15 December 2022
EMA/CHMP/904661/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Kerendia

finerenone

On 15 December 2022, 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 an extension to an existing indication for the treatment of chronic kidney disease. For information, the full indications for Kerendia will therefore be as follows:[2]

> Kerendia is indicated for the treatment of chronic kidney disease (~~stage 3 and 4~~ with albuminuria) associated with type 2 diabetes in adults.
>
> For study results with respect to renal and cardiovascular events, see section 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 will be 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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