

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

JCOVDEN™

COVID-19 Vaccine (Ad26.COVS-S [recombinant])

Read this carefully before you start taking **JCOVDEN**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **JCOVDEN**.

What is **JCOVDEN** used for?

JCOVDEN is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus. JCOVDEN can be given to protect people aged 18 years and older.

How does **JCOVDEN** work?

JCOVDEN uses a recombinant, replication-incompetent human adenovirus type 26 vector to stimulate the body's natural defenses (immune system) and produce its own protection (antibodies) against the virus.

The vaccine is given as a single dose, by injection with a needle, usually in the upper arm.

You cannot get COVID-19 from this vaccine.

As with any vaccine, JCOVDEN may not fully protect all those who receive it. Even after you have had the vaccine, continue to follow the recommendations of local public health officials to prevent spread of COVID-19.

What are the ingredients in **JCOVDEN**?

Medicinal ingredients: recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein 5×10^{10} virus particles (VP)*

* Produced in the PER.C6® TetR Cell Line and by recombinant DNA technology.

Non-medicinal ingredients:

- 2-hydroxypropyl-β-cyclodextrin (HBCD)
- Citric acid monohydrate
- Ethanol
- Hydrochloric acid
- Polysorbate-80
- Sodium chloride
- Sodium hydroxide
- Trisodium citrate dihydrate
- Water for injection

JCOVDEN comes in the following dosage forms:

Colourless to slightly yellow, clear to very opalescent suspension provided in a multiple dose vial of 5 doses of 0.5 mL, each dose containing 5×10^{10} virus particles of adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein.

Do not use JCOVDEN if:

- you have previously had a severe allergic reaction to any of the active substance(s) or any of the other ingredients of JCOVDEN
- you have ever had a severe allergic reaction after a dose of any other 'adenovirus-based vaccine'
- you have ever had a diagnosis of capillary leak syndrome, a very rare, serious condition where fluid (plasma) leaks out of the small blood vessels into the body tissues. (see **What are the possible side effects from using JCOVDEN**).
- you currently have symptoms that could be due to COVID-19. Talk to your healthcare professional about your symptoms and getting a COVID-19 test. Your healthcare professional will advise you when you are able to receive the vaccine.
- you have had a blood clot occurring at the same time as having low levels of blood platelets (thrombosis with thrombocytopenia syndrome, TTS) after receiving JCOVDEN or any other adenovirus-vectored COVID-19 vaccine (see **What are the possible side effects from using JCOVDEN**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JCOVDEN. Talk about any health conditions or problems you may have, including if you:

- Have ever had a severe allergic reaction after any type of vaccine
- Have had a history of venous sinus thrombosis in the brain with low platelets (thrombocytopenia), a history of TTS, a history of heparin-induced thrombocytopenia (HIT), or a history of very low platelets (immune thrombocytopenia)
- Have been told you are at risk of blood clots
- Have previously experienced episodes of capillary leak syndrome.
- Have a weakened immune system due to a medical condition or are on a medicine that affects your immune system
- Are pregnant, think you may be pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have a bleeding problem, bruise easily or use a blood thinning medication
- Have a high fever or severe infection
- Have any serious illness
- Have ever fainted following any needle injection

Do not drive or use machines if you are feeling unwell after vaccination.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given JCOVDEN.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There is no information on the use of JCOVDEN with other vaccines. Tell your healthcare professional if you have recently taken or might take any other vaccine.

How JCOVDEN is given:

- Your doctor, pharmacist, or nurse will inject the vaccine into a muscle (intramuscular injection) - usually in your upper arm.
- During and after each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for at least 15 minutes to monitor for signs of an allergic reaction.

Usual dose:

A single dose (0.5 mL) primary vaccination of JCOVDEN should be administered in individuals 18 years of age and older. A booster dose of JCOVDEN may be given at least 2 months after the primary vaccination in individuals 18 years of age and older.

Overdose:

In the event of suspected overdose with JCOVDEN, contact your regional poison control centre.

What are possible side effects from using JCOVDEN?

Like all vaccines, JCOVDEN can cause side effects. In clinical studies with the vaccine, most of the side effects, happened within 2 days of getting the injection, were mild to moderate in intensity, and resolved within 1-2 days.

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

The following side effects may happen with this vaccine:

Very common (may affect more than 1 in 10 people):

- headache
- nausea
- muscle aches
- pain at injection site
- feeling very tired (fatigue)

Common (may affect up to 1 in 10 people):

- fever
- redness at injection site
- swelling at injection site
- chills
- joint pain

Uncommon (may affect up to 1 in 100 people):

- rash
- muscle weakness
- arm or leg pain
- feeling weak

- feeling generally unwell
- dizziness

Rare (may affect up to 1 in 1000 people):

- allergic reaction, including hives

Should you develop any serious symptoms or symptoms that could be an allergic reaction, seek medical attention immediately. Symptoms of an allergic reaction include:

- hives (bumps on the skin that are often very itchy)
- swelling of the face, tongue or throat
- difficulty breathing

Very rare (may affect up to 1 in 10000 people):

- persistent ringing in the ears (tinnitus)
 - diarrhea
 - unusual feeling in the skin, such as a persistent tingling feeling (paresthesia)
 - swollen lymph nodes (lymphadenopathy)
 - vomiting
 - decreased feeling or sensitivity, especially in the skin (hypoesthesia)
 - serious nerve inflammation, which may cause paralysis and difficulty breathing (Guillain-Barré syndrome, Transverse Myelitis)
 - unexplained bleeding
- **Thrombosis with thrombocytopenia syndrome (TTS):** A combination of blood clots and low level of platelets, in some cases together with bleeding, has been observed very rarely in unusual locations (e.g., brain, liver) following vaccination with JCOVDEN. Seek medical attention right away if any of the following symptoms occur within the first month following vaccination:
 - new severe headaches, worsening or persistent headaches; blurred vision, confusion or seizures
 - shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
 - unexplained skin bruising or pinpoint round spots under the skin beyond the site of vaccination
 - **Venous thromboembolism (VTE):** Blood clots in veins have been observed rarely following vaccination with JCOVDEN. In individuals with a pre-existing increased risk for thromboembolism, the possible increased risk of VTE with vaccine use should be considered.
 - **Capillary leak syndrome (CLS):** Very rare cases of CLS have been reported following vaccination with JCOVDEN. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek medical attention right away if you develop these symptoms in the days following vaccination.
 - **Guillain-Barré syndrome (GBS):** GBS is a neurological disorder where inflammation of peripheral nerves causes rapid muscle weakness and can sometimes lead to paralysis. This has been reported very rarely after vaccination with JCOVDEN. Seek immediate medical

attention if you develop weakness and paralysis in the extremities that can progress to the chest and face.

- **Transverse Myelitis (TM):** TM is a neurological disorder where the inflammation of the spinal cord causes weakness in the arms or legs, sensory symptoms (such as tingling, numbness, pain or loss of pain sensation) or problems with bladder or bowel function. This has been reported very rarely after vaccination with JCOVDEN. Seek immediate medical attention if you develop weakness, sensory symptoms or problems with bladder or bowel function.
- **Immune thrombocytopenia:** Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have been reported very rarely, usually within the first four weeks following vaccination with JCOVDEN.

These may not be all the possible side effects of JCOVDEN. If you experience any side effects not listed here, tell your healthcare professional.

Tell your doctor, pharmacist or nurse if you have any side effects that bother you, interfere with your daily activities, or do not go away.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Janssen Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

Storage:

Your doctor, pharmacist or nurse is responsible for storing this vaccine and disposing of any unused product correctly.

Keep JCOVDEN out of reach and sight of children.

If you want more information about JCOVDEN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.janssen.com/canada), or by calling Janssen Inc. at: 1-800-567-3331.

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