16 December 2021
EMA/CHMP/610605/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kerendia

finerenone

On 16 December 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 Kerendia, intended for the treatment of chronic kidney disease associated with type 2 diabetes in adults.

The applicant for this medicinal product is Bayer AG.

Kerendia will be available as 10 mg and 20 mg film-coated tablets. The active substance of Kerendia is finerenone, an aldosterone antagonist belonging to diuretics (ATC code: C03DA05). Finerenone is a non-steroidal, selective antagonist of the mineralocorticoid receptor. It reduces the expression of pro-inflammatory and pro-fibrotic mediators.

The benefit of Kerendia is its ability to delay the progression of kidney disease in adults with chronic kidney disease and type 2 diabetes compared with placebo.

The most common side effects are hyperkalaemia, decreased eGFR and hypotension.

The full indication is:

> Kerendia is indicated for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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