Package leaflet: Information for the user

JCOVDEN suspension for injection
COVID-19 vaccine (Ad26.COV2-S [recombinant])

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are vaccinated because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What JCOVDEN is and what it is used for

JCOVDEN is a vaccine used for preventing COVID-19 caused by the SARS-CoV-2 virus.

JCOVDEN is given to adults aged 18 years and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and specialised white blood cells that work against the virus, so giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you are given JCOVDEN

Do not have the vaccine if
- You are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).
- 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 any COVID-19 vaccine.
- You have a previous diagnosis of capillary leak syndrome, (a condition causing fluid leakage from small blood vessels).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given JCOVDEN if:
- you have ever had a severe allergic reaction after injection of any other vaccine,
- you have ever fainted following any needle injection,
- you have a severe infection with a high temperature (over 38°C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold,
- you have a problem with bleeding or bruising, or if you are taking an anticoagulant medicine (to prevent blood clots),

- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines),
- you have risk factors for blood clots in your veins (venous thromboembolism (VTE)).

As with any vaccine, vaccination with JCOVDEN may not fully protect all those who receive it. It is not known how long you will be protected.

Blood disorders
- ***Venous thromboembolism:*** Blood clots in veins (venous thromboembolism (VTE)) have been observed rarely following vaccination with JCOVDEN.
- ***Thrombosis with thrombocytopenia syndrome:*** A combination of blood clots and low levels of 'platelets' in the blood has been observed very rarely following vaccination with JCOVDEN. This includes severe cases with blood clots, including in unusual locations, such as the brain, liver, bowel and spleen in some cases in combination with bleeding. These cases mostly occurred within the first three weeks following vaccination and in individuals below 60 years of age. Fatal outcome has been reported.
- ***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.

Seek immediate medical attention, if you experience symptoms that may be signs of blood disorders: severe or persistent headaches, seizures (fits), mental status changes or blurred vision, unexplained bleeding, unexplained skin bruising beyond the site of vaccination which appear a few days after vaccination, pinpoint round spots beyond the site of vaccination, develop shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain. Inform your healthcare provider that you have recently received JCOVDEN.

Capillary leak syndrome
Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with JCOVDEN. At least one affected patient 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 immediate medical attention if you develop these symptoms in the days following vaccination.

Neurological disorders
- ***Guillain-Barré syndrome***
  Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face (Guillain-Barré syndrome, GBS). This has been reported very rarely after vaccination with JCOVDEN.
- ***Inflammation of the spinal cord (transverse myelitis)***
  Seek immediate medical attention if you develop 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.

Myocarditis and pericarditis
There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with JCOVDEN (see section 4). These conditions have occurred more often in males less than 40 years of age. In most of these people, symptoms began within 14 days following vaccination. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine: chest pain; shortness of breath; feelings of having a fast-beating, fluttering, or pounding heart.

Risk of severe adverse events after a booster dose
The risk of severe adverse events (such as blood disorders including thrombosis with thrombocytopenia syndrome, CLS, GBS, myocarditis and pericarditis) after a booster dose of JCOVDEN is unknown.

Children and adolescents
JCOVDEN is not recommended for children aged below 18 years. Currently there is not enough information available on the use of JCOVDEN in children and adolescents younger than 18 years of age.

Other medicines and JCOVDEN
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or vaccines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

Driving and using machines
Some of the side effects of JCOVDEN listed in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

JCOVDEN contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose of 0.5 mL, that is to say essentially 'sodium-free'.

JCOVDEN contains ethanol
This medicine contains 2 mg of alcohol (ethanol) in each dose of 0.5 mL. The amount of ethanol in this medicine is equivalent to less than 1 mL beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How JCOVDEN is given

Your doctor, pharmacist or nurse will inject the vaccine into the muscle - usually in the upper arm.

How much vaccine will you receive

A single-dose primary vaccination (0.5 mL) of JCOVDEN is injected.

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

JCOVDEN may be administered as a single booster dose to eligible individuals 18 years of age and older who have completed primary vaccination with an mRNA COVID-19 vaccine or an adenoviral vector-based COVID-19 vaccine. The dosing interval for the booster dose is the same as that authorised for a booster dose of the vaccine used for primary vaccination.

After the injection your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, JCOVDEN can cause side effects, although not everybody gets them. Most of the side effects occur in the 1 or 2 days of getting the vaccination.

Get medical attention immediately if within 3 weeks of vaccination you get any of the following symptoms:

- experience severe or persistent headaches, blurred vision, mental status changes or seizures (fits);
- develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain;
- notice unusual skin bruising or pinpoint round spots beyond the site of vaccination.

Get **urgent** medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain

The following side effects can happen with this vaccine.

Very common: may affect more than 1 in 10 people

- headache
- nausea
- muscle aches
- pain where the injection is given
- feeling very tired

Common: may affect up to 1 in 10 people

- redness where the injection is given
- swelling where the injection is given
- chills
- fever

Uncommon: may affect up to 1 in 100 people

- rash
- joint pain
- muscle weakness
- arm or leg pain
- feeling weak
- feeling generally unwell
- cough
- sneezing
- sore throat
- back pain
- tremor
- diarrhoea
- vomiting
- dizziness

Rare: may affect up to 1 in 1000 people

- allergic reaction
- hives
- excessive sweating
- swollen lymph nodes (lymphadenopathy)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)

- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- persistent ringing in the ears (tinnitus)
- blood clots in veins (venous thromboembolism (VTE))
- temporary, usually one-sided facial drooping (including Bell's palsy)

Very Rare: may affect up to 1 in 10000 people
- blood clots often in unusual locations (e.g., brain, liver, bowel, spleen) in combination with low level of blood platelets
- serious nerve inflammation, which may cause paralysis and difficulty breathing (Guillain-Barré syndrome (GBS))

Unknown (cannot be estimated from the available data)
- severe allergic reaction
- capillary leak syndrome (a condition causing fluid leakage from small blood vessels)
- low levels of blood platelets (immune thrombocytopenia) that can be associated with bleeding (see section 2, 'Blood Disorders')
- inflammation of the spinal cord (transverse myelitis)
- inflammation of small blood vessels (small vessel vasculitis) with skin rash or small red or purple, flat, round spots under the skin's surface or bruising
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis)

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store JCOVDEN

Keep this vaccine out of the sight and reach of children.

Store vial in the original carton to protect from light.

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

Store and transport frozen at -25°C to -15°C. The expiry date for storage at -25°C to -15°C is printed on the vial and outer carton after "EXP".

The vaccine comes ready to use once thawed. The vaccine may be supplied frozen at -25°C to -15°C or thawed at 2°C to 8°C.

When stored frozen at -25°C to -15°C, the vaccine can be thawed either at 2°C to 8°C or at room temperature:
- at 2°C to 8°C: a carton of 10 or 20 vials will take approximately 13 hours to thaw, and a single vial will take approximately 2 hours to thaw.
- at room temperature (maximally 25°C): a carton of 10 or 20 vials will take approximately 4 hours to thaw, and a single vial will take approximately 1 hour to thaw.

Do not re-freeze vaccine once thawed.

The vaccine can also be stored in a refrigerator or transported at 2°C to 8°C for a single period of up to 11 months, not exceeding the original expiry date (EXP). Upon moving the product to 2°C to 8°C

storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out. The vaccine can also be transported at 2°C to 8°C as long as the appropriate storage conditions (temperature, time) are applied.

6. Contents of the pack and other information

What JCOVDEN contains

- The active substance is Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein*(Ad26.COV2-S) not less than 8.92 $\log_{10}$ infectious units (Inf.U) in each 0.5 mL dose.
  * Produced in the PER.C6 TetR Cell Line and by recombinant DNA technology.

  This product contains genetically modified organisms (GMOs).

- The other ingredients (excipients) are:
  - 10 vial pack: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid (for pH-adjustment), polysorbate-80, sodium chloride, sodium hydroxide (for pH-adjustment), trisodium citrate dihydrate, water for injections (see section 2 JCOVDEN contains sodium and JCOVDEN contains ethanol).
  - 20 vial pack: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid (for-pH adjustment), polysorbate-80, sodium chloride, sodium hydroxide (for pH-adjustment), water for injections (see section 2 JCOVDEN contains sodium and JCOVDEN contains ethanol).

What JCOVDEN looks like and contents of the pack
Suspension for injection (injection). The suspension is colorless to slightly yellow, clear to very opalescent suspension (pH 6-6.4).

2.5 mL suspension in a multi-dose vial (type I glass) with a rubber stopper, aluminium crimp and blue plastic cap. Each vial contains 5 doses of 0.5 mL.

JCOVDEN is available in a pack containing 10 or 20 multi-dose vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

Manufacturer
Janssen Biologics B.V.
Einsteinweg 101
2333 CB Leiden
The Netherlands

Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium

For any additional information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Malta
AM MANGION LTD
Tel: +356 2397 6000

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Scan the QR code below (also available on the carton and QR card) to get the package leaflet in different languages.

Or visit the URL: www.covid19vaccinejanssen.com

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

- As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of JCOVDEN. Individuals should be monitored by a healthcare professional after vaccination for at least 15 minutes.
- JCOVDEN must not be mixed with other medicinal products or diluted in the same syringe.
- JCOVDEN must not be administered by intravascular, intravenous, subcutaneous or intradermal injection under any circumstances.
- Immunisation should be carried out by intramuscular injection only, preferably in the deltoid muscle of the upper arm.
- Syncope (fainting) may occur with any injection, including JCOVDEN. Procedures should be in place to prevent injury from falling and to manage syncopal reactions.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Instructions for administration and handling

This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

Store and transport frozen at -25°C to -15°C. The expiry date for storage at -25°C to -15°C is printed on the vial and outer carton after “EXP”.

The vaccine comes ready to use once thawed. The vaccine may be supplied frozen at -25°C to -15°C or thawed at 2°C to 8°C.

When stored frozen at -25°C to -15°C, the vaccine can be thawed either at 2°C to 8°C or at room temperature:

- at 2°C to 8°C: a carton of 10 or 20 vials will take approximately 13 hours to thaw, and a single vial will take approximately 2 hours to thaw.
- at room temperature (maximally 25°C): a carton of 10 or 20 vials will take approximately 4 hours to thaw, and a single vial will take approximately 1 hour to thaw.

Do not re-freeze vaccine once thawed.

The vaccine can also be stored in a refrigerator or transported at 2°C to 8°C for a single period of up to 11 months, not exceeding the original expiry date (EXP). Upon moving the product to 2°C to 8°C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out. The vaccine can also be transported at 2°C to 8°C as long as the appropriate storage conditions (temperature, time) are applied.

Keep the vials in the original carton in order to protect from light and to record the expiry for the different storage conditions, if applicable.

JCOVDEN is a colorless to slightly yellow, clear to very opalescent suspension (pH 6-6.4). The vaccine should be inspected visually for particulate matter and discoloration prior to administration. The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering prior to administration. If any of these should exist, do not administer the vaccine.

Before administering a dose of vaccine, swirl the vial gently in an upright position for 10 seconds. Do not shake. Use a sterile needle and sterile syringe to extract a single-dose of 0.5 mL from the multi-dose vial and administer by intramuscular injection only into the deltoid muscle of the upper arm.

A maximum of 5 doses can be withdrawn from the multi-dose vial. Discard any remaining vaccine in the vial after 5 doses have been extracted.

After the first puncture of the vial the vaccine (vial) can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximum 25°C) for a single period of up to 3 hours. Discard if vaccine is not used within this time. After the first puncture of the vial, record the date and time the vial should be discarded on each vial label.

Disposal

Any unused vaccine or waste material should be disposed of in compliance with the local guidance for pharmaceutical waste. Potential spills should be disinfected with agents with viricidal activity against adenovirus.