

# COVID-19 Vaccine Janssen

This vaccine has **provisional approval** in Australia for preventing COVID-19 caused by the SARS-CoV-2 virus in adults aged 18 years and older. This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this vaccine, speak to your doctor or pharmacist.

▼ This vaccine is new. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I receiving COVID-19 Vaccine Janssen?

COVID-19 Vaccine Janssen contains the active ingredient Ad26.COVS.2.S.

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

COVID-19 Vaccine Janssen is given to adults aged 18 years and older.

For more information, see Section [1. Why am I receiving COVID-19 Vaccine Janssen?](#) in the full CMI.

### 2. What should I know before I receive COVID-19 Vaccine Janssen?

Do not receive if you have ever had an allergic reaction to any of the ingredients listed at the end of the full CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

COVID-19 Vaccine Janssen should not be given to children under 18 years.

For more information, see Section [2. What should I know before I receive COVID-19 Vaccine Janssen?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with COVID-19 Vaccine Janssen and affect how it works.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I receive COVID-19 Vaccine Janssen?

Your doctor, pharmacist or nurse will give the vaccine as an injection into the muscle (usually in the upper arm).

You will receive one injection.

More information can be found in Section [4. How do I receive COVID-19 Vaccine Janssen?](#) in the full CMI.

### 5. What should I know after receiving COVID-19 Vaccine Janssen?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• <b>Call your doctor straight away if you:</b> Notice signs of severe allergic reaction which include feeling faint, dizzy or light-headed, changes in your heartbeat, difficulty breathing, shortness of breath, wheezing, rash or hives, itching, swelling of the face, lips, throat or tongue, nausea or vomiting, or stomach pain</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how COVID-19 Vaccine Janssen affects you. Some of the side effects of COVID-19 Vaccine Janssen listed in section 6 may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines. Do not drive or use machines if you are feeling unwell after vaccination.</li></ul>

For more information, see Section [5. What should I know after receiving COVID-19 Vaccine Janssen?](#) in the full CMI.

### 6. Are there any side effects?

Most of the side effects are mild to moderate in intensity and resolved within 1-2 days.

The common side effects are: headache, nausea, muscle aches, pain, redness or swelling where the injection is given, feeling very tired, fever, chills, cough, joint pain.

Very rare serious side effects are blood clots: symptoms may include severe or persistent headaches, seizures (fits), mental status changes or blurred vision, unexplained skin bruising beyond the site of vaccination which appear a few days after vaccination,

pinpoint round spots beyond the site of vaccination, shortness of breath, chest pain, leg pain, leg swelling, persistent abdominal pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This vaccine 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# COVID-19 Vaccine Janssen

**Active ingredient(s):** Ad26.COV2.S

This vaccine has **provisional approval** in Australia for preventing COVID-19 caused by the SARS-CoV-2 virus in adults aged 18 years and older. This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed

## Consumer Medicine Information (CMI)

This CMI provides important information about using COVID-19 Vaccine Janssen. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COVID-19 Vaccine Janssen.**

**Where to find information in this CMI:**

- [1. Why am I receiving COVID-19 Vaccine Janssen?](#)
- [2. What should I know before I receive COVID-19 Vaccine Janssen?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I receive COVID-19 Vaccine Janssen?](#)
- [5. What should I know after receiving COVID-19 Vaccine Janssen?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I receiving COVID-19 Vaccine Janssen?

**COVID-19 Vaccine Janssen contains the active ingredient Ad26.COV2.S.**

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

COVID-19 Vaccine Janssen is given to adults aged 18 years and older.

COVID-19 Vaccine Janssen 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 should I know before I receive COVID-19 Vaccine Janssen?

### Warnings

**Do not receive COVID-19 Vaccine Janssen if:**

- you have previously had a severe allergic reaction to the active substance, or any of the ingredients listed at the end of this CMI. Always check the ingredients to make sure you can receive this vaccine

### Talk to your doctor, pharmacist or nurse if:

- you have ever had a severe allergic reaction after injection of any other vaccine,
- you have previously had a blood clot in the brain (venous sinus thrombosis) with low platelets, blood cells that help your body stop bleeding (thrombocytopenia); or a history of heparin-induced thrombocytopenia (HIT)
- 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 been given another injection or are taking any other medicines or vaccines (see Section 3).

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given COVID-19 Vaccine Janssen.

As with all vaccines, vaccination with COVID-19 Vaccine Janssen may not fully protect all those who receive it. It is not known how long you will be protected.

After vaccination, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Blood disorders

A combination of blood clots and low levels of 'platelets' (cells that help blood to clot) in the blood has been observed very rarely following vaccination with COVID-19 Vaccine Janssen. 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 occurred within the first three weeks following vaccination, and occurred mostly in women below 60 years of age. Fatal outcome has been reported.

Seek immediate medical attention if you experience:

- severe or persistent headaches
- seizures (fits)
- mental status changes
- blurred vision
- unexplained skin bruising beyond the site of vaccination which appear a few days after vaccination
- pinpoint round spots beyond the site of vaccination
- shortness of breath
- chest pain
- leg pain
- leg swelling
- persistent abdominal pain

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor, pharmacist or nurse will discuss with you whether you can be given the vaccine.

### **Children and adolescents younger than 18 years of age**

COVID-19 Vaccine Janssen is not recommended for children aged below 18 years.

No information is available on the use of COVID-19 Vaccine Janssen in children and adolescents younger than 18 years of age.

## **3. What if I am taking other medicines?**

Tell your doctor if you have been given another injection or are taking any other medicines or vaccines, including any over-the counter (OTC) medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COVID-19 Vaccine Janssen.**

## **4. How do I receive COVID-19 Vaccine Janssen?**

### **How much you will receive**

- A single dose (0.5 mL) of COVID-19 Vaccine Janssen is injected.
- After the injection of the vaccine, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

### **How COVID-19 Vaccine Janssen is given**

Your doctor, pharmacist or nurse will inject the vaccine into the muscle (intramuscular injection), usually in the upper arm.

## **If you miss an appointment to receive COVID-19 Vaccine Janssen**

- If you miss an appointment, tell your doctor and arrange another visit.
- If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

## **5. What should I know after receiving COVID-19 Vaccine Janssen?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- Notice signs of allergic reaction which include feeling faint, dizzy or light-headed, changes in your heartbeat, rash, itching, difficulty breathing, shortness of breath, wheezing, swelling of the face, lips, throat or tongue, nausea or vomiting, or stomach pain.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how COVID-19 Vaccine Janssen affects you.**

Some of the side effects of COVID-19 Vaccine Janssen listed in section 6 may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

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

### **Looking after your vaccine**

COVID-19 Vaccine Janssen is usually stored in the doctor's surgery or clinic, hospital or at the pharmacy.

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

## **6. Are there any side effects?**

All vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary. Most of the side effects occur in the 1 or 2 days of getting the vaccination.

However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• headache</li> <li>• muscle aches, muscle weakness</li> <li>• tremor</li> <li>• excessive sweating</li> <li>• fever</li> <li>• pain, redness, swelling where the injection is given</li> <li>• chills</li> <li>• cough, sneezing</li> <li>• sore throat</li> <li>• joint pain</li> <li>• back pain</li> <li>• arm or leg pain</li> <li>• feeling very tired</li> <li>• feeling weak</li> <li>• feeling generally unwell</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Severe allergic reaction, such as:</b></p> <ul style="list-style-type: none"> <li>• feeling faint, dizzy or light-headed</li> <li>• changes in your heartbeat</li> <li>• difficulty breathing</li> <li>• shortness of breath</li> <li>• wheezing</li> <li>• swelling of the face, lips, throat, or tongue</li> <li>• rash or hives</li> <li>• itching</li> <li>• nausea or vomiting</li> <li>• stomach pain</li> </ul> <p><b>May occur within 3 weeks of vaccination -</b></p> <p><b>Blood clots, often in unusual locations (e.g., brain, liver, bowel, spleen) in combination with low level of blood platelets.</b></p> <p><b>Symptoms may include:</b></p> <ul style="list-style-type: none"> <li>• severe or persistent headaches</li> <li>• seizures (fits)</li> <li>• mental status changes</li> <li>• blurred vision</li> <li>• unexplained skin bruising beyond the site of vaccination which appear a few days after vaccination</li> <li>• pinpoint round spots beyond the site of vaccination</li> <li>• shortness of breath</li> <li>• chest pain</li> <li>• leg pain</li> <li>• leg swelling</li> <li>• persistent abdominal pain</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this vaccine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

### What COVID-19 Vaccine Janssen contains

<b>Active ingredient (main ingredient)</b>	Ad26.COV2.S* 5×10 <sup>10</sup> virus particles (VP) in one 0.5 mL dose.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Citric acid monohydrate</li><li>• Sodium citrate dihydrate</li><li>• Polysorbate 80</li><li>• Hydroxypropylbetadex</li><li>• Ethanol absolute</li><li>• Hydrochloric acid</li><li>• Sodium chloride</li><li>• Sodium hydroxide</li><li>• Water for injections</li></ul>

\* The vaccine was manufactured using material sourced from a human embryo (Human Embryonic Retinal cells: PER.C6 cells).

**Do not receive this vaccine if you are allergic to any of these ingredients.**

This product contains genetically modified organisms (GMOs).

### What COVID-19 Vaccine Janssen looks like

COVID-19 Vaccine Janssen is a colourless to slightly yellow, clear to very opalescent suspension (pH 6-6.4) for intramuscular injection. The suspension comes in a multi-dose vial (Type I glass) with a rubber stopper, aluminium crimp and blue plastic cap.

Each multi-dose vial contains 5 doses of 0.5 mL.

COVID-19 Vaccine Janssen is available in a pack containing 10 multi-dose vials.

AUST R 350150

### Who distributes COVID-19 Vaccine Janssen

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Rd

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

This CMI was prepared in June 2021.