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Regkirona® (active substance: regdanvimab)

Temporary authorisation in Switzerland: 12 January 2022

Infusion for the treatment of COVID-19

About the medicine

The medicinal product Regkirona, containing the active substance regdanvimab, can be used in adults who have been diagnosed with COVID-19 and in whom there is a risk of developing a severe form of COVID-19. Patients must not be reliant on supplemental oxygen or be hospitalised due to COVID-19.

The national recommendations and the circulating coronavirus variants should also be considered.

Mode of action

Regdanvimab, the active substance of Regkirona, is a monoclonal antibody. A monoclonal antibody is a protein that can bind to other specific proteins. Regdanvimab binds to the spike protein of SARS-CoV-2, the pathogen that causes COVID-19. This prevents the virus from entering the body's cells.

Use

Regkirona, containing the active substance regdanvimab, is a prescription-only medicine. Regkirona is a concentration for infusion available in 16 mL vials containing 960 mg regdanvimab, which corresponds to 60 mg/mL.

The usual dosage is 40 mg per kilogram of body weight. Regkirona is administered as an infusion into a vein by a medical professional. The patient is clinically monitored for at least one hour after administration.

Regkirona should be administered as soon as possible after a positive SARS-CoV-2 test.

Efficacy

The efficacy of Regkirona was tested against a dummy drug (placebo) in a study (CT-P59 3.2) in 1,315 patients. Patients had to be treated within 7 days of the onset of COVID-19 symptoms, and could not already require oxygen therapy or be hospitalised. Study participants were considered to be high-risk patients if they were at high risk of developing a severe form of COVID-19 and met at least one of the following criteria: aged over

50, obesity with a body mass index of more than 30 kg/m^2, cardiovascular disease including high blood pressure, chronic lung disease, diabetes mellitus, chronic kidney disease, chronic liver disease and immunosuppressed patients. It was demonstrated that in the group of high-risk patients, only 3.1% (14 out of 446 people) had to be hospitalised versus 11.1% (48 out of 434 people) in the placebo group. The majority of study participants were infected with the original SARS-CoV-2 virus or the alpha variant. No data are available on the efficacy of Regkirona against the currently circulating virus variants.

Precautions, undesirable effects & risks

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

The most commonly reported undesirable effects, affecting 1 in 1,000 people, are infusion-related reactions. These include allergic reactions that may be life-threatening (known as anaphylactic shock).

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

Why the medicinal product has been authorised

The efficacy of Regkirona in high-risk patients who are infected with SARS-CoV-2 was demonstrated in study CT-P59 3.2. Early administration of this monoclonal antibody reduced the number of cases of severe illness with hospitalisation, supplemental oxygen and death.

The efficacy of Regkirona could not be demonstrated in non-high-risk patients or in the case of administration after the seventh day of symptomatic COVID-19. As vaccinated individuals were not included in the study, efficacy could not be determined here. The clinical efficacy of Regkirona as regards the new virus variants must be actively monitored.

The safety profile of Regkirona is considered to be positive.

For these reasons, the medicinal product Regkirona has been authorised temporarily in Switzerland (Art. 9a TPA). The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Regkirona, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals can answer any further questions.

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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.

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