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Regkirona (*regdanvimab*)

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

What is Regkirona and what is it used for?

Regkirona is a medicine used for treating COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of their disease becoming severe.

Regkirona contains the active substance regdanvimab.

How is Regkirona used?

Regkirona is given as a single infusion (drip) into a vein within 7 days of the start of COVID-19 symptoms; the dose depends on the patient's body weight.

The medicine can only be obtained with a prescription and should be given in healthcare facilities where patients can be monitored while receiving the infusion and for at least 1 hour afterwards, and where they can be adequately managed in case they develop severe allergic reactions, including anaphylaxis.

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

How does Regkirona work?

The active substance in Regkirona, regdanvimab, is a monoclonal antibody with activity against SARS-CoV-2, the virus that causes COVID 19. A monoclonal antibody is a type of protein that has been designed to attach to a specific structure (called an antigen). Regdanvimab has been designed to attach to the spike protein of SARS-CoV-2. When regdanvimab attaches to the spike protein, the virus is unable to enter the body's cells.

What benefits of Regkirona have been shown in studies?

A main study involving 1,315 patients with COVID-19 showed that Regkirona led to fewer patients requiring hospitalisation or oxygen therapy, or dying, when compared with placebo (a dummy treatment). Among the patients at increased risk of their illness becoming severe, 3.1% of patients treated with Regkirona (14 out 446) were hospitalised, required supplemental oxygen or died within 28 days of treatment compared with 11.1% of patients on placebo (48 out of 434).

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The majority of patients in the study were infected with the original SARS-CoV-2 virus or the Alpha variant; data on the efficacy of Regkirona against some circulating SARS-CoV-2 variants is currently limited.

What are the risks associated with Regkirona?

Infusion-related reactions, including allergic reactions and anaphylaxis, may affect up to 1 in 1,000 people given Regkirona.

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

Why is Regkirona authorised in the EU?

Regkirona was shown to be effective at reducing the risk of hospitalisation or death in patients with COVID-19 at increased risk of the disease becoming severe. The safety profile of Regkirona is considered favourable. The European Medicines Agency therefore decided that Regkirona'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 Regkirona?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Regkirona have been included in the summary of product characteristics and the package leaflet.

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

Other information about Regkirona

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

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

This overview was last updated in 11-2021.