11 November 2021
EMA/CHMP/629963/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ronapreve

casirivimab / imdevimab

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ronapreve, intended for the treatment of COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. In addition Ronapreve is also intended for prophylaxis against COVID-19 in people aged 12 years and older.

The applicant for this medicinal product is Roche Registration GmbH.

Detailed recommendations for the use of this product are described in the product information (PI), which is published in English here.

The European public assessment report (EPAR) will be published after the marketing authorisation has been granted by the European Commission and will make this information available in all official European Union languages.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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