▼Kerendia® (finerenone) 10 mg, 20mg & 40mg film-coated tablets

Prescribing Information: United Kingdom

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

Presentation: 10 mg/ 20 mg/ 40 mg finerenone film-coated tablets. **Indication: Chronic kidney disease associated with type 2 diabetes (10 mg/ 20 mg presentation*):*** Kerendia is indicated for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults. **Heart failure with LVEF ≥ 40% (10 mg/ 20 mg/ 40 mg presentation):** Kerendia is indicated for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥40% in adults. **Please note:** The 40 mg dose is only licensed for heart failure with LVEF ≥ 40% indication. **Posology & method of administration: For Chronic Kidney Disease associated with Type 2 Diabetes: Adults: The recommended target dose is 20 mg finerenone once daily. The maximum recommended dose is 20 mg finerenone once daily.** Estimated glomerular filtration rate (eGFR) and serum potassium have to be measured to determine if treatment can be initiated**. Kerendia is indicated for CKD stage 3 and 4 (eGFR 25 to <60 mL/min/1.73 m²) with albuminuria**. **Starting dose: 10 mg once daily** if serum potassium ≤4.8 mmol/L; if serum potassium >4.8 to 5.0 mmol/L, starting may be considered with additional monitoring; if serum potassium >5.0 mmol/L, treatment should not be initiated. **Four weeks after initiation or at re-start of finerenone or increase in dose, 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 20 mg once daily**; if patient's current finerenone dose is 20 mg and serum potassium ≤4.8 mmol/L, maintain 20 mg once daily; if serum potassium >4.8 to 5.5 mmol/L, maintain current finerenone dose (10 mg or 20 mg once daily); if serum potassium >5.5 mmol/L, withhold finerenone (10 mg and 20 mg doses) & restart at 10 mg (for 20 mg once daily current dose) or consider re-starting at 10 mg once daily (for 10 mg once daily current dose) when serum potassium ≤5.0 mmol/L. Local guidelines for the management of hyperkalaemia have to be followed. Thereafter, serum potassium has to be re-measured periodically based on patient characteristics and serum potassium level. **For Heart Failure with LVEF ≥40%*:*** ***Adults***: The recommended target dose depends on eGFR at initiation of finerenone treatment: **40 mg once daily** if eGFR **≥60 mL/min/1.73 m²**; **20 mg once daily** if eGFR **≥ 25 to <60 mL/min/1.73 m²**. The maximum recommended dose is **40 mg finerenone once daily**. **The 40 mg dose is licensed only for heart failure.** eGFR and serum potassium have to be measured to determine if treatment can be initiated and to determine the starting dose. If serum potassium **≤5.0 mmol/L**, finerenone treatment can be initiated; if serum potassium **>5.0 mmol/L, finerenone treatment should not be initiated**. Starting dose: eGFR **≥60 = 20 mg** once daily; eGFR **≥ 25 to <60 = 10 mg** once daily; eGFR <25 = initiation of finerenone treatment is not recommended. Serum potassium and eGFR have to be remeasured **4 weeks** after initiation or re-start or change in dose. Thereafter, serum potassium and eGFR have to be re-measured periodically based on patient characteristics and serum potassium levels. If serum potassium **≤5.0 mmol/L** and eGFR not decreased **≥30%** compared to previous measurement, **increase dose** (10 mg→20 mg, or 20 mg→40 mg) or **maintain 40 mg once daily dose,** if 40 mg is current finerenone dose; if serum potassium **5.0 to <5.5 mmol/L**, **maintain current dose** or **decrease dose** (40 mg →20 mg) if eGFR has decreased > 30% compared to the previous measurement; if serum potassium **5.5 to <6.0 mmol/L**, **decrease dose** (20 mg→10 mg or 40 mg→20 mg) or **withhold** (for current dose of 10 mg once daily) and restart 10 mg once daily when serum potassium < 5.5 mmol/L; if serum potassium **≥6.0 mmol/L**, **withhold finerenone** and re-start at 10 mg once daily when serum potassium <5.5 mmol/L or if repeatedly ≥5.5 mmol/L, wait to re-start until <5.0 mmol/L. If eGFR decreases by **≥40%**, consider reducing dose or withholding. Once eGFR stabilised, consider increasing dose or restarting finerenone.

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 (≥65 years):*** No dose adjustment is necessary in elderly patients, but regular monitoring of renal function is recommended. ***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 for the respective indication. Finerenone treatment should be discontinued in patients who have progressed to end-stage renal disease (eGFR < 15 mL/min/1.73 m^2). ***Body weight:*** No dose adjustment is necessary based on body weight. ***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. **For Chronic Kidney Disease (CKD) associated with Type 2 Diabetes (T2D):**For guidance on initiation, withholding and restarting finerenone based on serum potassium thresholds, see *posology and method of administration* section above. Local guidelines for the management of hyperkalaemia have to be followed. **Heart failure with LVEF ≥40%:** The threshold for withholding finerenone differs from that for CKD associated with T2D. For guidance on initiation, withholding and restarting finerenone based on serum potassium thresholds, including criteria for patients with repeated potassium elevations, see *posology and method of administration* section above. Local guidelines for the management of hyperkalaemia have to be followed. **Worsening of Renal Function in Heart failure with LVEF ≥40%:** An increased incidence of worsening of renal function has been reported in patients with heart failure with LVEF ≤40% treated with finerenone. Monitoring of renal function is recommended periodically during treatment and as needed based on patient characteristics. Elderly patients and patients with impaired renal function (eGFR <60 mL/min/1.73 m²) are at higher risk for worsening of renal function and should be monitored more frequently.

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. **For 40 mg dose:** At 40 mg once daily, finerenone is a weak inhibitor of the CYP3A4 and CYP2C8 enzymes in vivo. The potentially increased exposure of sensitive CYP3A4 and CYP2C8 substrates with a narrow therapeutic window needs to be considered when used concomitantly with finerenone 40 mg once daily. Grapefruit or grapefruit juice should not be consumed during finerenone treatment. The risk of hyperkalaemia also may increase with the intake of concomitant medicinal products that may increase serum potassium 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 or potassium-enriched salt substitutes, 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. **Fertility:** There are no data on the effect of finerenone on human fertility. Animal studies have shown impaired female fertility at exposures in excess to the maximum human exposure, indicating low clinical relevance **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: For Chronic Kidney Disease associated with Type 2 Diabetes: *Very common*:** hyperkalaemia. ***Common*:** hyponatraemia, hyperuricaemia, hypotension, pruritus, glomerular filtration rate decreased. Blood creatinine increased. ***Uncommon:*** Haemoglobin decreased **Heart Failure with LVEF ≥40%*:* *Common*:** hyperkalaemia, hyponatraemia, hyperuricaemia, hypotension, diarrhoea, constipation, renal impairment, acute kidney injury, blood creatinine increased, glomerular filtration rate decreased. Prescribers should consult 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. 40mg 2 x 14 blister pack: £36.68 OR 10mg 28 tablets: £36.68. 20mg 28 tablets: £36.68. 40mg 28 tablets: £36.68 **MA Number(s): United Kingdom** - PLGB 00010/0751 (10 mg), PLGB 00010/0752 (20 mg), PL 00010/0766 (40 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