▼Kerendia® (finerenone) 10 mg, 20mg film-coated tablets

Prescribing Information: United-Kingdom

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 10 mg/ 20 mg finerenone tablet. **Indication:** Kerendia is indicated for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults. **Posology & method of administration:** ***Adults*****:** Estimated glomerular filtration rate (eGFR) and serum potassium have to be measured to determine if treatment can be initiated. The starting dose for patients with eGFR ≥ 25 to < 60 mL/min/1.73 m^2 is 10 mg once daily if serum potassium ≤ 4.8 mmol/L; if serum potassium > 4.8 to 5.0 mmol/L, starting 10 mg once daily may be considered with additional serum potassium monitoring within the first 4 weeks based on patient characteristics and serum potassium levels; if serum potassium > 5.0 mmol/L, treatment should not be initiated. Four weeks after initiation, serum potassium and eGFR have to be remeasured. If serum potassium ≤4.8 mmol/L and eGFR has not decreased by >30% compared to previous measurement, increase to 20mg once daily; if serum potassium >4.8 to 5.5 mmol/L maintain 10 mg once daily; if serum potassium >5.5 mmol/L withhold finerenone & consider re-starting at 10 mg once daily when serum potassium ≤ 5.0 mmol/L. eGFR and serum potassium have to be remeasured 4 weeks after a dose increase or re-start of treatment. Thereafter, serum potassium has to be remeasured periodically and as needed based on patient characteristics and serum potassium levels. Maintain current dose of 10 mg or 20 mg once daily if serum potassium > 4.8 to 5.5 mmol/L. Withhold 10 mg once daily treatment if serum potassium >5.5 mmol/L and consider re-starting at 10 mg once daily when serum potassium ≤ 5.0 mmol/L. Withhold 20 mg once daily treatment if serum potassium >5.5 mmol/L and re-start at 10 mg once daily when serum potassium ≤ 5.0 mmol/L. Ongoing monitoring of renal function should be performed as needed according to standard practice. Tablets may be taken with a glass of water and with or without food. For patients who are unable to swallow whole tablets, Kerendia tablets may be crushed and mixed with water or soft foods, such as apple sauce, directly before oral use. Tablets should not be taken with grapefruit or grapefruit juice. Missed doses should be taken as soon as the patient realises but only on the same day. The patient should not take 2 doses to make up for a missed dose. ***Children & adolescents*****:** The safety and efficacy of finerenone in children and adolescents aged under 18 years have not yet been established. No data are available. ***Elderly:*** No dose adjustment is necessary in elderly patients. ***Renal impairment:*** Initiation of treatment: In patients with eGFR < 25 mL/min/1.73 m^2, finerenone treatment should not be initiated due to limited clinical data. Continuation of treatment: In patients with eGFR ≥ 15 mL/min/1.73 m^2, finerenone treatment can be continued with dose adjustment based on serum potassium. eGFR should be measured 4 weeks after initiation to determine whether the starting dose can be increased to the recommended daily dose of 20 mg. Due to limited clinical data, finerenone treatment should be discontinued in patients who have progressed to end-stage renal disease (eGFR < 15 mL/min/1.73 m^2). ***Hepatic impairment:*** No initial dose adjustment is required for mild/ moderate hepatic impairment (moderate: consider additional serum potassium monitoring and adapt monitoring according to patient characteristics); finerenone should not be initiated in patients with severe hepatic impairment: **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients; concomitant treatment with strong inhibitors of CYP3A4; Addison's disease. **Warnings & precautions:** Hyperkalaemia has been observed in patients treated with finerenone. Risk factors to develop hyperkalaemia include low eGFR, higher serum potassium and previous episodes of hyperkalaemia. In these patients more frequent monitoring has to be considered. Finerenone treatment should not be initiated in patients with serum potassium >5.0 mmol/L, with eGFR < 25 mL/min/1.73 m^2, or severe hepatic impairment. If serum potassium >5.5 mmol/L, finerenone treatment has to be withheld. Serum potassium and eGFR have to be remeasured in all patients 4 weeks after initiation, re-start or increase in dose of finerenone. Due to limited clinical data, finerenone treatment should be discontinued in patients who have progressed to end stage renal disease (eGFR < 15 mL/min/1.73 m^2). This medicinal product contains lactose and sodium. **Interactions:** Concomitant use of Kerendia with strong CYP3A4 inhibitors is contraindicated. Serum potassium should be monitored during concomitant use of finerenone with moderate or weak CYP3A4 inhibitors. Finerenone should not be used concomitantly with strong or moderate CYP3A4 inducers. Grapefruit or grapefruit juice should not be consumed during finerenone treatment. Kerendia should not be used concomitantly with potassium-sparing diuretics and other mineralocorticoid receptor antagonists. Kerendia should be used with caution and serum potassium should be monitored when taken concomitantly with potassium supplements, trimethoprim, or trimethoprim/sulfamethoxazole. Temporary discontinuation of finerenone may be necessary when patients have to take trimethoprim, or trimethoprim/sulfamethoxazole. The risk for hypotension increases with concomitant use of multiple other antihypertensive medicinal products. In these patients, blood pressure monitoring is recommended. **Pregnancy & lactation:** There are no data from the use of finerenone in pregnant women. Studies in animals have shown reproductive toxicity. Women of childbearing potential should use effective contraception during finerenone treatment. Kerendia should not be used during pregnancy unless the clinical condition of the woman requires treatment with finerenone. If the woman becomes pregnant while taking finerenone, she should be informed of potential risks to the foetus. It is unknown whether finerenone/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Kerendia therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **Undesirable effects:** *Very common*: hyperkalaemia. *Common*: hyponatraemia, hyperuricaemia, hypotension, pruritus, glomerular filtration rate decreased. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** The most likely manifestation of overdose is anticipated to be hyperkalaemia. If hyperkalaemia develops, standard treatment should be initiated. Finerenone is unlikely to be efficiently removed by haemodialysis given its fraction bound to plasma proteins of about 90%. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** 10mg 2 x 14 blister pack: £36.68. 20mg 2 x 14 blister pack: £36.68 OR 10mg 28 tablets: £36.68. 20mg 28 tablets: £36.68. **MA Number(s): United Kingdom** - PLGB 00010/0751 (10 mg), PLGB 00010/0752 (20 mg);.**Further information available from:** Bayer plc,400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000.

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Reporting adverse events and quality complaints

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at http://yellowcard.mhra.gov.uk/ or search MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc.

If you want to report an adverse event or quality complaint, reports can be directed to: Tel: 0118 2063500 or Email: pvuk@bayer.com

Further information is available on the "contact" tab at www.bayer.co.uk