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Ronapreve® (active substances: casirivimab, imdevimab)

First authorisation in Switzerland: 23 December 2021

Medicinal product (solutions for injection and infusion) for the treatment and prevention of COVID-19 in adolescents and adults

About the medicinal product

The medicinal product Ronapreve consists of the active substances casirivimab and imdevimab and is administered as a solution for infusion into the veins or as a solution for injection into the tissue under the skin.

It is used for the treatment of adults and adolescents (aged 12 years and older and weighing at least 40 kg) with confirmed coronavirus infection. The symptoms of COVID-19 range from mild infections to severe disease. Ronapreve is only used for patients who do not require oxygen therapy or hospitalisation due to COVID-19 and who are at increased risk of progression to severe disease. Certain characteristics (e.g. advanced age) increase the risk of the disease becoming severe.

Ronapreve is also used for the prevention of COVID-19 in adults and adolescents (aged 12 years and older and weighing at least 40 kg) who are unable to mount an adequate immune response to COVID-19.

Ronapreve is not intended as a replacement for vaccination against COVID-19.

Mode of action

Ronapreve is a combination product consisting of two active substances, casirivimab and imdevimab.

Casirivimab and imdevimab are monoclonal antibodies. Monoclonal antibodies are proteins that can bind specifically to other proteins. Both of the active substances in Ronapreve bind to the spike protein of SARS-CoV-2, the pathogen that causes COVID-19. This prevents the virus from entering the body's cells. This can help the body to overcome the viral infection and avoid severe disease.

Indication

Ronapreve, containing the active substances casirivimab and imdevimab, is a prescription-only medicine.

Both active substances are supplied in 6 ml vials, each containing 120 mg of active substance per millilitre.

The recommended dosage for the treatment of COVID-19 for adults and adolescents aged 12 years and older and weighing at least 40 kg is 600 mg of casirivimab and 600 mg of imdevimab. They are administered together as a single infusion into the veins (intravenously). Alternatively, the infusion can also be administered into the tissue under the skin (subcutaneously) if intravenous administration is not feasible or would lead to a delay in treatment.

The recommended dosage for the prevention of COVID-19 prior to exposure to the COVID-19 virus is 600 mg of casirivimab and 600 mg of imdevimab intravenously or subcutaneously as an initial dose, followed by 300 mg of casirivimab and 300 mg of imdevimab intravenously or subcutaneously every 4 weeks.

As treatment for COVID-19 Ronapreve should be started as soon as possible after the positive COVID-19 test result or, as disease prevention, as soon as possible after exposure to the COVID-19 virus.

Ronapreve should be used according to the official recommendations and taking into account the local epidemiological data on the COVID-19 virus variants in circulation.

Efficacy

The efficacy of Ronapreve for the treatment of adults with confirmed COVID-19 who are not hospitalised or who do not require oxygen therapy was investigated in study COV-2067. Over 4,500 male and female patients received either Ronapreve or placebo (dummy drug) as treatment.

The primary objective of the trial was to compare the efficacy of Ronapreve versus placebo in the treatment of patients with COVID-19 who were not receiving inpatient care and who were at increased risk of disease progression.

The treatment with Ronapreve was started within 7 days of the onset of symptoms.

The results show that Ronapreve reduces the risk of severe illness with COVID-19 or of dying compared to placebo. The intravenous administration of 1,200 mg of Ronapreve reduced the risk by 70 % compared to placebo (1.0 % versus 3.2 %).

Study COV-2069 was conducted to evaluate the efficacy of Ronapreve in preventing COVID-19 in subjects who came into contact with individuals infected with COVID-19. The study participants had not previously been vaccinated against COVID-19. The study participants received either Ronapreve or placebo.

The study participants were assigned to groups A and B. COVID-19 was not detected in the blood serum of any of the study participants. Furthermore, those in group A had a negative PCR test result, while those in group B had a positive PCR test result. In group A, the preventive treatment with Ronapreve reduced the risk of developing COVID-19 by 81 % compared to placebo.

In group B, the risk of developing COVID-19 during the treatment with Ronapreve was reduced by 31 % compared to placebo.

Precautions, undesirable effects, & risks

Ronapreve must not be used in those who are hypersensitive to the active substances or any of the excipients.

The most common undesirable effects are hypersensitivity reactions and infusion-related reactions, including reactions at the injection site.

Rare cases of acute allergic (anaphylactic) reactions, for example breathing problems, were observed after the administration of Ronapreve. These occurred within 1 hour after the end of the infusion. For this reason, patients are observed during the intravenous infusion of the medicinal product and for at least 1 hour after the end of the infusion.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

In the pivotal study COV-2067 with non-hospitalised, symptomatic adults with COVID-19 who were at increased risk of progression to severe disease, Ronapreve significantly reduced the percentage of COVID-19-related hospitalisations or all-cause deaths through to day 29.

In study COV-2069, which evaluated the efficacy of Ronapreve in preventing COVID-19 in subjects who came into contact with individuals infected with COVID-19, the administration of Ronapreve reduced the risk of developing COVID-19.

Both for reducing the risk of developing severe COVID-19 and for preventing COVID-19 in individuals who cannot mount an adequate immune response to COVID-19 vaccination, Swissmedic reached the following conclusion: Taking all the risks and precautions into account, and based on the available data, the benefits of Ronapreve outweigh its potential safety risks.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ronapreve®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.