Kerendia® ▼ finerenone

Prescribing information and adverse event reporting are available further down the page

This material is intended for HCPs in Great Britain only

BAYER

FIDELIO-DKD

Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes

Bakris GL *et al*. N Engl J Med 2020; 383(23): 2219-29.

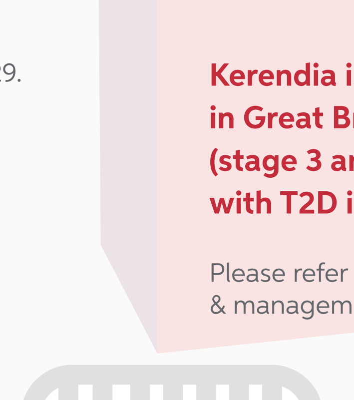
Figures are adapted from Bakris[1]

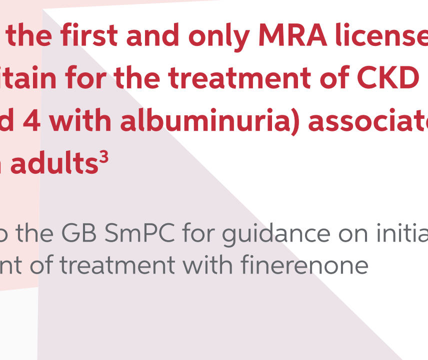
Kerendia is a selective, mineralocorticoid receptor antagonist[2]

Kerendia is the first and only MRA licensed in Great Britain for the treatment of CKD (stage 3 and 4 with albuminuria) associated with T2D in adults[3]

Please refer to the GB SmPC for guidance on initiation & management of treatment with finerenone

Kerendia is pharmacologically distinct from steroidal MRAs[4,5]





FIDELIO-DKD was designed to test the hypothesis that Kerendia slows CKD progression in patients with T2D[1]

Study design[1]

Phase 3, randomised, double-blind, placebo-controlled, multicentre, clinical trial conducted in 48 countries

In GB, finerenone is licensed in adults for the treatment of stage 3 & 4 CKD with albuminuria associated with T2D. The starting dose is 10 mg OD. For further information on initiation and continuation of treatment consult SmPC

1:1 randomisation
n=5734
adults with CKD + T2D

Kerendia 10 or 20 mg OD**
(dose depending on eGFR and potassium levels)
+ Optimised RAS blockade* & glucose-lowering therapy

n=2833

n=2841

Placebo
+ Optimised RAS blockade* & glucose-lowering therapy

Median follow-up: 2.6 years

*Includes an ACEi or ARB at the maximum tolerated dose

**10 mg if screening eGFR was ≥25 to <60 mL/min/1.73 m²; 20 mg if ≥60 mL/min/1.73 m², up-titration encouraged from month 1 if serum potassium ≤4.8 mmol/L & eGFR stable (maintain 10 mg once daily, if eGFR has decreased >30% compared to the previous measurement)

Primary composite renal outcome:[1]

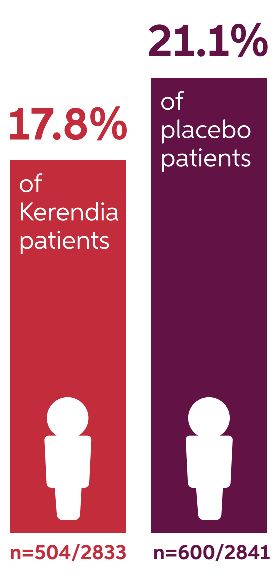
Kidney failure*, or

Sustained decline of ≥40% in eGFR from baseline over ≥4 weeks, or

Death due to renal causes

Kerendia significantly slowed CKD progression over and above optimised background therapy with an ACEi or ARB[1]

Incidence of primary composite renal outcome[1]



RRR: 18%

HR: 0.82
95% CI: 0.73-0.93
p=0.001
Median follow-up 2.6 years

At 36 months	
ARR: 3.4% 95% CI: 0.6-6.2	**NNT: 29** 95% CI: 16-166 (to prevent one primary outcome)

*Defined as end-stage kidney disease (initiation of dialysis for ≥90 days or kidney transplantation), or an eGFR <15 ml/min/1.73 m² over ≥4 weeks

Secondary composite CV outcome:[1]

Death from CV causes, or

Non-fatal MI, or

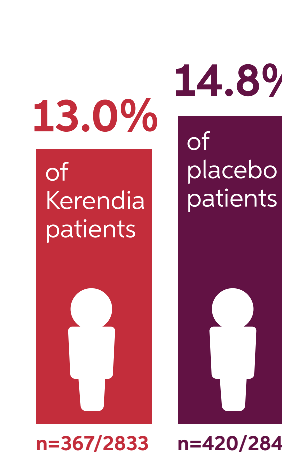
Non-fatal stroke, or

Hospitalisation for heart failure

A statistically significant difference in favour of Kerendia was shown for the key secondary composite endpoint[1]

Kerendia is not indicated for reducing cardiovascular events

Incidence of secondary composite CV outcome[1]



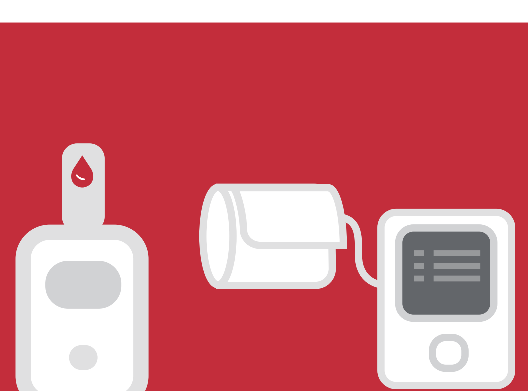
RRR: 14%

HR: 0.86
95% CI: 0.75-0.99
p=0.03
Median follow-up 2.6 years

At 36 months
ARR: 2.4% 95% CI: 0.3-4.5

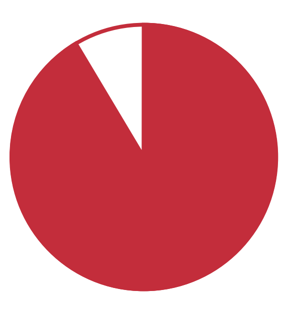
Kerendia delayed CKD progression in patients with T2D despite having no effect on glycaemic control and resulting in only a modest reduction in blood pressure[1]*

*Adverse reactions occurring in >1% of patients includes hypotension; the risk increases with concomitant use of multiple other antihypertensive medicines



The incidence of any treatment-emergent AE was similar across the Kerendia and placebo groups[1]*

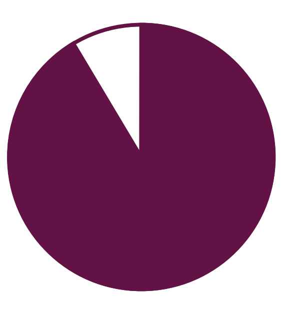
Kerendia



87.3% of patients

n=2468/2827

Placebo



87.5% of patients

n=2478/2831

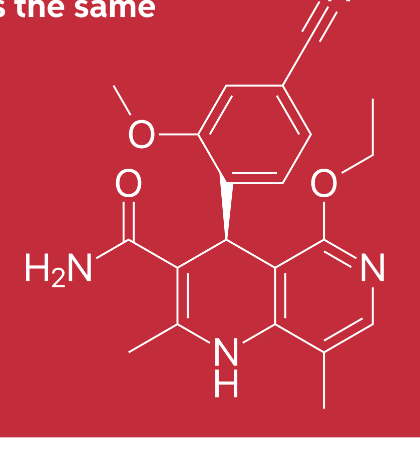
*Defined as those that started or worsened during finerenone or placebo intake or up to 3 days after any temporary or permanent interruption

Due to Kerendia's selectivity for the MR receptor, within the FIDELIO-DKD trial no patients taking Kerendia suffered breast hyperplasia and the number of patients who developed gynaecomastia was the same across both Kerendia and placebo arms[1]

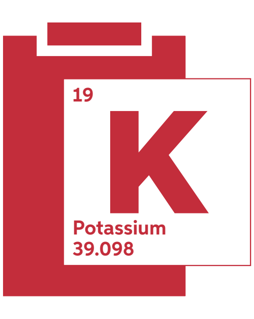
Reproductive system and breast disorders

4.5% of Kerendia patients
n=126/2827

5.2% of placebo patients
n=146/2831



Majority of hyperkalaemia events in patients treated with finerenone were mild to moderate and resolved. Permanent discontinuation of the trial regimen due to hyperkalaemia was 2.3%[1,3]



*As reported by investigators using the Medical Dictionary for Regulatory Activities (MEDRA) preferred terms "hyperkalaemia" and "blood potassium increased"

†A causal relationship between any AE and administration of Kerendia or placebo was based on the opinion of the reporting investigator

Investigator-reported hyperkalaemia[1]*

18.3% of Kerendia patients
n=516/2827

9.0% of placebo patients
n=255/2831

Hyperkalaemia related to trial regimen[1]†

11.8% of Kerendia patients
n=333/2827

4.8% of placebo patients
n=135/2831

Permanent discontinuation due to hyperkalaemia[1]

2.3% of Kerendia patients
n=64/2827

0.9% of placebo patients
n=25/2831

For patients treated with finerenone serum potassium and eGFR have to be remeasured in all patients 4 weeks after initiation or re-start of finerenone treatment or increase in dose. Thereafter, serum potassium has to be assessed periodically and as needed based on patient characteristics and serum potassium levels

Efficacy result
Kerendia delayed CKD progression in adults with CKD associated with T2D vs placebo[1]

Safety result
The incidence of any treatment-emergent AE was similar across the Kerendia and placebo groups[1]

FIDELIO-DKD

For your adult patients with CKD (stage 3 and 4 with albuminuria) associated with T2D[3]

Delay CKD progression with Kerendia

Please refer to the Great Britain **Summary of Product Characteristics** before prescribing Kerendia

References:
1. Bakris GL *et al*. N Engl J Med 2020; 383(23): 2219-29.
2. Agarwal R *et al*. Nephrol Dial Transplant 2022; 37(6): 1014-23.
3. Great Britain Kerendia Summary of Product Characteristics. July 2023
4. Kolkhof P *et al.* Handb Exp Pharmacol 2017; 243: 271-305.
5. Agarwal R *et al.* Eur Heart J 2021; 42(2): 152-61.

ACEi: angiotensin converting enzyme inhibitor
AE: adverse event
ARB: angiotensin receptor blocker
ARR: absolute risk reduction
CI: confidence interval
CKD: chronic kidney disease
CV: cardiovascular
DKD: diabetic kidney disease
eGFR: estimated glomerular filtration rate
HR: hazard ratio
MI: myocardial infarction
MRA: mineralocorticoid receptor antagonist
NNT: number needed to treat
OD: once daily
RAS: renin-angiotensin-aldosterone system
RRR: relative risk reduction
T2D: type 2 diabetes

This link will take you to a 3rd party website. Bayer have no control over the content and management of this website

To read the full FIDELIO-DKD study, scan this QR code or click here

Stay connected with Bayer electronic communications about Bayer's products, services and events **by registering at: https://go.bayer.com/UKConsent**

Alternatively open your phone camera application, hold it over the QR code and tap the link that appears.

Kerendia® ▼ finerenone

This promotional material has been developed and funded by Bayer plc and is intended for HCPs in Great Britain only.

Date of preparation: July 2023

PP-KER-GB-0503

BAYER

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 https://yellowcard.mhra.gov.uk. 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: 01182063500 or email: pvuk@bayer.com

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

▼ Kerendia® (finerenone) 10 mg, 20mg film-coated tablets.
Prescribing Information: Great Britain
(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 m² 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 m², finerenone treatment should not be initiated due to limited clinical data. Continuation of treatment: In patients with eGFR ≥15 mL/min/1.73 m², 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 m²). ***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 m², 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 m²). 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:** 10 mg 2 x 14 blister pack: £36.68. 20 mg 2 x 14 blister pack: £36.68 OR 10 mg 28 tablets: £36.68. 20 mg 28 tablets: £36.68. **MA Number(s):** *Great Britain* - 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.
Date of preparation: July 2023
Kerendia® is a trademark of the Bayer Group

▼ 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