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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 and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of their disease becoming severe.

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.

How is Ronapreve used?

Ronapreve is given as a single treatment by infusion (drip) into a vein or by injection under the skin. The recommended dose is 600 mg of casirivimab and 600 mg of imdevimab.

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, following an initial dose of 600 mg casirivimab and 600 mg imdevimab, a dose of 300 mg of casirivimab and 300 mg of imdevimab may be given every four weeks until prevention is no longer required.

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.

For more information about using Ronapreve, see the package leaflet or contact your healthcare provider.

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

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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?

Treatment of COVID-19

A main study (COV-2067) involving patients 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).

Prevention of COVID-19

A main study (COV-2069) 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 people) 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 people) of people who received a placebo.

What are the risks associated with Ronapreve?

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

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

Why is Ronapreve authorised in the EU?

Ronapreve showed a clinically meaningful effect in preventing hospitalisation and death in patients with COVID-19, while also showing benefits in preventing COVID-19. Although vaccination is the main way of preventing COVID-19, there is an unmet medical need in people who have been exposed to COVID-19 as well as in people who cannot be vaccinated and who require long-term prevention. The safety profile of Ronapreve is favourable. The European Medicines Agency decided that Ronapreve's benefits are greater than its risks 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.

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

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