For your adult patients with T2D and CKD

Intervene with Kerendia® (finerenone) as adjunct therapy.[1]

Kerendia® is indicated as an adjunct to standard of care in adults with chronic kidney disease (CKD) and type 2 diabetes (T2D) to reduce the risk of:

- End-stage kidney disease and a sustained decrease in estimated glomerular filtration rate,
- Cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure.

Kerendia® is the first and only MRA to be indicated as adjunct therapy to standard of care in adults with T2D and CKD.[2*]

MRA=mineralocorticoid receptor antagonist.
*Comparative clinical significance has not been established.

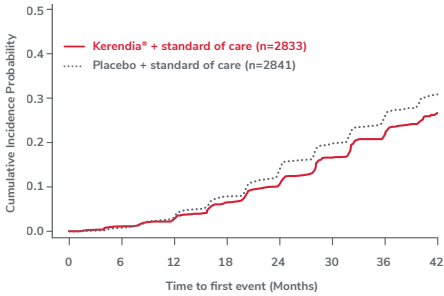
Pr Kerendia®
(finerenone)
10 mg • 20 mg Tablets

FIDELIO-DKD

In patients receiving standard of care, including a maximum tolerated dose of ACEi/ARB therapy...

Kerendia® (finerenone) significantly reduced the risk of the primary renal composite endpoint vs. placebo.[1*†]

Time to first occurrence of kidney failure, sustained decline in eGFR of ≥40%, or renal death
(primary composite endpoint)[1]



18% RRR
HR 0.82;
95% CI: 0.73-0.93;
p=0.0014[‡]

Incidence of composite endpoint occurred in 504 Kerendia® patients (17.8%) vs. 600 placebo patients (21.1%).

- **The NNT to prevent one primary outcome event was 29** (95% CI: 16-166) on the basis of an absolute between-group difference of 3.4 percentage points (95% CI: 0.6-6.2) after 3 years.[3]
- **Individual composite endpoint components:**[1]
  Kidney failure: 7.3% vs. 8.3% placebo (HR 0.87; 95% CI: 0.72-1.05)

  Sustained eGFR decline ≥40%: 16.9% vs. 20.3% placebo (HR 0.81; 95% CI: 0.72-0.92)

  Renal death: <0.1% vs. <0.1% placebo

FIGARO-DKD

In the FIGARO-DKD trial...[1†]

A lower incidence rate of the secondary composite outcome of kidney failure, sustained eGFR decline of ≥40%, or renal death was observed in the Kerendia® group compared to placebo; however this difference did not achieve statistical significance (HR 0.87; 95% CI: 0.76-1.01; *p*=0.0689).

ACEi=angiotensin-converting-enzyme inhibitor; ARB=angiotensin receptor blocker; CI=confidence interval; eGFR=estimated glomerular filtration rate; HR=hazard ratio; NNT=number needed to treat; RRR=relative risk reduction.

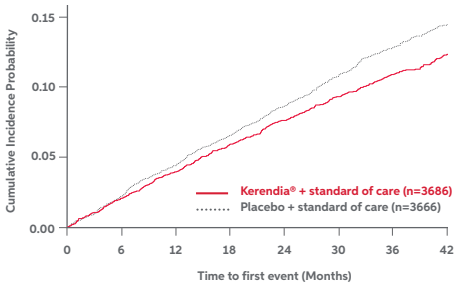
Open to view CV outcomes and study parameters.

FIGARO-DKD

In patients receiving standard of care, including a maximum tolerated dose of ACEi/ARB therapy...

Kerendia® (finerenone) significantly reduced the risk of the primary CV composite endpoint vs. placebo.[1†]

Time to first occurrence of CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF
(primary composite endpoint)



- **The NNT to prevent one primary outcome event was 47** (95% CI: 26-226) on the basis of an absolute between-group difference of 2.1 percentage points (95% CI: 0.4-3.8) after 3.5 years.[4†]

- **Individual composite endpoint components:**[1]
  HF hospitalization: 3.2% vs. 4.4% placebo
  (HR 0.71; 95% CI: 0.56-0.90)

  CV death: 5.3% vs. 5.8% placebo
  (HR 0.90; 95% CI: 0.74-1.09)

  Non-fatal MI: 2.8% vs. 2.8% placebo
  (HR 0.99; 95% CI: 0.76-1.31)

  Non-fatal stroke: 2.9% vs. 3.0% placebo
  (HR 0.97; 95% CI: 0.74-1.26)

FIDELIO-DKD

In the FIDELIO-DKD trial...[1*]

- Kerendia® significantly reduced the risk of the **secondary CV composite endpoint** of time to first occurrence of CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF vs. placebo: **14% RRR** (HR 0.86; 95% CI: 0.75-0.99; *p*=0.0339)‡

- **Individual composite endpoint components:**

  HF hospitalization: 4.9% vs. 5.7% placebo (HR 0.86; 95% CI: 0.68-1.08)

  CV death: 4.5% vs. 5.3% placebo (HR 0.86; 95% CI: 0.68-1.08)

  Non-fatal MI: 2.5% vs. 3.1% placebo (HR 0.80; 95% CI: 0.58-1.09)

  Non-fatal stroke: 3.2% vs. 3.1% placebo (HR 1.03; 95% CI: 0.76-1.38)

CV=cardiovascular; HF=heart failure; MI=myocardial infarction.

* Randomized, double-blind, placebo-controlled, multicentre phase III study of 5674 adults with T2D and CKD. Patients were randomly assigned to receive either Kerendia® 10 mg or 20 mg once daily (n=2833) or placebo (n=2841) and were followed for a median duration of 2.6 years. The primary endpoint in the FIDELIO-DKD study was a composite of time to first occurrence of kidney failure (defined as chronic dialysis or kidney transplantation, or a sustained decrease in eGFR to <15 mL/min/1.73m^2 over at least 4 weeks), a sustained decline in eGFR of 40% or more compared to baseline over at least 4 weeks, or renal death.

† Randomized, double-blind, placebo-controlled, multicentre phase III study of 7352 adults with T2D and CKD. Patients were randomly assigned to receive either Kerendia® 10 mg or 20 mg once daily (n=3686) or placebo (n=3666) and were followed for a median duration of 3.4 years. The primary endpoint of the FIGARO-DKD study was a composite of time to first occurrence of CV death, non-fatal MI, non-fatal stroke, or hospitalization for heart failure.

‡ Cox proportional hazards model and log rank test.

SAFETY INFORMATION

The safety profile of Kerendia® (finerenone) was demonstrated in a clinical trial program including over 13,000 patients with T2D and CKD.[1*]

Adverse reactions reported in ≥1% of Kerendia® patients and more frequently than placebo (pooled results from FIGARO-DKD and FIDELIO-DKD)[1]

	Kerendia® (n=6510)	Placebo (n=6489)
Anemia	**6.5%**	**6.1%**
Hyperkalemia[a]	**14%**	**6.9%**
Leading to hospitalization in FIGARO-DKD	0.6%	<0.1%
Leading to hospitalization in FIDELIO-DKD	1.4%	0.3%
Leading to permanent discontinuation in FIGARO-DKD	1.2%	0.4%
Leading to permanent discontinuation in FIDELIO-DKD	2.3%	0.9%
Hyperuricemia[b]	**5.1%**	**3.9%**
Hyponatremia[c]	**1.3%**	**0.7%**
Hypotension[d]	**4.6%**	**3.9%**
Pruritus	**2.9%**	**2.2%**

a. Includes *Blood potassium increased* and *Hyperkalemia*.
b. Includes *Blood uric acid increased* and *Hyperuricemia*.
c. Includes *Blood sodium decreased* and *Hyponatremia*.
d. Includes *Blood pressure decreased*, *Blood pressure diastolic decreased*, *Diastolic hypotension* and *Hypotension*.

The majority of hyperkalemia events in patients treated with Kerendia® were mild to moderate.[1]

There were no hyperkalemia-related deaths in the FIGARO-DKD or FIDELIO-DKD clinical trials.[3,4]

Rates of permanent discontinuation due to adverse reactions:[1]

- FIGARO-DKD: Kerendia® 6% vs. 5% placebo
- FIDELIO-DKD: Kerendia® 7% vs. 6% placebo

* The safety profile of Kerendia® in patients with chronic kidney disease and type 2 diabetes was evaluated in two pivotal phase III studies: FIDELIO-DKD and FIGARO-DKD. In the FIDELIO-DKD study, 2833 patients received Kerendia® (10 or 20 mg once daily) with a mean duration of treatment of 2.2 years. In the FIGARO-DKD study, 3686 patients received Kerendia® (10 or 20 mg once daily) with a mean duration of treatment of 2.9 years.[1]

Indications and Clinical Use:
Kerendia® (finerenone) is indicated as an adjunct to standard of care in adults with chronic kidney disease (CKD) and type 2 diabetes (T2D) to reduce the risk of:

- End-stage kidney disease and a sustained decrease in estimated glomerular filtration rate,
- Cardiovascular death, non-fatal myocardial infarction and hospitalization for heart failure.

Greater sensitivity of some older individuals (≥65 years of age) cannot be ruled out.

Contraindications:

- Patients receiving concomitant systemic treatment with strong CYP3A4 inhibitors.
- Patients with Addison's disease.

Relevant Warnings and Precautions:

- Consider additional serum potassium monitoring in patients using concomitant weak or moderate CYP3A4 inhibitors.
- Avoid concomitant use with moderate or strong CYP3A4 inducers.
- Avoid concomitant intake of grapefruit or grapefruit juice.
- Avoid use in patients with severe hepatic impairment (Child Pugh C). Consider additional serum potassium monitoring in patients with moderate hepatic impairment (Child Pugh B).
- Hyperkalemia can occur in patients with CKD and T2D, which may be aggravated by therapy, and in rare cases lead to serious, sometimes fatal arrhythmias. Kerendia® can cause hyperkalemia. Consider more frequent monitoring in high-risk patients.
- Initiation not recommended if serum potassium >5.0 mmol/L. If serum potassium >4.8-5.0 mmol/L, initiation may be considered with additional monitoring within the first 4 weeks. Withhold Kerendia® if serum potassium >5.5 mmol/L, and follow local guidelines for hyperkalemia management. Restart Kerendia® at 10 mg if serum potassium ≤5.0 mmol/L.
- Initiation of Kerendia® can cause an initial decrease in eGFR. Remeasure serum potassium and eGFR 4 weeks after initiation, re-start or up-titration of Kerendia®. Thereafter, remeasure serum potassium periodically and as needed.
- Avoid concomitant use of potassium-sparing diuretics and other mineralocorticoid receptor antagonists. Use with caution and monitor serum potassium when taken with concomitant use of potassium supplements, trimethoprim, or trimethoprim-sulfamethoxazole.
- Perform ongoing monitoring of renal function according to standard practice. Initiation not recommended in patients with eGFR <25 mL/min/1.73m². Continue with caution in patients who progress to eGFR <25 mL/min/1.73m² and discontinue in those who progress to end-stage kidney disease (eGFR <15 mL/min/1.73m²). A greater risk of glomerular filtration rate decrease has been observed with Kerendia®.
- Do not use during pregnancy without careful consideration of the risks and benefits. Women of childbearing potential should use effective contraception. If a patient becomes pregnant during treatment, inform them of the potential risks to the fetus.
- Breast-feeding women should either discontinue breast-feeding or discontinue Kerendia®, considering the benefits for the child and woman.

For More Information:
Consult the Product Monograph at www.bayer.com/sites/default/files/kerendia-pm-en.pdf for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-800-265-7382 or emailing canada.medinfo@bayer.com.

References: 1. Kerendia® (finerenone) Product Monograph. Bayer Inc. October 14, 2022. **2.** Data-on-file. Bayer Inc. **3.** Bakris GL, Agarwal R, Anker SD, et al. Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. *N Engl J Med.* 2020;383:2219-2229. **4.** Pitt B, Filippatos G, Agarwal R, et al. Cardiovascular Events with Finerenone in Kidney Disease and Type 2 Diabetes. *N Engl J Med.* 2021;385:2252-2263.

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REVIEWED BY PAAB

Kerendia® (finerenone) 10 mg • 20 mg Tablets

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