

Consumer Medicine Information (CMI) summary

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

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given RONAPREVE?

RONAPREVE contains the active ingredients casirivimab and imdevimab. RONAPREVE is used in patients 12 years and older and weighing at least 40 kg to:

- treat COVID-19 in those who are at an increased risk of progressing to severe disease, or
- prevent COVID-19 post-exposure, in those who are unlikely to be protected by a COVID-19 vaccine.

For more information, see Section [1. Why am I being given RONAPREVE?](#) in the full CMI.

2. What should I know before I am given RONAPREVE?

You must not be given RONAPREVE if you have ever had an allergic reaction to casirivimab and imdevimab or any of the ingredients listed at the end of this CMI.

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

For more information, see Section [2. What should I know before I am given RONAPREVE?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

4. How is RONAPREVE given?

Treatment: RONAPREVE is given either as a single infusion into the vein (intravenous infusion) or an injection under the skin (subcutaneous injection) after a positive test for the SARS-COV-2 virus.

Prevention: RONAPREVE is given by either intravenous infusion or a subcutaneous injection. It can be given as a single dose following exposure to SARS-COV-2 or it can be repeated once every 4 weeks if required.

More information can be found in Section [4. How is RONAPREVE given?](#) in the full CMI.

5. What should I know while I am being given RONAPREVE?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you experience any problems with this medicine.• Tell your doctor if you are pregnant or breast feeding.
Driving or using machines	<ul style="list-style-type: none">• RONAPREVE is unlikely to affect your ability to drive or use machines.
Looking after your medicine	<ul style="list-style-type: none">• It is unlikely that you will have to store RONAPREVE at home. If you have to store it, keep it in the refrigerator at 2°C to 8°C (do not freeze) in the outer carton.

For more information, see Section [5. What should I know while I am being given RONAPREVE?](#) in the full CMI.

6. Are there any side effects?

A very serious side effect associated with RONAPREVE is anaphylaxis, which may include the following symptoms: fever, chills, flushing, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

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 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

RONAPREVE®

Active ingredient(s): *casirivimab and imdevimab*

Ronapreve has **provisional approval** in Australia for the indications below:

Treatment of COVID-19 in adult and adolescents (aged 12 years and older and weighing at least 40 kg) who do not require supplemental oxygen for COVID-19 and who are at increased risk of progressing to severe COVID-19.

Prevention of COVID-19 in adult and adolescents (aged 12 years and older and weighing at least 40 kg) who have been exposed to SARS-CoV-2 AND who either:

- have a medical condition making them unlikely to respond to or be protected by vaccination, OR
- are not vaccinated against COVID-19

Ronapreve is not intended to be used as a substitute for vaccination against COVID-19.

This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing trials continues to be gathered and assessed.

Consumer Medicine Information (CMI)

This leaflet provides important information about using RONAPREVE.

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 RONAPREVE.

Where to find information in this leaflet:

1. [Why am I being given RONAPREVE?](#)
2. [What should I know before I am given RONAPREVE?](#)
3. [What if I am taking other medicines?](#)
4. [How is RONAPREVE given?](#)
5. [What should I know while I am being given RONAPREVE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given RONAPREVE?

RONAPREVE contains the active ingredients casirivimab and imdevimab.

Casirivimab and imdevimab are a type of protein called monoclonal antibodies. Casirivimab and imdevimab are used together to stop a virus called the coronavirus or SARS-COV-2 from getting into your cells and causing COVID-19.

COVID-19 is an illness which can affect your lungs, airways and other organs. COVID-19 illnesses can be very mild (sometimes with no symptoms), however in some cases symptoms can be severe and can result in hospitalisation or even death.

What Ronapreve is used for

RONAPREVE is used in patients 12 years and older and weighing at least 40 Kg to:

- treat patients with COVID-19. These are patients who are infected with coronavirus (SARS-COV-2) and:
 - do not require oxygen to treat COVID-19, and

- are at increased risk of progressing to severe COVID-19 based on the evaluation of your doctor.
- prevent COVID-19 in individuals who have come into contact with coronavirus (SARS-COV-2)
 - have an illness or condition making them unlikely to respond to or be protected by vaccination against coronavirus (SARS-COV-2), or
 - have not received a COVID-19 vaccine.

Ronapreve is not intended to replace COVID-19 vaccines.

If you have any questions about RONAPREVE, how it works or why this medicine has been prescribed for you, ask your doctor.

2. What should I know before I am given RONAPREVE?

Do not use RONAPREVE if:

- you are allergic to casirivimab, imdevimab, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, 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?](#)

Pregnancy and breastfeeding

- Tell your doctor or nurse if you are pregnant, or if you might be pregnant. There is not enough information to be sure that this medicine is safe for use in pregnancy. RONAPREVE will only be given if the potential benefits of treatment outweighs the potential risks to the mother and the unborn child.

- Talk to your doctor if you are breastfeeding. It is not yet known whether RONAPREVE passes into human milk or what the effects might be on the baby or milk production. Your doctor will help you decide whether to keep breastfeeding or to start treatment with this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

If you are getting a COVID-19 vaccine, tell your doctor, nurse or pharmacist that you have used or are using RONAPREVE.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RONAPREVE.

4. How is RONAPREVE given?

How much RONAPREVE is given

- The recommended dose in adults and adolescent patients 12 years of age and older, weighing at least 40 kg, for treatment and prevention of COVID-19 is a single dose of 600 mg of casirivimab and 600 mg of imdevimab.
- The recommended dose for ongoing prevention of COVID-19 in adults and adolescent patients 12 years of age and older, weighing at least 40 kg, is 300 mg of casirivimab and 300 mg of imdevimab given every four weeks, as required.

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

How you will be given RONAPREVE

- RONAPREVE will be given to you in a healthcare facility under the supervision of a healthcare professional who is experienced in the use of this type of treatment. They will watch you closely while you are being given this medicine. This is in case you get any side effects.
- RONAPREVE is given as:
 - an infusion into your vein (intravenous infusion), that lasts for 20 to 30 minutes, or
 - as subcutaneous (under the skin) injections into your upper thigh, upper arm, or stomach.
- Your doctor or nurse will decide how long you will be monitored after you are given the medicine, in case you have any side effects.

If you miss a dose of RONAPREVE

If you miss a dose of RONAPREVE, you should be given the dose as soon as possible. Your doctor will adjust your dosing schedule to ensure the appropriate time between doses.

Before stopping treatment with RONAPREVE for ongoing prevention of COVID-19

- Do not stop treatment with RONAPREVE without first talking to your doctor.

If you are given too much RONAPREVE

Your doctor will ensure you are given the correct amount of RONAPREVE. If you think that you have been given too much RONAPREVE, contact your doctor.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I am being given RONAPREVE?

Things you should do

- Tell any other doctors you see that you have had this medicine to treat or prevent COVID-19
- if you are getting a COVID-19 vaccine, tell the doctor, nurse or pharmacist you have had this medicine.

Call your doctor straight away if you experience the following symptoms within 24 hours of receiving RONAPREVE:

- nausea, fever, chills, rash, dizziness or lightheadedness, difficulty breathing, shortness of breath, chest pain or rapid heartbeat.

Remind any doctor, nurse, dentist or pharmacist you visit that you have been given or are using RONAPREVE.

Things you should not do:

- Do not stop treatment with RONAPREVE unless your doctor tells you to.

Monitoring and care during your treatment with RONAPREVE for continuous prevention of COVID-19

Your doctor will monitor you throughout your treatment with RONAPREVE to allow for prompt medical assistance if necessary.

Driving or using machines

It is unlikely that RONAPREVE will affect your ability to drive or use any machines or tools.

Looking after your medicine

It is unlikely that you will have to store RONAPREVE at home. If you have to store it:

- Store RONAPREVE in the refrigerator at 2°C to 8°C in the original carton to protect from light.
- Do not freeze. Do not shake.
- Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. 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.

Side effects with intravenous infusion:

Less serious side effects

Less serious side effects	What to do
<p>Nervous system:</p> <ul style="list-style-type: none"> dizziness or fainting <p>Vascular (circulatory) system:</p> <ul style="list-style-type: none"> flushing of the skin <p>Gastrointestinal system:</p> <ul style="list-style-type: none"> nausea <p>Skin:</p> <ul style="list-style-type: none"> rash red, itchy welts on the skin <p>General:</p> <ul style="list-style-type: none"> chills <p>Respiratory system:</p> <ul style="list-style-type: none"> abnormally rapid breathing 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Infusion related reactions:</p> <ul style="list-style-type: none"> nausea, headache, rash, shortness of breath, light headedness, low blood pressure or rapid pulse <p>Nervous system:</p> <ul style="list-style-type: none"> fainting followed by muscle jerks 	<p>Speak to your doctor as soon as possible if you have any of these serious side effects.</p>

Very serious side effects

Very serious side effects	What to do
<p>Immune system:</p> <ul style="list-style-type: none"> fever, chills, flushing, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin 	<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>

Side effects with subcutaneous injection:

Less serious side effects

Less serious side effects	What to do
<p>Nervous system:</p> <ul style="list-style-type: none"> dizziness or fainting <p>Skin:</p> <ul style="list-style-type: none"> redness, itching, rash or scaly patches on the skin <p>Injection site reactions:</p> <ul style="list-style-type: none"> itching, redness, irritation at the site of the injection 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Blood and lymph system:</p> <ul style="list-style-type: none"> painful, warm, or red lump under the skin, fever or night sweats <p>Nervous system:</p> <ul style="list-style-type: none"> fainting followed by muscle jerks 	<p>Speak to your doctor as soon as possible if you have any of these serious side effects.</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. By reporting side effects, you can help provide more information on the safety of this medicine.

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

7. Product details

This medicine is only available with a doctor's prescription.

What RONAPREVE contains

Active ingredient (main ingredient)	casirivimab and imdevimab
Other ingredients (inactive ingredients)	Histidine Histidine hydrochloride monohydrate Polysorbate 80 Sucrose Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What RONAPREVE looks like

RONAPREVE solution for infusion or injection is available as:

- a single use pack containing 2 single-use glass vials; one containing casirivimab and the other containing imdevimab (AUST R 373839)
- a multidose pack containing 2 multidose glass vials; one containing casirivimab and the other containing imdevimab (AUST R 374310)

Each of the vials contains a clear to slightly milky, colourless to pale yellow liquid.

Who distributes RONAPREVE

RONAPREVE is distributed in Australia by:

Roche Products Pty Ltd

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

Medical enquiries: 1800 233 950

This leaflet was prepared on 25 November 2022.