Kerendia® ▼ finerenone

Adverse event reporting and Prescribing Information for Kerendia® (finerenone) is available via the QR code on the right.

Either click here or scan the QR code for adverse event reporting information and prescribing information.

For direct access to this prescribing information, please ensure that your device's browser settings have automatic PDF download enabled.

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.

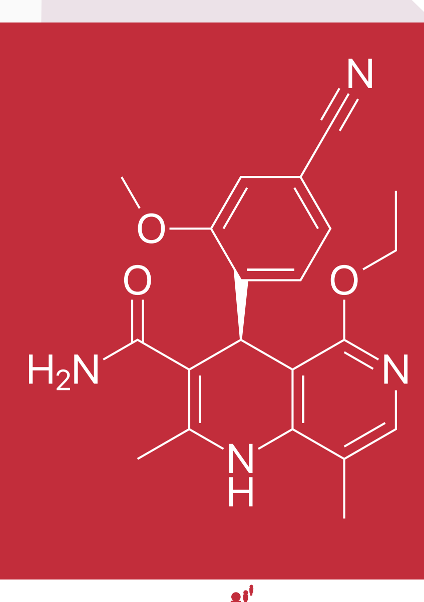
Figures are adapted from Bakris[1]

Kerendia is a selective, mineralocorticoid receptor antagonist[2]

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

Please refer to the 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 the UK, 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]

17.8% of Kerendia patients (n=504/2833)

21.1% of placebo patients (n=600/2841)

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%	NNT: 29
95% CI: 0.6-6.2	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

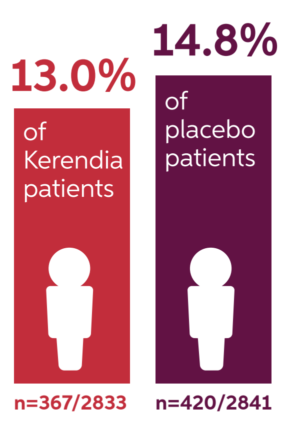
Non-fatal stroke, or

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]



13.0% of Kerendia patients (n=367/2833)

14.8% of placebo patients (n=420/2841)

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 versus placebo despite having no effect on glycaemic control and resulting in only a modest reduction in blood pressure[1]*

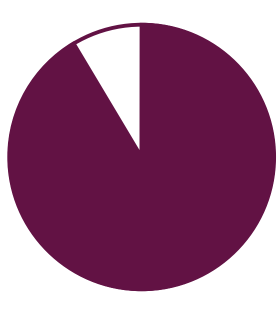
*Adverse reactions occurring in >1% of patients includes hypotension; the risk increases with concomitant use of multiple other antihypertensive medicines

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

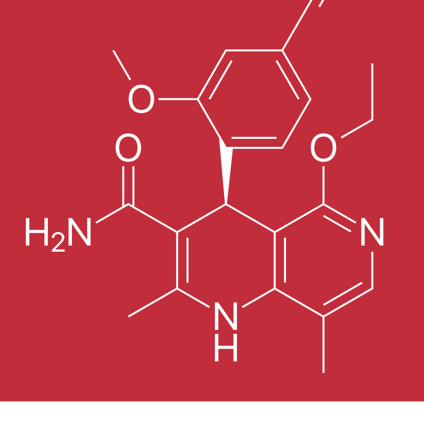
*Defined as those that started or worsened during finerenone or placebo intake or up to 3 days after any temporary or permanent interruption

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]

19 K Potassium 39.098

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

*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

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

Delay CKD progression with Kerendia®[1]

NICE RECOMMENDED

NICE recommends Kerendia®, the first and only UK licensed non-steroidal MRA, as an add-on to standard of care for stage 3 and 4 CKD (with albuminuria) associated with T2D[3]

Kerendia® slows CKD progression in T2D and can significantly delay progression of renal disease (vs. placebo)[1]

Diabetic kidney disease is progressive and irreversible; act now with Kerendia® to significantly reduce the risk of renal & CV events for your patient (vs. placebo)[1]

Please refer to the **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. Kerendia Summary of Product Characteristics
   Kolkhof P *et al*. Handb Exp Pharmacol 2017; 243: 271-305.
4. Agarwal R *et al*. Eur Heart J 2021; 42(2): 152-61.
5. NICE. Finerenone for treating chronic kidney disease in type 2 diabetes [TA877]. Available at: https://www.nice.org.uk/guidance/ta877. Accessed December 2024.

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

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 system
RRR: relative risk reduction
T2D: type 2 diabetes

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