ≥18 years: IM: 0.5 mL per dose for 2 doses administered 28 to 84 days (4 to 12 weeks) apart; may use either the AstraZeneca COVID-19 Vaccine or Covishield vaccine to complete the series (AstraZeneca Canadian product monograph; Covishield Canadian product monograph). **Note:** The World Health Organization recommends an interval of 56 to 84 days (8 to 12 weeks) between doses due to increased efficacy and immunogenicity observed with a longer dose interval. If the second dose is inadvertently administered early (<28 days after the first dose), then dose does not need to be repeated (WHO 2021).

Premedication: The Centers for Disease Control and Prevention (CDC) does not recommend routine prophylactic administration of antihistamines, antipyretic/analgesic medications (eg, acetaminophen, nonsteroidal anti-inflammatory drugs), or aspirin/anticoagulants for the purpose of preventing postvaccination symptoms. Antihistamines may mask cutaneous symptoms of anaphylaxis, which could delay the diagnosis and management of the reaction. The impact of antipyretic/analgesic medications on antibody response is unknown. Antipyretic/analgesic medications may be taken after vaccination for the treatment of postvaccination local/systemic symptoms (if medically appropriate). Aspirin or anticoagulants as part of routine drug therapy do not need to be stopped prior to vaccination (CDC 2021a).

Dosing recommendations for deviation in dose preparation or administration: If dose volume was too high, do **not** repeat dose. If dose volume was too low but more than half of the dose was administered, do **not** repeat the dose. If less than half the dose or the amount is unknown, repeat the dose in the opposite arm. If a patient 16 to 17 years of age inadvertently receives a COVID-19 adenovirus vector vaccine by Janssen, no additional doses of any type of COVID-19 vaccine are needed (CDC 2021a).

Dosing: Renal Impairment: Pediatric

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Hepatic Impairment: Pediatric

There are no dosage adjustments provided in the manufacturer's labeling.

Use: Labeled Indications

See "Use: Off-Label: Adult."

* See Uses in AHFS Essentials for additional information.

Use: Off-Label: Adult

COVID-19 prevention Level of Evidence [A]

Janssen COVID-19 Vaccine (adenovirus vector): Available under an FDA emergency use authorization (EUA) and an interim order from Health Canada for active immunization to prevent COVID-19 in persons ≥18 years of age. Data from a phase 3 randomized, placebo-controlled, double-blind study support the

use of the Janssen COVID-19 Vaccine in preventing COVID-19 caused by SARS-CoV-2 in persons ≥18 years of age ([Ref]).

AstraZeneca COVID-19 Vaccine (adenovirus vector)/Covishield [Canadian products]: Available under a Health Canada interim order for active immunization to prevent COVID-19 in persons ≥18 years of age ([Ref]). Health Canada has reviewed the manufacturing information for these vaccines and found them to be comparable ([Ref]). Data from 4 phase 2/3 randomized, controlled, blinded studies support the use of the AstraZeneca COVID-19 Vaccine in preventing symptomatic COVID-19 caused by SARS-CoV-2 in persons ≥18 years of age ([Ref]).

Advisory Committee on Immunization Practices: The Advisory Committee on Immunization Practices (ACIP) recommends any age-appropriate FDA-authorized COVID-19 vaccine if no contraindications exist; ACIP does not have a preferential recommendation for any COVID-19 vaccine product ([Ref]).

Canadian Guidance: The National Advisory Committee on Immunization (NACI) has made recommendations for prioritization of initial COVID-19 vaccine supplies and on the use of COVID-19 vaccines; see recommendations for details ([Ref]).

Level of Evidence Definitions

Level of Evidence Scale

Clinical Practice Guidelines

ACIP, "General Best Practice Guidelines for Immunization"

CDC/ACIP, “The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020,” 2020

CDC/ACIP, “The Advisory Committee on Immunization Practices’ Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020,” 2020

CDC/ACIP, “The Advisory Committee on Immunization Practices’ Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021,” 2021

CDC, "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States," 2021

CDC, "Interim Public Health Recommendations for Fully Vaccinated People," 2021

IDSA, "Vaccination of the Immunocompromised Host," 2013

NACI, "Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada," 2021

NACI, "Recommendations on the Use of COVID-19 Vaccine(s)," 2021

NACI/CATMAT, "Canadian Immunization Guide"

WFH/EAHAD/EHC/NHF, “COVID-19 Vaccination Guidance for People with Bleeding Disorders,” 2020

WHO, “Interim Recommendations for Use of the AZD1222 (ChAdOx1-S [Recombinant]) Vaccine Against COVID-19 Developed by Oxford University and AstraZeneca,” 2021

Administration: IM

Do not shake. For the Janssen product, gently swirl the vial in an upright position for 10 seconds before withdrawing each dose of vaccine (FDA 2021). Administer IM in the deltoid muscle (FDA 2021; AstraZeneca Canadian product monograph). Use proper injection technique in the deltoid muscle (eg, injecting in the central, thickest part of the muscle) to reduce the risk of shoulder injury related to vaccine administration (Cross 2016; Foster 2013). To prevent syncope-related injuries, adolescents and adults should be vaccinated while seated or lying down (ACIP [Kroger 2021]).

Do not routinely administer simultaneously with other vaccines; allow a minimum interval of 14 days before or after other vaccines. If administration of other vaccines is needed and the benefits outweigh the unknown risks (eg, tetanus for wound management, measles or hepatitis A during an outbreak, rabies for postexposure prophylaxis) or to avoid barriers or delays to COVID-19 vaccination, may consider <14-day interval. If administered within 14 days of another vaccine, doses of either vaccine do not need to be repeated (CDC 2021a).

Inappropriate administration technique: If administered SUBQ or into a muscle other than the deltoid or anterolateral thigh (alternate administration site), do **not** repeat dose (CDC 2021a).

Patients at risk for hemorrhage: For patients at risk of hemorrhage following IM injection, the vaccine should be administered IM if, in the opinion of the physician familiar with the patient's bleeding risk, the vaccine can be administered by this route with reasonable safety. If the patient receives antihemophilia or other similar therapy, IM vaccination can be scheduled shortly after such therapy is administered. A fine needle (≤23 gauge) can be used for the vaccination and firm pressure applied to the site (without rubbing) for at least 2 minutes. The patient should be instructed concerning the risk of hematoma from the injection. Patients on anticoagulant therapy should be considered to have the same bleeding risks and treated as those with clotting factor disorders (ACIP [Kroger 2021]).

Administration: Pediatric

Parenteral: IM: Adolescents ≥18 years: Do not shake. For the Janssen product, gently swirl the vial in an upright position for 10 seconds before withdrawing each dose of vaccine (FDA 2021). Administer IM in the deltoid muscle (AstraZeneca Canadian product monograph; FDA 2021). Use proper injection technique in the deltoid muscle (eg, injecting in the central, thickest part of the muscle) to reduce the risk of shoulder injury related to vaccine administration (Cross 2016; Foster 2013). To prevent syncope-related injuries, adolescents and adults should be vaccinated while seated or lying down (ACIP [Kroger 2021]).

Do not routinely administer simultaneously with other vaccines; allow a minimum interval of 14 days before or after other vaccines. If administration of other vaccines is needed and the benefits outweigh the unknown risks (eg, tetanus for wound management, measles or hepatitis A during an outbreak, rabies for postexposure prophylaxis) or to avoid barriers or delays to COVID-19 vaccination, may consider <14-day interval. If administered within 14 days of another vaccine, doses of either vaccine do not need to be repeated (CDC 2021a).

Inappropriate administration technique: If administered SubQ or into a muscle other than the deltoid or anterolateral thigh (alternate administration site), do not repeat dose (CDC 2021a).

Patients at risk for hemorrhage: For patients at risk of hemorrhage following IM injection, the vaccine should be administered IM if, in the opinion of the physician familiar with the patient's bleeding risk, the vaccine can be administered by this route with reasonable safety. If the patient receives antihemophilia or other similar therapy, IM vaccination can be scheduled shortly after such therapy is administered. A fine needle (23 gauge or smaller) can be used for the vaccination and firm pressure applied to the site (without rubbing) for at least 2 minutes. The patient should be instructed concerning the risk of hematoma from the injection. Patients on anticoagulant therapy should be considered to have the same bleeding risks and treated as those with clotting factor disorders (ACIP [Kroger 2021]).

Storage/Stability

Note: Carton and vial labels may contain different storage information; information in health care provider fact sheet issued as part of emergency use authorization supersedes any information on cartons or vials (FDA 2021).

Janssen COVID-19 Vaccine*:* Store intact vials refrigerated at 2°C to 8°C (36°F to 46°F) and protect from light. Do not freeze. Intact vials may be stored at 9°C to 25°C (47°F to 77°F) for up to 12 hours. Do not refreeze thawed vials. After the first vial puncture, store the vial/filled syringes refrigerated at 2°C to 8°C (36°F to 46°F) for up to 6 hours or at room temperature (≤25°C [77°F]) for up to 2 hours (FDA 2021; data on file [Janssen 2021]); may be held in vial or syringes at room temperature for up to 3 hours from first vial puncture (Janssen Canadian product monograph). Discard if not used within these times. Multidose vials do not contain a preservative (FDA 2021; Janssen Canadian product monograph). Expiration date checker: https://vaxcheck.jnj.

AstraZeneca COVID-19 Vaccine/Covishield [Canadian products]: Store intact vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. After first opening, may store at room temperature up to 30°C (86°F) for up to 6 hours or refrigerated at 2°C to 8°C (36°F to 46°F) for up to 48 hours. The vial may be returned to the refrigerator, but the cumulative storage time at room temperature must not exceed 6 hours, and the vial should be discarded by 48 hours following initial puncture. Multidose vials do not contain a preservative (AstraZeneca Canadian product monograph).

Preparation for Administration: Adult

Reconstitution and/or dilution is not required.

Janssen COVID-19 Vaccine: If vaccine is still frozen upon receipt, thaw prior to administration. Two methods may be used to thaw: Thaw in the refrigerator at 2°C to 8°C (36°F to 46°F); or thaw at room temperature (≤25°C [≤77°F]) for ~2 hours (for a carton of 10 vials) or ~1 hour (for an individual vial). Gently swirl vial in an upright position for 10 seconds; do **not** shake. Liquid should be a colorless to slightly yellow, clear to very opalescent suspension; discard vial if any other discoloration or particulates are present. Do not refreeze thawed vials (FDA 2021; Janssen Canadian product monograph).

AstraZeneca COVID-19 Vaccine/Covishield [Canadian products]: Do not shake the vial (AstraZeneca United Kingdom product monograph). AstraZeneca vaccine should be a colorless to slightly brown, clear to slightly opaque solution. Covishield should be a colorless, slightly clear to slightly opaque solution.

Discard vial if any other discoloration or particulates are present (AstraZeneca Canadian product monograph; Covishield Canadian product monograph).

Preparation for Administration: Pediatric

Reconstitution and/or dilution is not required.

Janssen vaccine: If vaccine is still frozen upon receipt, thaw prior to administration. Two methods may be used to thaw: Thaw in the refrigerator at 2°C to 8°C (36°F to 46°F); or thaw at room temperature (≤25°C [77°F]) for approximately 2 hours (for a carton of 10 vials) or approximately 1 hour (for an individual vial). Gently swirl vial in an upright position for 10 seconds; do not shake. Liquid should be a colorless to slightly yellow, clear to very opalescent suspension; discard vial if any other discoloration or particulates are present. Do not refreeze thawed vials (FDA 2021).

AstraZeneca vaccine/Covishield [Canadian products]: Do not shake the vial (AstraZeneca United Kingdom product monograph). AstraZeneca vaccine should be a colorless to slightly brown, clear to slightly opaque solution. Covishield should be a colorless, slightly clear to slightly opaque solution. Discard vial if any other discoloration or particulates are present (AstraZeneca Canadian product monograph; Covishield Canadian product monograph).

Medication Patient Education with HCAHPS Considerations

What is this drug used for?

• It is used to prevent COVID-19.

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

• Pain, redness, or swelling where the injection was given, headache, muscle or joint pain, fever of 100.4°F (38°C) or higher, chills, upset stomach, or feeling tired or unwell

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Fast heartbeat, dizziness, passing out, or weakness

• Blood clots with low platelet levels like bruising or tiny blood spots away from the injection site, severe headache, headache that does not go away, stomach pain that does not go away, leg swelling or pain, chest pain, shortness of breath, blurred eyesight, seizures, or feeling confused

• Bell's palsy like weak or drooping muscles on one side of your face

• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

Health care provider fact sheet: https://www.fda.gov/media/146304/download

Patient fact sheet: https://www.fda.gov/media/146305/download

Note: This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

Consumer Information Use and Disclaimer: This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a limited summary of general information about the medicine's uses from the patient education leaflet and is not intended to be comprehensive. This limited summary does NOT include all information available about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not intended to provide medical advice, diagnosis or treatment and does not replace information you receive from the healthcare provider. For a more detailed summary of information about the risks and benefits of using this medicine, please speak with your healthcare provider and review the entire patient education leaflet.

Medication Safety Issues

Sound-alike/look-alike issues:

Prescribing and Access Restrictions

The Janssen COVID-19 Vaccine is not commercially available; it is available under emergency use authorization (EUA) from the FDA. The US federal government, in conjunction with state health departments, will allocate a supply of the vaccine to individual sites of care across the United States.

As part of the EUA, information consistent with fact sheets pertaining to emergency use of the COVID-19 vaccines must be provided to recipients/caregivers, and certain mandatory requirements for administration under the EUA must be met as outlined in the FDA EUA letter.

Janssen COVID-19 Vaccine: The health care provider fact sheet is located at: https://www.fda.gov/media/146304/download. The patient fact sheet is located at: https://www.fda.gov/media/146305/download.

The vaccine provider should include vaccination information in the state/local jurisdiction Immunization Information System (IIS) or other designated system and provide a paper record card as a backup.

Additionally, the vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS) (https://vaers.hhs.gov/reportevent.html or 1-800-822-7967):

- 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
- cases of COVID-19 that result in hospitalization or death

The vaccination provider is also responsible for responding to FDA requests for more information. Additional adverse events may be reported to VAERS and the manufacturer. Adverse events related to

the Janssen vaccine may be reported to Janssen Biotech, Inc via email: JNJvaccineAE@its.jnj.com; phone: 1-800-565-4008; or fax: 1-215-293-9955.

Contraindications

History of a severe allergic reaction (eg, anaphylaxis) after a previous dose or to a component of the formulation; history of immediate allergic reaction (regardless of severity and occurring within 4 hours) to a previous dose; known allergy to any component of the formulation (eg, polysorbate 80) (CDC 2021a).

AstraZeneca COVID-19 Vaccine/Covishield [Canadian labeling]: Major venous and/or arterial thrombosis with thrombocytopenia following previous dose of AstraZeneca COVID-19 Vaccine or Covishield.

Warnings/Precautions

Concerns related to adverse effects:

• Shoulder injury related to vaccine administration: Vaccine administration that is too high on the upper arm may cause shoulder injury (eg, shoulder bursitis or tendinopathy) resulting in shoulder pain and reduced range of motion following injection. Use proper injection technique for vaccines administered in the deltoid muscle (eg, injecting in the central, thickest part of the muscle) to reduce the risk of shoulder injury related to vaccine administration (Cross 2016; Foster 2013).

• Syncope: Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs (ACIP [Kroger 2021]).

Disease-related concerns:

• Acute illness: The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and the etiology of the disease. In general, it is recommended to defer vaccine administration in patients with moderate or severe acute illness (with or without fever) and to provide vaccination in patients with mild acute illness (with or without fever) (ACIP [Kroger 2021]). The Canadian product information for the AstraZeneca and Covishield vaccines states to postpone vaccination in patients with acute severe febrile illness or acute infection (AstraZeneca Canadian product monograph; Covishield Canadian product monograph).

• Bleeding disorders: Use with caution in patients with a history of bleeding disorders (including thrombocytopenia); bleeding or hematoma may occur from IM administration; if the patient receives antihemophilia or other similar therapy, IM injection can be scheduled shortly after such therapy is administered (ACIP [Kroger 2021]). For more information on administering the COVID-19 vaccine in patients with bleeding disorders, see society recommendations (eg, US National Hemophilia Foundation, World Federation of Hemophilia).

• Immune-mediated syndrome: Persons with a history of immune-mediated syndrome characterized by thrombosis and thrombocytopenia (eg, heparin-induced thrombocytopenia) should be offered a different COVID-19 vaccine (ie, mRNA vaccine) if the person is within 90 to 180 days postresolution of illness (CDC 2021a).

• SARS-CoV-2 infection or exposure (CDC 2021a):

- *Persons with current or prior history of COVID-19 or asymptomatic SARS-CoV-2 infection:* Vaccination should be offered to persons regardless of history of symptomatic or asymptomatic SARS-CoV-2 infection, including those with prolonged symptoms. Based on data from clinical trials, vaccination in persons with evidence of prior SARS-CoV-2 infection is safe. Defer vaccination in persons with known current SARS-CoV-2 infection until the person has recovered from acute illness (if symptomatic) and no longer requires isolation. This applies to those persons who develop SARS-CoV-2 infection before receiving any vaccine doses and also those who develop infection after the first dose but before the second dose.

For vaccinated persons who subsequently develop COVID-19, prior receipt of a COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.

- *Persons who received passive antibody COVID-19 therapy:* There are currently no data on the safety and efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. As a precaution, it is recommended to defer vaccination for at least 90 days following receipt of COVID-19 convalescent plasma or anti-COVID-19 monoclonal antibody therapy. Vaccination within 90 days after passive antibody therapy does not need to be repeated.

- *Persons who received antibody therapies that are not specific to COVID-19:* There is no recommended minimum interval between vaccination and antibody therapies that are not specific to COVID-19 (eg, IVIG, hepatitis B immune globulin) (CDC 2021a).

- *Vaccinated persons who subsequently develop COVID-19:* Prior receipt of a COVID-19 vaccine should not affect treatment decisions (eg, monoclonal antibodies, convalescent plasma) or timing of such treatments (CDC 2021a). If a person is fully vaccinated and ≥2 weeks postvaccination and tests positive for SARS-CoV-2, the CDC recommends holding the specimen and contacting the state health department.

- *Persons with known SARS-CoV-2 exposure:* Vaccination for outbreak management or postexposure prophylaxis is not currently recommended. Persons with known exposure should wait to seek vaccination until after their quarantine period has ended. For persons in congregate settings (eg, long-term care facilities, correctional facilities, homeless shelters), residents with known exposure may be vaccinated unless they have symptoms consistent with COVID-19.

Concurrent drug therapy issues:

• Anticoagulant or aspirin therapy: Aspirin or anticoagulants as part of routine drug therapy do not need to be stopped prior to vaccination; however, clinicians administering vaccine should be aware of potential bleeding or hematoma that could occur due to IM administration (ACIP [Kroger 2021]; CDC 2021a). Prophylactic aspirin or anticoagulant administration is not recommended (CDC 2021a).

• Medications for postvaccination adverse reactions: Antipyretic or analgesic medications (eg, acetaminophen, nonsteroidal anti-inflammatory drugs) may be taken for the treatment of postvaccination local/systemic symptoms (if medically appropriate). However, routine prophylactic

administration of these medications for the purpose of preventing postvaccination symptoms is not currently recommended; impact on antibody response is unknown (CDC 2021a).

• Vaccines: Do not routinely administer simultaneously with other vaccines; allow a minimum interval of 14 days before or after other vaccines. If administration of other vaccines is needed and the benefits outweigh the unknown risks (eg, tetanus for wound management, measles or hepatitis A during an outbreak, rabies for postexposure prophylaxis) or to avoid barriers or delays to COVID-19 vaccination, may consider <14-day interval. If inadvertently administered within 14 days of another vaccine, doses of either vaccine do not need to be repeated. Safety and efficacy of COVID-19 vaccines administered simultaneously with other vaccines is unknown (CDC 2021a).

Special populations:

• Altered immunocompetence: Immunocompromised persons (including those with HIV or receiving immunosuppressant therapy) may have a diminished immune response to the vaccine (AstraZeneca product monograph; CDC 2021a; Covishield Canadian product monograph; FDA 2021; Janssen Canadian product monograph). Patients with stable HIV infection were included in the clinical trials (CDC 2021a; FDA 2021). Although data are not currently available to establish vaccine safety and efficacy in immunocompromised persons, the CDC recommends vaccination of immunocompromised patients if there are no contraindications. If possible, complete COVID-19 vaccination ≥2 weeks prior to initiation of immunosuppressive therapy. If completion of a whole vaccination series prior to initiation of therapy is not possible, persons receiving immunosuppressants can still receive COVID-19 vaccination. Revaccination is not recommended after immune competence is regained for those persons who received vaccination during chemotherapy or other immunosuppressive therapy (CDC 2021a). For more information on administering COVID-19 vaccine in specific disease states, see society recommendations (eg, American Cancer Society, National Multiple Sclerosis Society).

• Autoimmune conditions: Although data are not currently available to establish vaccine safety and efficacy in patients with autoimmune conditions or inflammatory disorders, the CDC recommends vaccination of patients with autoimmune conditions if there are no contraindications (CDC 2021a).

Dosage form specific issues:

• Interchangeability: There are no data on the interchangeability of COVID-19 vaccines. For those COVID-19 vaccines (adenovirus vector) that require a second dose, may use either the AstraZeneca COVID-19 Vaccine or the Covishield vaccine (Canadian products) (AstraZeneca Canadian product monograph; CDC 2021a; Covishield Canadian product monograph).

• Polysorbate 80: Some COVID-19 vaccines may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals (Isaksson 2002; Lucente 2000; Shelley 1995). See manufacturer's labeling. Polysorbate and polyethylene glycol are structurally related; cross-reactive hypersensitivity may occur (CDC 2021a).

• Traceability: The vaccine name, batch/lot number, expiration date, and other administration details must be recorded in order to improve traceability (AstraZeneca Canadian product monograph; Covishield Canadian product monograph; FDA 2021; Janssen Canadian product monograph).

Other warnings/precautions:

• Effective immunity: Vaccination may not result in effective immunity in all patients. Response depends upon multiple factors (eg, type of vaccine, age of patient) and may be improved by administering the vaccine at the recommended dose, route, and interval (ACIP [Kroger 2021]). Vaccines may not be effective if administered during periods of altered immune competence (ACIP [Kroger 2021]).

• Mammograms: Temporary contralateral or ipsilateral lymphadenopathy after a COVID-19 vaccination has been reported. To avoid possible misinterpretation of mammogram screening, mammograms are recommended prior to vaccination or 4 to 6 weeks after the second dose. When this is not possible, the mammogram technologist or radiologist should be informed when and which vaccine was administered and what arm the injection was given (ACOG 2021). Imaging needed for acute symptoms, or urgent treatment planning or complications, should not be delayed (Becker 2021).

* See Cautions in AHFS Essentials for additional information.

Reproductive Considerations

COVID-19 (adenovirus vector) vaccines are investigational vaccines permitted for use under emergency use authorization (EUA). Pregnant patients were excluded from the original vaccine trials (Folegatti 2020; Sadoff 2021); however, vaccination is encouraged for patients planning a pregnancy. Routine pregnancy testing is not required prior to vaccination, and pregnancy does not need to be delayed following vaccination (ACOG 2021; CDC 2021a; WHO 2021).

COVID vaccines do not increase the risk of infertility. Use of the Janssen COVID-19 Vaccine should not be withheld from individuals planning a pregnancy who meet the criteria for vaccination based on the Advisory Committee on Immunization Practices recommended priority groups (ACOG 2021).

Current American College of Obstetricians and Gynecologists and CDC recommendations do not have a product preference; any age-appropriate vaccine may be used for patients who may become pregnant and who do not otherwise have contraindications to the vaccine. Thrombosis with thrombocytopenia syndrome (TTS) has been rarely reported with use of the Janssen COVID-19 Vaccine. The risk of TTS is not expected to be increased in patients using combination hormonal contraceptives (CHCs) and patients using CHCs may receive any FDA-approved vaccine; however, because current cases of this adverse event have been primarily observed in females between 18 and 49 years of age, these patients should be made aware that other COVID-19 vaccines are also available (ACOG 2021; CDC 2021a). Patients do not need to discontinue or change their hormonal contraceptive method prior to vaccination with the Janssen COVID-19 Vaccine (ACOG 2021).

Pregnancy Considerations

COVID-19 (adenovirus vector) vaccines are investigational vaccines permitted for use under emergency use authorization (EUA). Pregnant patients were excluded in the original clinical studies (Folegatti 2020; Sadoff 2021). Adverse events were not observed in animal reproduction studies using the Janssen COVID-19 Vaccine (adenovirus vector) vaccine. Animal reproduction studies using the AstraZeneca COVID-19 Vaccine (adenovirus vector) are ongoing.

Outcome information following COVID-19 vaccination during pregnancy is being collected. Information following inadvertent administration of the AstraZeneca COVID-19 Vaccine (adenovirus vector) to

patients later determined to be pregnant is limited at this time (Voysey 2021a). The Janssen COVID-19 Vaccine is an Ad26-vectored vaccine; other Ad26-vectored vaccines have acceptable safety profiles when used during pregnancy. Studies in pregnant patients have begun or are planned (ACOG 2021; CDC 2021a).

The risk of severe illness from COVID-19 infection is increased in pregnant patients and pregnancy is one of the high-risk medical conditions defined by the Centers for Disease Control and Prevention (CDC). The decision to vaccinate during pregnancy should be individualized, considering the individual risks of infection and severe disease with the available safety information and benefits of the vaccine. The Janssen COVID-19 Vaccine (adenovirus vector) should not be withheld from pregnant patients who meet the criteria for vaccination based on the Advisory Committee on Immunization Practices recommended priority groups. Patients who are pregnant may choose to be vaccinated and can be offered the Janssen COVID-19 Vaccine (adenovirus vector) (ACOG 2021; CDC 2021a). Vaccination of pregnant patients may be done in any setting authorized to administer the vaccine (ACOG 2021).

Current American College of Obstetricians and Gynecologists and CDC recommendations do not have a product preference; any age-appropriate vaccine may be used for patients who are pregnant and who do not otherwise have contraindications to the vaccine. Thrombosis with thrombocytopenia syndrome (TTS) has been rarely reported with use of the Janssen COVID-19 Vaccine. The risk of TTS is not expected to be increased in pregnant patients and pregnant patients may receive any FDA-approved vaccine; however, because current cases of this adverse event have been primarily observed in females between 18 and 49 years of age, these patients should be made aware that other COVID-19 vaccines are also available (ACOG 2021; CDC 2021a). Information related to COVID-19 vaccines continues to emerge; refer to current guidelines for vaccinating pregnant patients.

Rh_o(D) immune globulin is not expected to interfere with an immune response to the COVID-19 vaccine. Treatment should not be withheld in patients planning to be vaccinated or who recently received the COVID-19 vaccine. There is no recommended minimum interval between COVID-19 vaccination and Rh_o(D) immune globulin administration (ACOG 2021; CDC 2021a).

Data collection to monitor maternal and infant outcomes following exposure to COVID-19 vaccines during pregnancy is ongoing:

Pregnant patients who are vaccinated with the Janssen COVID-19 Vaccine (adenovirus vector) vaccine are encouraged to enroll in the International Registry of Coronavirus Exposure in Pregnancy (IRCEP) (https://c-viper.pregistry.com/).

All patients who become pregnant within 30 days of exposure to a COVID-19 vaccine are encouraged to enroll in the CDC V-SAFE monitoring program (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html) (ACOG 2021; CDC 2021a).

Health care providers are encouraged to enroll pregnant patients exposed to COVID-19 vaccines in the Organization of Teratology Information Specialists (OTIS) pregnancy registry (1-877-311-8972; https://mothertobaby.org/join-study/).

Breast-Feeding Considerations

It is not known if the vaccine virus is present in breast milk.

COVID-19 (adenovirus vector) vaccines are investigational vaccines permitted for use under emergency use authorization (EUA). Patients who were breastfeeding were excluded from the original clinical trials (Folegatti 2020; Sadoff 2021). There are no specific data on the effects of COVID-19 vaccines on the breastfed infant or on milk production/excretion (CDC 2021a).

The Janssen COVID-19 Vaccine should not be withheld from patients who are breastfeeding and meet the criteria for vaccination based on the Advisory Committee on Immunization Practices recommended priority groups. Patients who are breastfeeding may choose to be vaccinated and can be offered the vaccine (ACOG 2021; CDC 2021a). The initiation of breastfeeding does not need to be avoided, and breastfeeding does not need to be discontinued in patients who are vaccinated (ACOG 2021).

Current American College of Obstetricians and Gynecologists and CDC recommendations do not have a product preference; any age-appropriate vaccine may be used for patients who are breastfeeding and who do not otherwise have contraindications to the vaccine. Thrombosis with thrombocytopenia syndrome has been rarely reported with use of the Janssen COVID-19 Vaccine; however, because current cases of this adverse event have been primarily observed in females between 18 and 49 years of age, these patients should be made aware that other COVID-19 vaccines are also available (ACOG 2021; CDC 2021a).

Based on available information, the efficacy of the AstraZeneca COVID-19 Vaccine (adenovirus vector) is not expected to be decreased in lactating patients. Patients who are breastfeeding and meet the criteria for vaccination may be offered the vaccine. Breastfeeding does not need to be discontinued following vaccination (WHO 2021).

Health care providers are encouraged to enroll breastfeeding patients exposed to COVID-19 vaccines in the Organization of Teratology Information Specialists (OTIS) pregnancy registry (1-877-311-8972; https://mothertobaby.org/join-study/).

Adverse Reactions (Significant): Considerations

Janssen:

Hypersensitivity reactions

Local reactions

Systemic reactions (excluding hypersensitivity)

Thrombosis with thrombocytopenia syndrome

AstraZeneca/Covishield (Canadian products):

Local reactions

Systemic reactions

Thrombosis with thrombocytopenia

Adverse Reactions

The following adverse reactions and incidences are derived from the FDA-issued emergency use authorization (EUA) for the Janssen COVID-19 Vaccine and the product information for the AstraZeneca COVID-19 Vaccine (adenovirus vector)/Covishield [Canadian products], unless otherwise specified. Refer to EUA and Canadian product information for respective products for information regarding reporting adverse reactions (AstraZeneca Canadian product monograph; Covishield Canadian product monograph; FDA 2021).

Janssen:

>10%

Gastrointestinal: Nausea (12% to 16%) (See Table 1)

Local: Pain at injection site (33% to 59%) (See Table 2)

Nervous system: Fatigue (30% to 44%) (See Table 3), headache (30% to 44%) (See Table 4)

Neuromuscular & skeletal: Myalgia (24% to 39%) (See Table 5)

Miscellaneous: Fever (3% to 13%) (See Table 6)

1% to 10%: Local: Erythema at injection site (5% to 9%) (See Table 7), swelling at injection site (3% to 7%) (See Table 8)

Frequency not defined:

Cardiovascular: Thromboembolism (including deep vein thrombosis, pulmonary embolism, and transverse sinus thrombosis; unsolicited; data insufficient to determine causal relationship)

Dermatologic: Urticaria

Hypersensitivity: Anaphylaxis, angioedema, hypersensitivity reaction

Nervous system: Seizure (unsolicited; data insufficient to determine causal relationship)

Neuromuscular & skeletal: Asthenia

Otic: Tinnitus (unsolicited; data insufficient to determine causal relationship)

Post-authorization:

Cardiovascular: Arterial thrombosis, portal vein thrombosis, thrombosis (splanchnic-vein)

Hematologic & oncologic: Thrombocytopenia (syndrome in combination with thrombosis [TTS]) (CDC 2021d)

Nervous system: Cerebral hemorrhage, cerebral sinus thrombosis

AstraZeneca/Covishield (Canadian products):

>10%:

Gastrointestinal: Nausea (6% to 24%) (See Table 9)

Local: Pain at injection site (10% to 60%) (See Table 10), tenderness at injection site (32% to 79%) (See Table 11), warm sensation at injection site (4% to 17%) (See Table 12)

Nervous system: Chills (2% to 37%) (See Table 13), fatigue (27% to 65%) (See Table 14), headache (20% to 61%) (See Table 15), malaise (10% to 48%) (See Table 16)

Neuromuscular & skeletal: Arthralgia (7% to 28%) (See Table 17), myalgia (14% to 52%) (See Table 18)

Miscellaneous: Fever (≤12%; feverishness: 4% to 39%) (See Table 19)

1% to 10%:

Gastrointestinal: Vomiting (≤2%) (See Table 20)

Local: Erythema at injection site (≤3%) (See Table 21), induration at injection site (≤3%) (See Table 22), injection site pruritus (2% to 7%) (See Table 23), swelling at injection site (≤3%) (See Table 24)

<1%:

Dermatologic: Diaphoresis, pruritus, skin rash

Gastrointestinal: Decreased appetite (See Table 25)

Nervous system: Dizziness, drowsiness

Frequency not defined:

Nervous system: Facial nerve paralysis (unsolicited; possibly related; 14 days after the second dose)

Neuromuscular & skeletal: Asthenia

Post-authorization:

Cardiovascular: Arterial thrombosis, portal vein thrombosis (Greinacher 2021), pulmonary embolism (Greinacher 2021), thrombosis (splanchnic-vein and other) (Greinacher 2021)

Hematologic & oncologic: Disseminated intravascular coagulation (Greinacher 2021), thrombocytopenia (in combination with thrombosis; also referred to as vaccine-induced [VITT]) (Greinacher 2021; Merchant 2021)

Nervous system: Cerebral hemorrhage (Greinacher 2021; Schultz 2021), cerebral sinus thrombosis (Greinacher 2021; Merchant 2021)

* See Cautions in AHFS Essentials for additional information.

Metabolism/Transport Effects

None known.

Drug Interactions Open Interactions

Acetaminophen: May diminish the therapeutic effect of Vaccines. Management: Consider avoiding routine prophylactic use of acetaminophen before or during vaccine administration when possible.

Acetaminophen is still recommended to treat fevers and/or pain that occurs after vaccination. *Risk D: Consider therapy modification*

Antihistamines: May enhance the adverse/toxic effect of COVID-19 Vaccine (Adenovirus Vector). Specifically, the prophylactic use of antihistamines may mask symptoms and delay diagnosis and management of anaphylaxis. Management: Do not administer antihistamines to COVID-19 adenovirus vector vaccine recipients prior to vaccination to prevent allergic reactions. Use may mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis. *Risk D: Consider therapy modification*

COVID-19-Directed Monoclonal Antibodies: May diminish the therapeutic effect of COVID-19 Vaccine (Adenovirus Vector). Management: Postpone administration of the vaccine until at least 90 days after treatment with COVID-19 directed monoclonal antibody products to minimize any possible interference with immune response to the vaccine. *Risk D: Consider therapy modification*

Immunosuppressants: May diminish the therapeutic effect of COVID-19 Vaccine (Adenovirus Vector). *Risk C: Monitor therapy*

Propacetamol: May diminish the therapeutic effect of Vaccines. Management: Consider avoiding routine prophylactic use of propacetamol before or during vaccine administration when possible. Propacetamol is still recommended to treat fevers and/or pain that occurs after vaccination. *Risk D: Consider therapy modification*

Test Interactions

COVID-19 vaccines will not affect results of SARS-CoV-2 viral testing (antigen or nucleic acid amplification tests). A test that detects antibody (IgG and/or IgM) to the SARS-CoV-2 nucleocapsid protein should be used to assess for prior infection in COVID-19–vaccinated individuals. A positive SARS-CoV-2 antibody test that detects antibody (IgG and/or IgM) to the SARS-CoV-2 spike protein may indicate either prior infection or vaccination (CDC 2021a).

Inactive vaccines do not interfere with tuberculosis (TB) test results, and there are currently no data regarding the impact of COVID-19 vaccines on TB tests, including tuberculin skin tests and interferon gamma release assays. If TB testing is required for policy (eg, onboarding or entry into a facility), testing may be performed prior to vaccination or at the same encounter. If vaccination has already occurred, defer TB testing for ≥4 weeks following completion of vaccination; if testing cannot be deferred, consider retesting individuals with negative results ≥4 weeks following completion of vaccination. If TB testing is required for medical diagnosis, consider delaying TB testing until ≥4 weeks after completion of COVID-19 vaccination; if testing cannot be delayed, patients with negative results should be considered for retesting ≥4 weeks following completion of vaccination. For more information, see CDC recommendations (CDC 2021a).

Monitoring Parameters

Monitor for hypersensitivity and syncope for 15 minutes following administration (ACIP [Kroger 2021]). Observe patients for 30 minutes after vaccination in patients with the following: a history of anaphylaxis (due to any cause); a history of an allergic reaction of any severity within 4 hours of receipt of a vaccine or injectable therapy; or a person with a contraindication to a different type of COVID-19 vaccine (CDC

2021a). If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.

Antibody testing to assess for SARS-CoV-2 immunity following vaccination is not currently recommended (CDC 2021a).

Advanced Practitioners Physical Assessment/Monitoring

Ensure patient is monitored for 15 minutes following administration, or 30 minutes for high-risk individuals.

Nursing Physical Assessment/Monitoring

Monitor all patients for 15 minutes following administration for symptoms of reaction. Monitor high-risk patients for 30 minutes following administration (patients with a history of allergic reactions to previous vaccines, anaphylaxis for any reason, or contraindications to different COVID-19 vaccines). For patients with high-risk for bleeding, apply pressure to injection site for 2 minutes following injection.

Product Availability

In February 2021, the FDA and Health Canada authorized the use of Johnson & Johnson's Janssen COVID-19 Vaccine (adenovirus vector) and Health Canada permitted use of the AstraZeneca COVID-19 Vaccine (adenovirus vector) and Covishield (manufactured by Serum Institute of India under license from AstraZeneca) under an interim order for use for the COVID-19 pandemic.

Dosage Forms: US

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Suspension, Intramuscular [preservative free]:

Janssen COVID-19 Vaccine: 50 billion viral particles per 0.5 mL (2.5 mL) [contains alcohol, usp, polysorbate 80]

Dosage Forms: Canada

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution, Intramuscular:

Generic: 50 billion viral particles per 0.5 mL (4 mL, 5 mL)

Suspension, Intramuscular:

Generic: 50 billion viral particles per 0.5 mL (2.5 mL)

Generic Available (US)

Yes

Mechanism of Action

Promotes active immunity against COVID-19 caused by SARS-CoV-2 virus. The adenovirus vector in the vaccine is a recombinant, replication-incompetent adenovirus vector that expresses the SARS-CoV-2 spike (S) antigen without virus propagation. The vaccine then elicits an immune response to the S antigen, which contributes to protection against COVID-19 disease (FDA 2021; AstraZeneca Canadian product monograph). The Janssen vaccine contains a human adenovirus type 26 (Ad26) vector (FDA 2021). The AstraZeneca vaccine and Covishield [Canadian products] contain a chimpanzee adenovirus (ChAdOx1) vector (AstraZeneca Canadian product monograph; Covishield Canadian product monograph).

Efficacy:

Janssen COVID-19 Vaccine: Vaccine efficacy was ~67% for moderate to severe/critical laboratory-confirmed COVID-19 from day 14 onward postvaccination; vaccine efficacy was ~77% for severe/critical COVID-19 from day 14 onward postvaccination and ~85% from day 28 onward postvaccination (FDA 2021).

AstraZeneca COVID-19 Vaccine [Canadian product]: Vaccine efficacy was ~60% against symptomatic COVID-19 disease following completion of the 2-dose series (AstraZeneca Canadian product monograph).

Pharmacodynamics/Kinetics

Onset of action:

Janssen COVID-19 Vaccine: The vaccine efficacy values of ~67% for moderate to severe/critical laboratory-confirmed COVID-19 and ~77% for severe/critical COVID-19 is based on disease cases occurring from day 14 onward after the single dose. Vaccine efficacy of ~85% for severe/critical COVID-19 was based on cases occurring from day 28 onward after the single dose (FDA 2021).

AstraZeneca COVID-19 Vaccine [Canadian product]: Protection was shown to begin ~3 weeks after the first dose (AstraZeneca Canadian product monograph).

Duration: Data are currently insufficient to determine; clinical trials and epidemiologic surveillance are ongoing to evaluate break-through infections in vaccine recipients.

Dental: Local Anesthetic/Vasoconstrictor Precautions

No information available to require special precautions.

Dental: Effects on Dental Treatment

No significant effects or complications reported.

Dental: Effects on Bleeding

No information available to require special precautions.

Related Information

- Centers for Disease Control and Prevention (CDC) and Other Links
- COVID-19 Vaccine Tracker

- Immunization Administration Recommendations

Index Terms

Ad26.COV2.S; AstraZeneca COVID-19 Vaccine; AZD1222; ChAdOx1; ChAdOx1-S; Coronavirus Disease 2019 Vaccines; COVID-19 Vaccines; COVID19 Vaccines; Covishield; CV19 Vaccines; Janssen COVID-19 Vaccine; Johnson & Johnson COVID-19 Vaccine; SARS-CoV-2 (Adenovirus Vector) Vaccines; SARS-CoV-2 Vaccines; Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine

FDA Approval Date

February 27, 2021

References

Alade SL, Brown RE, Paquet A. Polysorbate 80 and E-Ferol toxicity. *Pediatrics*. 1986;77(4):593-597.[PubMed 3960626]

American College of Obstetricians and Gynecologists (ACOG). Vaccinating pregnant and lactating patients against COVID-19. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19. Updated April 28, 2021. Accessed April 29, 2021.

AstraZeneca COVID-19 vaccine (COVID-19 vaccine [ChAdOx1-S recombinant]) [product monograph]. Mississauga, Ontario, Canada: AstraZeneca Canada Inc; April 23, 2021.

Becker AS, Perez-Johnston R, Chikarmane SA, et al. Multidisciplinary recommendations regarding post-vaccine adenopathy and radiologic imaging: Radiology Scientific Expert Panel. *Radiology*. Published online February 24, 2021. doi:10.1148/radiol.2021210436[PubMed 33625298]

Blumenthal KG, Peter JG, Trubiano JA, Phillips EJ. Antibiotic allergy. *Lancet*. 2019;393(10167):183-198. doi:10.1016/S0140-6736(18)32218-9[PubMed 30558872]

Centers for Disease Control and Prevention (CDC). Cases of cerebral venous sinus thrombosis with thrombocytopenia after receipt of the Johnson & Johnson COVID-19 Vaccine. https://emergency.cdc.gov/han/2021/han00442.asp. Updated March 5, 2021c. Accessed March 8, 2021.

Centers for Disease Control and Prevention (CDC). Interim clinical considerations for use of COVID-19 vaccines currently authorized in the United States. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Updated April 27, 2021a. Accessed May 6, 2021.

Centers for Disease Control and Prevention (CDC). Interim public health recommendations for fully vaccinated people. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html. Updated April 27, 2021b. Accessed May 6, 2021.

Centers for Disease Control (CDC). Unusual syndrome with fatalities among premature infants: association with a new intravenous vitamin E product. *MMWR Morb Mortal Wkly Rep*. 1984;33(14):198-199. http://www.cdc.gov/mmwr/preview/mmwrhtml/00000319.htm[PubMed 6423951]

Centers for Disease Control (CDC). Updated recommendations from the advisory committee on immunization practices for use of the Janssen (Johnson & Johnson) COVID-19 Vaccine after reports of thrombosis with thrombocytopenia syndrome among vaccine recipients United States. *MMWR Morb Mortal Wkly Rep*. https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm. Updated April 27, 2021d. 2021;70:651-656. doi: http://dx.doi.org/10.15585/mmwr.mm7017e4

COVID-19 Vaccine AstraZeneca (COVID-19 vaccine (ChAdOx1-S [recombinant])) [UK prescribing information]. AstraZeneca; February 22, 2021.

Covishield COVID-19 vaccine (ChAdOx1-S [recombinant]) [product monograph]. Mississauga, Ontario, Canada: Verity Pharmaceutics Inc; April 23, 2021.

Cross GB, Moghaddas J, Buttery J, Ayoub S, Korman TM. Don't aim too high: avoiding shoulder injury related to vaccine administration. *Aust Fam Physician*. 2016;45(5):303-306.[PubMed 27166466]

Dooling K, Marin M, Wallace M, et al. The Advisory Committee on Immunization Practices' updated interim recommendation for allocation of COVID-19 vaccine - United States, December 2020. *MMWR Morb Mortal Wkly Rep*. 2021;69(5152):1657-1660. doi:10.15585/mmwr.mm695152e2[PubMed 33382671]

Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' interim recommendation for allocating initial supplies of COVID-19 vaccine - United States, 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(49):1857-1859. doi:10.15585/mmwr.mm6949e1[PubMed 33301429]

Folegatti PM, Ewer KJ, Aley PK, et al; Oxford COVID Vaccine Trial Group. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. *Lancet*. 2020;396(10249):467-478. doi:10.1016/S0140-6736(20)31604-4[PubMed 32702298]

Foster SL, Davis MV. Vaccine administration: preventing serious shoulder injuries. *J Am Pharm Assoc (2003)*. 2013;53(1):102-103. doi:10.1331/JAPhA.2013.13503[PubMed 23636163]

Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA, Eichinger S. Thrombotic thrombocytopenia after ChAdOx1 nCov-19 vaccination. *N Engl J Med*. Published online April 9, 2021. doi:10.1056/NEJMoa2104840[PubMed 33835769]

Health Canada. Recommendations on the use of COVID-19 vaccines. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html. Updated January 12, 2021. Accessed March 1, 2021.

Health Canada. Guidance on the prioritization of initial doses of COVID-19 vaccine(s). https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-prioritization-initial-doses-covid-19-vaccines.html. Updated December 18, 2020. Accessed March 1, 2021.

Isaksson M, Jansson L. Contact allergy to Tween 80 in an inhalation suspension. *Contact Dermatitis*. 2002;47:313. doi:10.1034/j.1600-0536.2002.4705104.x[PubMed 12534540]

Janssen COVID-19 Vaccine (SARS-CoV-2 Vaccine [Ad26.COV2.S, recombinant]) [product monograph]. Toronto, Ontario, Canada: Janssen Inc; April 23, 2021.

Janssen manufacturer communication March 8, 2021. Data on file.

Kroger A, Bahta L, Hunter P. General best practice guidelines for immunization: best practices guidance of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed April 30, 2021.

Lucente P, Iorizzo M, Pazzaglia M. Contact sensitivity to Tween 80 in a child. *Contact Dermatitis*. 2000;43:172.[PubMed 10985636]

Merchant HA. CoViD vaccines and thrombotic events: EMA issued warning to patients and healthcare professionals. *J Pharm Policy Pract*. 2021;14(1):32. doi:10.1186/s40545-021-00315-w[PubMed 33761987]

National Institute for Health and Care Excellence (NICE). Drug allergy: diagnosis and management. Clinical guideline 183.https://www.nice.org.uk/guidance/cg183. Published September 3, 2014. Accessed March 2, 2021.

Oliver SE, Gargano JW, Scobie H, et al. The Advisory Committee on Immunization Practices' interim recommendation for use of Janssen COVID-19 Vaccine — United States, February 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(9):329-332. https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7009e4-H.pdf.

Sadoff J, Le Gars M, Shukarev G, et al. Interim results of a phase 1-2a trial of Ad26.COV2.S Covid-19 Vaccine. *N Engl J Med*. Published online January 13, 2021. doi:10.1056/NEJMoa2034201[PubMed 33440088]

Schultz NH, Sørvoll IH, Michelsen AE, et al. Thrombosis and thrombocytopenia after ChAdOx1 nCoV-19 vaccination. *N Engl J Med*. Published online April 9, 2021. doi:10.1056/NEJMoa2104882[PubMed 33835768]

Shelley WB, Talanin N, Shelley ED. Polysorbate 80 hypersensitivity. *Lancet*. 1995;345(8980):1312-1313. doi:10.1016/s0140-6736(95)90963-x[PubMed 7746084]

US Food and Drug Administration (FDA). Fact sheet for healthcare providers administering vaccine: Emergency Use Authorization (EUA) of the Janssen COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). https://www.fda.gov/media/146304/download. Updated April 23, 2021. Accessed May 5, 2021.

Voysey M, Clemens SAC, Madhi SA, et al; Oxford COVID Vaccine Trial Group. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *Lancet*. 2021a;397(10269):99-111. doi:10.1016/S0140-6736(20)32661-1[PubMed 33306989]

Voysey M, Clemens SAC, Madhi SA, et al. Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials. *Lancet.* 2021b;397(10277):881-891. doi.org/10.1016/S0140-6736(21)00432-3[PubMed 33617777]

World Health Organization (WHO). Interim recommendations for use of the AZD122 (ChAdOx1-S [recombinant] vaccine against COVID-19 developed by Oxford University and AstraZeneca. https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1. Updated April 21, 2021. Accessed April 28, 2021.

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