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Kerendia® (active substance: finerenone)

First authorisation in Switzerland: 26 November 2021

Medicinal product for the treatment of chronic kidney disease and type 2 diabetes in adults

About the medicinal product

Kerendia contains the active substance finerenone and is used for the treatment of adults with chronic kidney disease and type 2 diabetes in order to delay the progression of kidney damage.

Chronic kidney disease refers to the sustained deterioration in renal function (particularly the filtration function), which ultimately leads to the accumulation of toxic metabolic products in the body.

In type 2 diabetes the blood sugar level rises as a result of the declining efficacy of the hormone insulin produced by the body (insulin resistance). A long-term rise in the blood sugar level damages the smaller blood vessels, e.g. in the kidneys. As a result, patients with type 2 diabetes have an increased risk of developing chronic kidney disease.

Kerendia was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA) and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Kerendia was submitted to the drug regulatory authorities in Singapore, Australia and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Mode of action

The active substance finerenone is what is known as a "mineralocorticoid receptor antagonist[1]" (MRA). Overactivation of the "mineralocorticoid receptor" is thought to be involved in the damage caused to the kidneys.

Use

Kerendia is a prescription-only medicine and is available in two different doses (10 mg and 20 mg of the active substance finerenone). The usual dosage is one 10 mg or 20 mg film-coated tablet a day, depending on the results of the blood test carried out by the doctor before the treatment in order to establish the correct dose.
The film-coated tablet should be taken at the same time every day and swallowed whole with a glass of water, with or without food. Kerendia should not be taken with grapefruit juice or grapefruit.

Efficacy

The efficacy of Kerendia in the treatment of type 2 diabetes and chronic kidney disease in adults was investigated in the FIDELIO-DKD study with a total of 5,674 participants. Half of the patients were treated with Kerendia and the other half with placebo (dummy drug).

The primary analysis[2] was based on a composite of three factors:

- the time to first occurrence of kidney failure
- a decrease in the eGFR (glomerular filtration rate[3]) of ≥40% compared to baseline over at least four weeks
- death due to kidney failure

The study demonstrated superiority of the treatment with Kerendia over placebo for the primary analysis factors described above.

Moreover, significantly fewer incidents of heart failure[4], non-fatal myocardial infarction and cardiovascular death occurred during the treatment with Kerendia compared to the treatment with placebo.

[1] Receptor antagonist: Receptors are very specific docking sites. Receptors exist for numerous substances. As soon as a specific substance (agonist) binds to its receptor, a reaction is triggered in the cell. An antagonist blocks a receptor, thereby preventing an agonist from binding to that receptor.

[2] Primary analysis: The primary analysis takes place when the primary endpoint of a clinical trial is reached. The primary endpoint is the main objective of the study determined before the trial starts. If the primary endpoint is reached or exceeded, the study proves that a treatment is effective. Secondary endpoints, on the other hand, refer to other effects that do not clearly prove efficacy or that do not allow any clear conclusions to be drawn about the actual target criterion (primary endpoint).

[3] Glomerular filtration rate (eGFR): The eGFR is an important parameter for assessing kidney function. It describes the rate at which the filtered fluid flows through the kidney.

[4] Heart failure: Heart failure is a condition in which the heart muscle is no longer strong enough to pump sufficient blood throughout the body.

Precautions, undesirable effects & risks

Kerendia must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most commonly reported undesirable effect in all the patients treated with Kerendia was an elevated potassium level (hyperkalaemia).

All precautions, risks and other possible side effects are listed in the Information for patients and the Information for healthcare professionals, which are updated as required (see link at the end of this document).

Why the medicinal product has been authorised

The pivotal study showed a significant and clinically relevant benefit for Kerendia compared to placebo, with a reduction in the risk of progression to chronic kidney disease. The risk of serious cardiovascular side effects was also lower.

Based on all the available data, the benefits of Kerendia outweigh the risks. Swissmedic has therefore authorised the medicinal product Kerendia for the treatment of adults with chronic kidney disease and type 2 diabetes in order to delay the progression of kidney damage.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Kerendia®

Information for patients (package leaflet): Information for patients Kerendia®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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