

COVID-19 Vaccine Janssen

New Zealand 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.

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.

- 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.

- 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.

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.

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 may receive COVID-19 Vaccine Janssen as a single dose as a primary vaccination.

You may also receive COVID-19 Vaccine Janssen as a booster dose after primary vaccination with COVID-19 Vaccine Janssen or after a primary vaccination course with a mRNA COVID-19 vaccine, an adenoviral vector-based COVID-19 vaccine or an inactivated whole virion COVID-19 vaccine.

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?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if you: Notice signs of severe allergic reaction which include feeling faint or light-headed, changes in your heartbeat, difficulty breathing, shortness of breath, wheezing, rash or hive, itching, or swelling of the face, lips, throat or tongue, nausea or vomiting or stomach pain
Driving or using machines	<ul style="list-style-type: none">• 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.

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

Very rare serious side effects: Blood clots (severe or persistent headaches, seizures (fits), mental status changes or blurred vision, unexplained skin bruising or pinpoint round spots beyond the site of vaccination, unusual or excessive bleeding, shortness of breath, chest pain, leg pain or swelling, persistent abdominal pain); Guillain-Barré syndrome (weakness and paralysis in the extremities that can progress to the chest and face, difficulty breathing); Capillary Leak Syndrome (rapid swelling of the arms and legs, sudden weight gain, feeling faint (low blood pressure)). 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.

COVID-19 Vaccine Janssen

Active ingredient(s): Ad26.COV2.S

New Zealand 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
- 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
- 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

Talk to your doctor, pharmacist or nurse 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 previously had a blood clot in the brain (venous sinus thrombosis) with low platelets, blood cells that help your body stop bleeding, (thrombocytopenia), or have had a heparin-induced thrombocytopenia (HIT).

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

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 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 mostly occurred within the first three weeks following vaccination. It has been reported in men and women 18 years of age and older, but more frequently in women below 50 years of age. Fatal outcome has been reported.

Immune thrombocytopenia: Very low levels of platelets have been very rarely reported usually within the first four weeks following vaccination with COVID-19 Vaccine Janssen. If you have ever had a diagnosis of immune thrombocytopenia, talk to your doctor, pharmacist or nurse before you are given COVID-19 Vaccine Janssen.

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
- unusual or excessive bleeding
- shortness of breath
- chest pain
- leg pain
- leg swelling
- persistent abdominal pain

Capillary leak syndrome

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with COVID-19 Vaccine Janssen. 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 events

Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face, or difficulty breathing (Guillain-Barré syndrome). This has been reported very rarely after vaccination with COVID-19 Vaccine Janssen.

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.

Currently there is not enough information 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) primary vaccination of COVID-19 Vaccine Janssen is injected.
- A booster dose (second dose) of COVID-19 Vaccine Janssen may be given at least 2 months after the primary vaccination in individuals 18 years of age and older. Higher immune responses are observed with an interval up to 6 months between the primary vaccination and booster dose.
- COVID-19 Vaccine Janssen may be administered as a single booster dose to eligible individuals who have completed a primary vaccination course with a mRNA COVID-19 vaccine, an adenoviral vector-based COVID-19 vaccine or an inactivated whole virion COVID-19 vaccine.
- 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"> • headache • dizziness • muscle aches, muscle weakness • tremor • excessive sweating • fever • pain, redness, swelling where the injection is given • chills • cough, sneezing • sore throat • joint pain • back pain • arm or leg pain • feeling very tired • feeling weak • feeling generally unwell • persistent ringing in the ears (tinnitus) • diarrhoea • unusual feeling in the skin, such as tingling or a crawling feeling (paresthesia) • swollen lymph nodes (lymphadenopathy) • vomiting • decreased feeling or sensitivity, especially in the skin (hypoesthesia) 	<p>Speak to your doctor if you have any of these side effects that bother you or do not go away, and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Severe allergic reaction, such as:</p> <ul style="list-style-type: none"> • feeling faint or light-headed • changes in your heartbeat • difficulty breathing • shortness of breath • wheezing • swelling of the face, lips, throat, or tongue • rash, hives • itching • nausea or vomiting • stomach pain 	<p>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.</p>
<p>Very Rare: may affect up to 1 in 10,000 people (may occur within 3 weeks of vaccination) -</p> <p>Blood clots, often in unusual locations (e.g., brain, liver, bowel, spleen) in combination with low level of blood platelets.</p> <p>Symptoms may include:</p> <ul style="list-style-type: none"> • 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 • unusual or excessive bleeding • shortness of breath • chest pain • leg pain • leg swelling • persistent abdominal pain 	
<p>Very rare: may affect up to 1 in 10,000 people -</p> <p>Guillain-Barré syndrome (serious nerve inflammation), which may cause:</p> <ul style="list-style-type: none"> • weakness and paralysis in the extremities that can progress to the chest and face • difficulty breathing 	

Serious side effects	What to do
<p>Unknown: frequency cannot be estimated from available data -</p> <p>Capillary leak syndrome (a condition causing fluid leakage from small blood vessels) that may occur in the days following vaccination.</p> <p>Symptoms may include:</p> <ul style="list-style-type: none"> • rapid swelling of the arms and legs • sudden weight gain • feeling faint (low blood pressure) 	<p>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.</p>

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

Who distributes COVID-19 Vaccine Janssen

JANSSEN-CILAG Pty Ltd

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

This CMI was prepared on 09 March 2023.

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.

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

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

* Produced in the PER.C6® TetR cell line and by recombinant DNA technology.

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

This product contains genetically modified organisms (GMOs) under GMO regulations in other jurisdictions. Please note that under the New Zealand Hazardous Substances and New Organisms (HSNO) Act, this product is not considered a GMO.

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 and blue plastic cap.

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