29 January 2026
EMADOC-1700519818-2833585
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Kerendia

finerenone

On 29 January 2026 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 Kerendia. The marketing authorisation holder for this medicinal product is Bayer AG.

The CHMP adopted a new indication associated with a new strength, 40 mg film-coated tablets, as follows:

> Kerendia is indicated for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults.

For information, the full indications for Kerendia will now be:[2]

> Kerendia is indicated for the treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults.
>
> For study results with respect to renal and cardiovascular events, see section 5.1.
>
> **Kerendia is indicated for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults.**

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

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