Information for patients, family and carers

Use of casirivimab and imdevimab in patients diagnosed with COVID-19 OR for post exposure prophylaxis

This information leaflet includes important information about the medicine casirivimab and imdevimab (Ronapreve®) injection when used in the treatment of, or for prevention after exposure to, COVID-19.

What is the potential benefit of casirivimab and imdevimab for COVID-19?

Casirivimab and imdevimab belongs to a group of medicines called monoclonal antibodies. It is provisionally approved to treat COVID-19, or prevent COVID-19 after exposure to the virus, in Australia. Casirivimab and imdevimab works by targeting the virus that causes COVID-19 and preventing it from infecting healthy cells. Casirivimab and imdevimab has been shown to reduce the risk of severe infection and hospitalisation for those with mild to moderate COVID-19. It has also been shown to reduce the risk of catching COVID-19 if you are exposed to the virus.

Casirivimab and imdevimab has been provisionally approved in Australia to treat COVID-19 in people who do not need oxygen but are at risk of severe illness caused by COVID-19. It has also been provisionally approved to prevent COVID-19 in people who have been exposed to the virus and meet certain criteria.

Recent clinical trials have studied how well Casirivimab and imdevimab works in COVID-19.

What should be considered when using casirivimab and imdevimab in COVID-19?

Because casirivimab and imdevimab is a new medicine and provisionally (not fully) registered to treat COVID-19 in Australia information about how well it works and how safe it is, is being collected. It is important that patients and their carers understand when and why casirivimab and imdevimab may be useful. Your doctors will provide more information about how well it works and how safe it is in your condition.

Because the use of casirivimab and imdevimab for COVID-19 is new, it is important you provide your formal consent before being treated with casirivimab and imdevimab. You can always change your mind about treatment with casirivimab and imdevimab and withdraw consent at any time.

What should the doctor know before casirivimab and imdevimab is used in COVID-19?

The doctor should know about:

- any medical conditions you have
- previous allergic reactions to any medicine
- all medicines including over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken
- the possibility of pregnancy or plans for pregnancy
- recent vaccinations or plans to get vaccinated

What are the side effects of casirivimab and imdevimab?

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many of them disappear with time or when treatment is stopped. Medical treatment may be needed with some side effects. Side effects may not be experienced. Some possible side effects that might be experienced during treatment with casirivimab and imdevimab are shown below. There is a possibility of experiencing other unknown side effects with casirivimab and imdevimab when it is used in people with COVID-19. Because casirivimab and imdevimab is a new medicine, patients who receive casirivimab and imdevimab will be monitored closely.

Possible side effects of casirivimab and imdevimab	What to do
Possible side effects which may appear after receiving casirivimab and imdevimab. Symptoms may include: • chills • upset stomach • dizziness • rash (hives) and flushing. Possible side effects which may appear at the site of casirivimab and imdevimab subcutaneous injection. Symptoms may include: • rash (hives) • itchiness • bruising • swelling • pain.	Immediately tell the doctor or nurse if these symptoms occur.
Allergic reactions, symptoms may include: • feeling short of breath, wheezing, difficulty breathing • swelling of the face, lips, tongue or other parts of the body • severe skin rash, itching, hives.	If in the community setting – Contact 000 or go straight to the Emergency Department at your nearest hospital. If in the hospital or outpatient setting – Immediately tell the doctor or nurse if these symptoms occur.

Please note: This is not a complete list of all possible side effects. Because casirivimab and imdevimab is a new medicine, it is important to report side effects to the doctor directly and/or to the Therapeutic Goods Administration at www.tga.gov.au/reporting-problems

If you are experiencing any side effects, including any of the ones listed above or are feeling unwell in any way, please call the healthcare worker on the phone number below for advice.

Name of healthcare worker to call: _____
Telephone number: _____

How is casirivimab and imdevimab given?

- Casirivimab and imdevimab is given by a doctor or nurse as a single dose. It can be given by slow injection into the body through a vein (intravenous administration), or by injection under the skin (subcutaneous injection). The slow injection (also called an infusion) can take between 20 and 30 minutes and will be given in a hospital or clinic setting. The injection under the skin is given using multiple syringes 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.
- The recommended dose of casirivimab and imdevimab is 600 mg of casirivimab and 600 mg of imdevimab given together.
- If casirivimab and imdevimab is used to prevent COVID-19 infection after you have been exposed to a positive case (known as post-exposure prophylaxis), repeat doses are sometimes given until prophylaxis is no longer required. In this case, the dose is 300 mg of casirivimab and 300 mg of imdevimab (given together) once every 4 weeks.

Are there special precautions with casirivimab and imdevimab treatment?

Use with other medicines

Casirivimab and imdevimab is a new medicine. So far, no medicine interactions have been identified for casirivimab and imdevimab in any clinical trials. However, it is important that the doctors and other health professionals (such as the pharmacist or nurse) are informed about all medications normally taken or planned. This includes over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines.

The doctor and pharmacist will check for potential medicine interactions before casirivimab and imdevimab is started and when it is stopped.

Vaccinations

There is evidence that casirivimab and imdevimab may reduce the effectiveness of the COVID-19 vaccine. For this reason, it is recommended that a COVID-19 vaccine is given at least 90 days after casirivimab and imdevimab. Make sure you tell the doctors about any of your recent vaccinations. Consult your doctor about future vaccinations and their timing, including any COVID-19 vaccinations.

Fertility, Pregnancy and Breastfeeding

- The effect of casirivimab and imdevimab on fertility is unknown.
- Casirivimab and imdevimab probably crosses the placenta from mother to baby. The impact on the baby is not known. Because COVID-19 can be very serious for pregnant women and the baby, casirivimab and imdevimab may be considered depending on the possibility of the mother progressing to severe COVID-19 and her COVID-19 vaccination status.
- It is unknown whether casirivimab and imdevimab is present in breast milk. Your doctor may advise you to stop breastfeeding during casirivimab and imdevimab treatment. Consult the doctor and pharmacist for information and advice.

More information about casirivimab and imdevimab

- Roche Products Pty Ltd. Australian Consumer Medicines Information – Ronapreve®. Therapeutic Goods Administration. Published October 2021. https://search.tga.gov.au/s/search.html?query=ronapreve&collection=tga-artg&profile=record