11 December 2025
EMADOC-1700519818-2608675
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Recarbrio

imipenem / cilastatin / relebactam

On 11 December 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 Recarbrio. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to the existing indication, as follows:[2]

> Recarbrio is indicated **in adult and paediatric patients from birth** for:
>
> - Treatment of hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)~~, in adults~~ (see sections 4.4 and 5.1).
> - Treatment of bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP~~, in adults~~.
> - Treatment of infections due to aerobic Gram-negative organisms ~~in adults~~ with limited treatment options (see sections 4.2, 4.4, and 5.1).
>
> Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website 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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