30 January 2025
EMA/516539/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ronapreve

casirivimab / imdevimab

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Ronapreve. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to the existing indication to include treatment of children aged 2 years and older who weigh at least 10 kg. For information, the full indications for Ronapreve will be as follows:[2]

Ronapreve is indicated for:

- Treatment of COVID-19 in adults~~, and~~ adolescents**, and children** aged ~~1~~2 years and older weighing at least ~~40~~**10** kg who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.
- Treatment of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg and receiving supplemental oxygen, who have a negative SARS-CoV-2 antibody test result.
- Prevention of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg.

Ronapreve should be used in accordance with official recommendations where available and based on information on the activity of casirivimab and imdevimab against presently circulating viral variants (see sections 4.4 and 5.1).

~~The use of Ronapreve should take into account information on the activity of Ronapreve against viral variants of concern. See sections 4.4 and 5.1.~~

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[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
[2] New text in bold, removed text as strikethrough

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