Patient information

Casirivimab and imdevimab (Ronapreve®)

What is casirivimab and imdevimab and how will it help me (or my child)?

Casirivimab and imdevimab (cas-i-RIVEE-mab and IM-DEV-i-mab) is a combination of medicines called monoclonal antibodies. It is also known by the brand name of Ronapreve® (ROW-NA-preev).

Ronapreve® has been developed to treat COVID-19. It works by sticking to the spike protein of the virus that causes COVID-19. This stops the virus from attaching to human cells and entering the body. This can help to overcome the infection and stop infected people from getting seriously sick. This type of medication may not be active against all variants or strains of the COVID-19 virus. For example, Ronapreve is not effective against the Omicron strain. Your doctor can test which strain you have to help choose the best treatment.

Ronapreve® reduces the risk of needing to go to hospital or dying from COVID-19 if used within 7 days of symptoms first appearing. It has also been shown to reduce the risk of catching COVID-19 if you have been exposed to the virus that causes it. When a medication is used to stop you from getting an infection it is called prophylaxis (pro-FILL-axis).

Ronapreve® is provisionally approved by the Therapeutic Goods Administration (TGA) in Australia to treat mild to moderate COVID-19 in adults and children over 12 years of age (and weighing 40kg or more) who are at risk of becoming severely ill. It has also been provisionally approved to prevent COVID-19 disease in people who have been exposed to the virus.

Preparing for the treatment

A doctor will discuss the risks and benefits of Ronapreve® treatment or prophylaxis with you or your carer (or the child’s parent/carer) and must obtain consent before it is given. The doctor will need to know about:

- Any existing medical conditions
- Any previous allergies to medications
• All medications, including over the counter or complementary medications that you (or your child) have been taking
• The possibility that you are pregnant or have plans for a future pregnancy
• If you are breastfeeding
• Any recent vaccinations or plans for COVID-19 vaccinations and boosters

Because Ronapreve® is a new medicine, information about how well it works and its safety is still being monitored. It is important that you and your carers understand when and why Ronapreve® may be useful. Your doctor will discuss with you about how well it works and how safe it is in your (or your child’s) condition.

If you have given consent, you have the right to change your mind at any time prior to the infusion or injections. Please discuss with your doctor.

**How is Ronapreve® given to me (or my child)?**

For treatment of COVID-19, Ronapreve® is given once as a single dose. For prophylaxis, the dose may need to be repeated every four weeks until you are no longer at risk from your exposure. Your doctor will discuss this with you.

Ronapreve® is usually given as an infusion “drip” into a vein (usually in the arm). The infusion is given by a nurse, at a hospital or other appropriate healthcare setting. The infusion takes about 30 minutes. Ronapreve® can also be injected under your skin (subcutaneous injection). If Ronapreve® is injected in this way, four (4) separate injections are given into your upper thighs, upper arms or tummy.

After the infusion is finished or the injections given, you (or your child) will need to stay and be observed by a nurse or doctor for one hour afterwards to make sure you (or your child) do not have an allergic reaction.

**What are the risks?**

All medicines have side effects. Sometimes they are serious, but most of the time they are not.

Some of the possible side effects and what to do are listed below.
**Possible side effects of Ronapreve®**

<table>
<thead>
<tr>
<th>Possible side effects which may appear after receiving Ronapreve®</th>
<th>What to do</th>
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<tr>
<td>• chills&lt;br&gt;• upset stomach&lt;br&gt;• dizziness&lt;br&gt;• rash (hives) and flushing</td>
<td>Immediately tell the doctor or nurse if these symptoms occur.</td>
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**Possible side effects which may appear at the site of the Ronapreve® subcutaneous injections:**

| • rash (hives)<br>• itchiness<br>• bruising<br>• swelling<br>• pain | |

**Allergic reactions may occur during or after receiving Ronapreve®**

| • feeling short of breath, wheezing, difficulty breathing<br>• swelling of the face, lips, tongue or other parts of the body<br>• severe skin rash, itching, hives | Allergic reactions may immediately tell the doctor or nurse if these symptoms occur. |

If the person has already left the healthcare facility, call an ambulance or go straight to the Emergency Department of your nearest hospital.

It is possible that other, yet unknown side effects may occur with Ronapreve®. Side effects should be reported to the doctor directly. Your doctor or healthcare provider will report the details of the reaction to the Therapeutic Goods Administration (TGA) and document this in your (or your child’s) medical record.

**What are the risks of not having Ronapreve®?**

Ronapreve® is used for the early treatment of COVID-19 in high risk patients with other medical conditions to prevent progression onto severe disease or death and reduce the need for intensive care admission.
Ronapreve® is also used to stop a person who has been exposed to someone infected with the SARS-CoV-2 virus from catching COVID-19.

The decision to receive Ronapreve® will depend on your (or your child’s) age, existing medical conditions and if you are vaccinated against COVID-19 or not.

Are there alternatives?

Other medications for COVID-19 are used for treatment of people who are already sick with COVID-19 and in hospital.

There is another new monoclonal antibody medication like Ronapreve® that works in the same way, called sotrovimab (Xevudy®). They are currently the only medications that are specifically made to target the virus that causes COVID-19 and prevent it from developing into severe disease. Ronapreve® needs to be given as early as possible and within 7 days of first getting symptoms.

Ronapreve® is currently the only medication that can be given to stop a person catching COVID if they have been a contact of someone who is known to be infected. It needs to be given as early as possible and within 4 days of being exposed to an infected person.

What should I (or my child) expect after treatment?

You will need to stay and be observed by the nurse or doctor for one hour after your infusion or injections to make sure that you don’t have an allergic reaction.

Delayed allergic reactions are rare but can still happen, so it is important that anyone who receives Ronapreve® watches carefully for any side effects. Any concerns should be reported to the doctor or nurse immediately.

When your (or your child’s) Ronapreve® infusion and observation period is finished, you will be given a letter to confirm where and when you (or your child) had the infusion. The details will also be kept on your (or your child’s) medical record.

Some patients may still develop severe COVID-19 after Ronapreve®. It is important that you monitor your symptoms. If you start to feel unwell or your symptoms are worse but not serious – call 13 HEALTH (13 43 25 84). If you have serious symptoms, like difficulty breathing – call 000 and ask for an ambulance.
When can I (or my child) get vaccinated?

There is very little information about the effect Ronapreve® might have on future COVID-19 vaccination or boosters. The current advice is to wait for 90 days after having Ronapreve® before getting a COVID-19 vaccine. This includes if you (or your child) are due for a second or third dose of vaccine. The doctor will discuss timing of vaccines with you and provide a letter that will state when you (or your child) can receive a future COVID-19 vaccine.

Is there any impact on fertility, pregnancy and breastfeeding?

Ronapreve® has not been tested on pregnant or breastfeeding women who have COVID-19. It may cross the placenta from mother to baby and the impact of this on the unborn baby is unknown. The effect of Ronapreve® on fertility is unknown. If you are pregnant, breastfeeding or planning a family, please discuss this with the doctor.

Where can I find support or more information?

- If you start to feel unwell or your symptoms are worse but not serious – call 13 HEALTH (13 43 25 84)
- If you have serious symptoms, like difficulty breathing – call 000 and ask for an ambulance