EMA/47158/2025
EMEA/H/C005814

Ronapreve (*casirivimab and imdevimab*)

An overview of Ronapreve and why it is authorised in the EU

What is Ronapreve and what is it used for?

Ronapreve is a medicine used for treating COVID-19 in adults, adolescents and children from 2 years of age and weighing at least 10 kilograms, who do not require supplemental oxygen and who are at increased risk of their disease becoming severe.

Ronapreve is also used for treating COVID-19 in adults and adolescents from 12 years of age (weighing at least 40 kilograms) who are receiving supplemental oxygen and who have a negative SARS-CoV-2 antibody test result.

The medicine can also be used to prevent COVID-19 in people aged 12 years and older weighing at least 40 kilograms.

Ronapreve contains two active substances, casirivimab and imdevimab.

The medicine should be used in accordance with official recommendations, where available, and based on information on the activity of casirivimab and imdevimab against circulating viral variants.

How is Ronapreve used?

The medicine can only be obtained with a prescription and should be given in healthcare facilities where patients can be adequately monitored and managed in case they develop severe allergic reactions, including anaphylaxis.

Ronapreve is given as a single treatment by infusion (drip) into a vein or by injection under the skin, depending on the patient's age and weight and on the intended use (treatment or prevention of COVID-19).

When used for treatment, it should be given within 7 days of the patient developing symptoms of COVID-19.

When used for prevention after contact with a person with COVID-19, Ronapreve should be given as soon as possible after contact occurred. Ronapreve may also be given to prevent COVID-19 when no contact has occurred. In these cases, Ronapreve is given every four weeks, until prevention is no longer required.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

For more information about using Ronapreve, see the package leaflet or contact your doctor or pharmacist.

How does Ronapreve work?

This medicine is made of casirivimab and imdevimab, two monoclonal antibodies. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen). Casirivimab and imdevimab have been designed to attach to the spike protein of SARS-CoV-2 (the virus causing COVID-19) at two different sites. When the active substances attach to the spike protein, the virus is unable to enter the body's cells.

What benefits of Ronapreve have been shown in studies?

The variants of SARS-CoV-2 that were circulating at the time of the studies were susceptible to Ronapreve.

Treatment of COVID-19

A main study involving adults with COVID-19 who did not require oxygen and were at increased risk of their illness becoming severe showed that Ronapreve at the authorised dose led to fewer hospitalisations or deaths when compared with placebo (dummy treatment). Overall, 0.9% of patients treated with Ronapreve (11 out of 1,192 patients) were hospitalised or died within 29 days of treatment compared with 3.4% of patients on placebo (40 out of 1,193 patients).

The effectiveness of Ronapreve in children and adolescents is expected to be comparable to that in adults, based on studies on the way Ronapreve is absorbed, modified and removed from the body. In addition, as part of the main study, 206 patients under 18 years of age with COVID-19 who were at increased risk of their illness becoming severe received Ronapreve. None of them were hospitalised or died due to COVID-19 within 4 weeks of treatment. The results also showed that the viral load (quantity of viruses) in the patients' nose and throat decreased rapidly after treatment. Ronapreve treatment was not compared with placebo or other treatments in this part of the study.

Another study involved over 9,700 adults and adolescents hospitalised with COVID-19, most of whom were receiving supplemental oxygen. In the group of patients who were seronegative at the start of the study (meaning they had a negative SARS-CoV-2 antibody test result), 24% (396 out of 1,633) of those who had received Ronapreve and usual care died within 4 weeks, compared with 30% (451 out of 1,520) of those who had received usual care alone. Results in patients who were seropositive at the start of the study (meaning that they had been previously exposed to the virus) did not show a benefit of Ronapreve treatment.

Prevention of COVID-19

A main study looked at the benefits of Ronapreve for prevention of COVID-19 in people who had close contact with an infected household member.

Ronapreve was found to be effective at preventing people from getting infected and developing symptoms after contact: amongst people who tested negative for SARS-CoV-2 following contact, fewer people given Ronapreve developed symptoms within 29 days of their test results compared with people given placebo (1.5% (11 out of 753) for Ronapreve compared with 7.8% (59 out of 752) for placebo).

Ronapreve was also found to be effective at preventing symptoms in infected people. Amongst the people who tested positive for SARS-CoV-2 after contact, 29% (29 out of 100) of people who received

Ronapreve developed symptoms compared with 42.3% (44 out of 104) of people who received a placebo.

What are the risks associated with Ronapreve?

For the full list of side effects and restrictions of Ronapreve, see the package leaflet.

The most common side effects with Ronapreve (which may affect up to 1 in 10 people) include hypersensitivity (allergic) reactions, which include infusion-related reactions and injection site reactions.

Why is Ronapreve authorised in the EU?

Ronapreve showed a clinically meaningful effect in preventing hospitalisation and death in patients with COVID-19 caused by SARS-CoV-2 variants circulating at the time of the main study, while also showing benefits in preventing COVID-19. Although vaccination is the main way of preventing COVID-19, at the time of approval there was an unmet medical need in people who had been exposed to COVID-19 as well as in people who could not be vaccinated and who required long-term prevention. The safety profile of Ronapreve is favourable. The European Medicines Agency decided that Ronapreve's benefits are greater than its risks when used against susceptible virus variants and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Ronapreve?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ronapreve have been included in the summary of product characteristics and the package leaflet. These include information for healthcare professionals about virus variants against which Ronapreve is not expected to provide protection and a reminder for them to check their national recommendations before using the medicine.

As for all medicines, data on the use of Ronapreve are continuously monitored. Suspected side effects reported with Ronapreve are carefully evaluated and any necessary action taken to protect patients.

Other information about Ronapreve

Ronapreve received a marketing authorisation valid throughout the EU on 12 November 2021.

Further information on Ronapreve can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ronapreve

This overview was last updated in 02-2025.