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Kerendia (*finerenone*)

An overview of Kerendia and why it is authorised in the EU

What is Kerendia and what is it used for?

Kerendia is a medicine used to treat chronic kidney disease in adults with type 2 diabetes.

It is used for patients with moderate or severe kidney damage who pass albumin (a type of protein) in their urine.

Kerendia contains the active substance finerenone.

How is Kerendia used?

Kerendia can only be obtained with a prescription.

Kerendia is available as tablets to be taken by mouth once a day. The dosage to be taken depends on the patient's kidney function.

For more information about using Kerendia, see the package leaflet or contact your doctor or pharmacist.

How does Kerendia work?

The active substance in Kerendia, finerenone, binds to a receptor (target) known as mineralocorticoid receptor (MR). MR is involved in the activation of processes that cause inflammation and scarring in the kidneys. By binding to MR, Kerendia blocks the start of these processes, preventing inflammation and scarring and leading to less kidney damage.

What benefits of Kerendia have been shown in studies?

Kerendia, in addition to standard treatment, was shown to be effective at slowing down kidney disease in one main study involving over 5,600 patients with chronic kidney disease and type 2 diabetes. In this study, 18% of patients taking Kerendia (504 out of 2,833) experienced a loss of kidney function compared with 21% of patients taking a placebo, or dummy treatment, (600 out of 2,841).

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What are the risks associated with Kerendia?

The most common side effect with Kerendia (which may affect more than 1 in 10 people) is the presence of high potassium levels in the blood. Other common side effects, which may affect up to 1 in 10 people, are low levels of sodium in the blood, low blood pressure, itching and loss of kidney function.

Kerendia must not be used in patients with Addison's disease (a condition that prevents the body from producing enough of the hormones cortisol and aldosterone). It must also not be used with certain medicines that strongly block the effects of CYP3A4, a liver enzyme that helps the body process many medicines.

For the full list of side effects and restrictions of Kerendia, see the package leaflet.

Why is Kerendia authorised in the EU?

Kerendia was shown to slow down loss of kidney function in adults with chronic kidney disease and type 2 diabetes. Overall, the medicine's side effects were considered manageable. Therefore, the European Medicines Agency decided that Kerendia's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Kerendia?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kerendia have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Kerendia are continuously monitored. Side effects reported with Kerendia are carefully evaluated and any necessary action taken to protect patients.

Other information about Kerendia

Kerendia received a marketing authorisation valid throughout the EU on 16 February 2022.

Further information on Kerendia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/kerendia.

This overview was last updated in 02-2022.