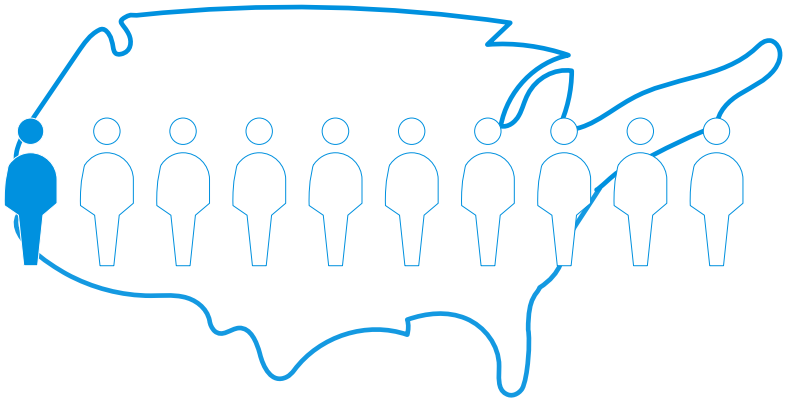
KERENDIA® (finerenone): A Treatment Option for Adults With CKD Associated With T2D

Please see the KERENDIA® Indication and Important Safety Information provided throughout the slide deck, and the accompanying Prescribing Information.

October 2021. MA-M_FIN-US-0153-1

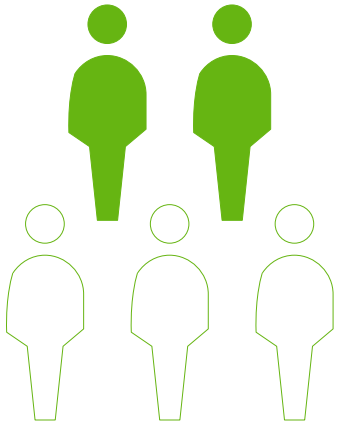
CKD Associated With T2D Is a Serious Public Health Issue

T2D is a leading cause of CKD in the US[1]



In 2018, **32.6M** Americans (~10%) had T2D[2]

≈40% of patients in the US



with **T2D** develop CKD[1,a]

Patients with CKD associated with **T2D** are at *increased risk* for *CV-related death* compared to patients with T2D alone[3,b]

[a]Study was conducted using NHANES 1999-2012 data. Projections for the US T2D population were based on NHANES sampling weights. [b]This study used data from NHANES III participants aged ≥20 years, who participated in a health examination and had available data on medications used, serum creatinine, and urine albumin and creatinine concentrations. Of these, the only participants who were included were those who had follow-up mortality data through 2006 (15,046 of 15,762 of NHANES III participants, 95.5%); 1430 (9.5%) of the 15,046 participants had T2D.

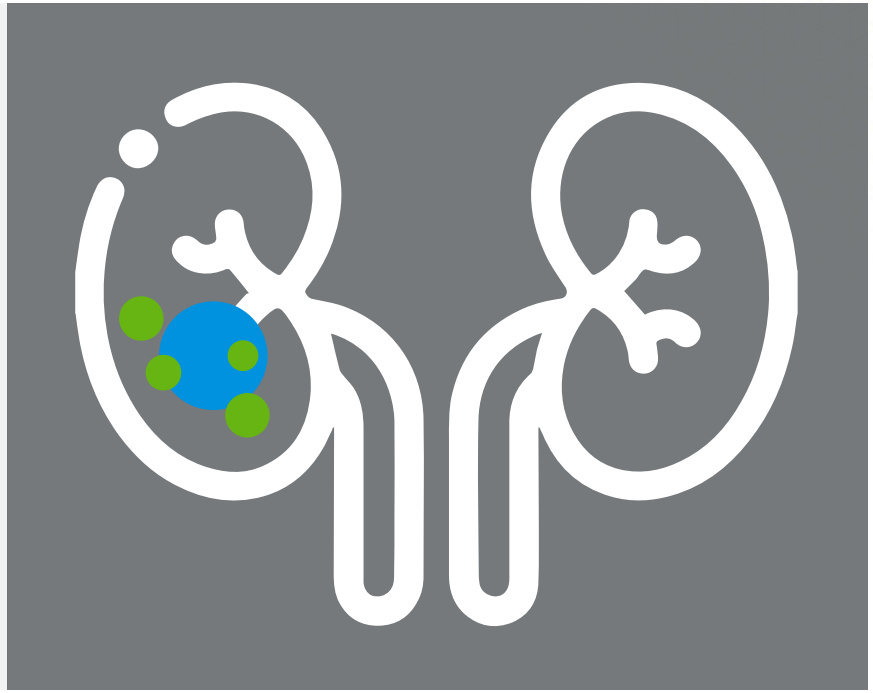
CKD, chronic kidney disease; CV, cardiovascular; NHANES, National Health and Nutrition Examination Survey; T2D, type 2 diabetes.

1. Bailey RA, et al. *BMC Res Notes*. 2014;7:415. **2.** American Diabetes Association. Statistics about diabetes. 2018. www.diabetes.org/diabetes-basics/statistics/. Accessed February 10, 2021.
3. Afkarian M, et al. *J Am Soc Nephrol.* 2013;24(2):302-308.

KERENDIA® (finerenone)

Indications and Usage

KERENDIA is a nonsteroidal mineralocorticoid receptor antagonist indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, CV death, nonfatal MI, and hospitalization for HF in adult patients with CKD associated with T2D.



CKD, chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HF, heart failure; MI, myocardial infarction; T2D, type 2 diabetes.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

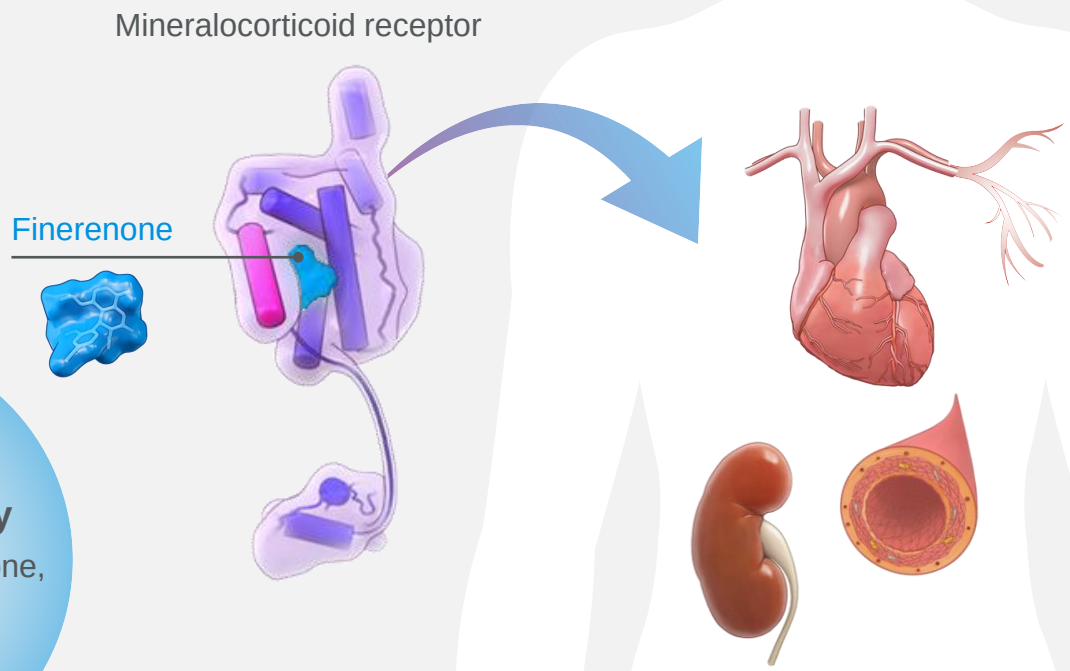
KERENDIA® (finerenone)

Nonsteroidal, Selective MRA: Mechanism of Action

Finerenone is a nonsteroidal, selective antagonist of the MR, which is activated by aldosterone and cortisol and regulates gene transcription

Finerenone has a **high potency and selectivity** for the MR

Finerenone has **no relevant affinity** for androgen, progesterone, estrogen, and glucocorticoid receptors



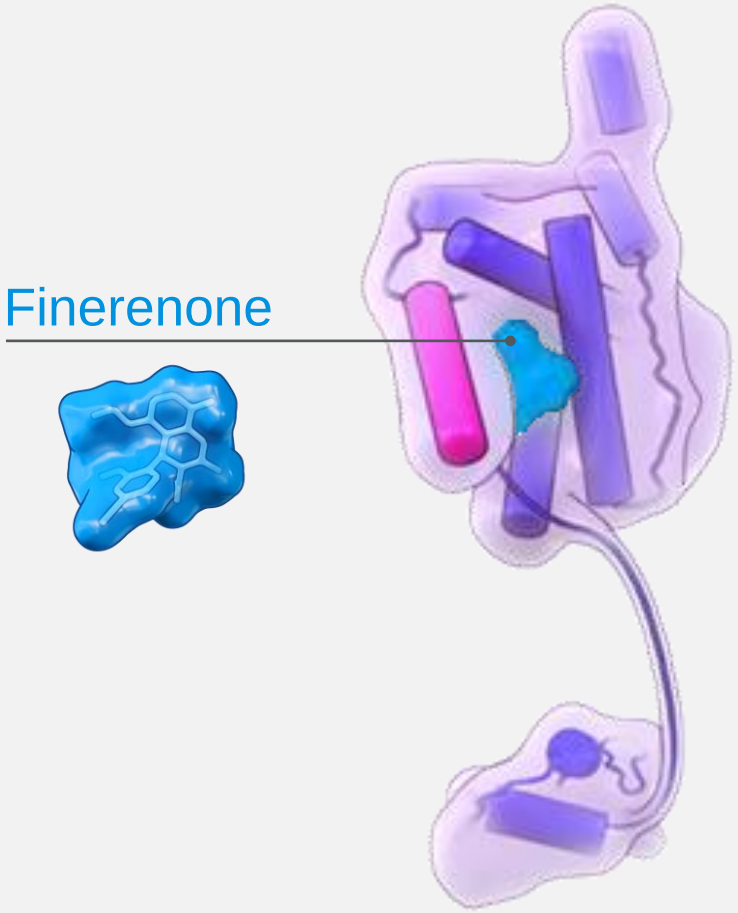
Finerenone blocks MR-mediated sodium reabsorption and MR overactivation in epithelial (kidney) and nonepithelial (heart and blood vessels) tissues

Mineralocorticoid receptor overactivation is thought to contribute to inflammation and fibrosis

MR, mineralocorticoid receptor; MRA, mineralocorticoid receptor antagonist.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Properties of Finerenone



Structural properties	**Nonsteroidal**
Potency to MR	**High**
Selectivity to MR	**High**
Bioavailability	**44% (C_{max} was achieved between 0.5 and 1.25 hours after dosing)**
Distribution	**Vss is 52.6L; plasma protein binding is 92%, primarily to serum albumin, in vitro**
Metabolites	**No active metabolites (primarily metabolized by CYP3A4 [90%] and to a lesser extent by CYP2C8 [10%])**
Terminal half-life	**2-3 h**
Clearance	**Systemic blood clearance of ~25 L/h**
Excretion	**~80% excreted in urine (<1% as unchanged)** **~20% excreted in feces (<0.2% as unchanged)**

MR, mineralocorticoid receptor; Vss, volume of distribution at steady-state.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Dosage and Administration

Prior to Initiation of KERENDIA

- Measure serum potassium levels and eGFR before initiation
- Do not initiate treatment if serum potassium is >5.0 mEq/L

Recommended Starting Dosage

eGFR (mL/min/1.73 m^2)	Starting dose
≥60	20 mg once daily
≥25 to <60	10 mg once daily
<25	Not recommended

eGFR, estimated glomerular filtration rate.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Dosage and Administration (Continued)

Monitoring and Dose Adjustment

- The target daily dose of KERENDIA is 20 mg
- Measure serum potassium 4 weeks after initiating treatment and adjust dose (see table)
- If serum potassium levels are >4.8 to 5.0 mEq/L, initiation of KERENDIA treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on clinical judgement and serum potassium levels
- Monitor serum potassium 4 weeks after a dose adjustment and throughout treatment, and adjust the dose as needed (see table)

Dose Adjustment Based on Current Serum Potassium Concentration and Current Dose

Current serum potassium (mEq/L)	Current KERENDIA dose	
	10 mg once daily	20 mg once daily
≤4.8	Increase the dose to 20 mg once daily.[a]	Maintain 20 mg once daily.
>4.8-5.5	Maintain 10 mg once daily.	Maintain 20 mg once daily.
>5.5	Withhold KERENDIA. Consider restarting at 10 mg once daily when serum potassium ≤5.0 mEq/L.	Withhold KERENDIA. Restart at 10 mg once daily when serum potassium ≤5.0 mEq/L.

[a]If eGFR has decreased by more than 30% compared to previous measurement, maintain 10 mg dose.

eGFR, estimated glomerular filtration rate.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Dosage and Administration (Continued)

KERENDIA target dose: **20 mg once daily**

KERENDIA may be taken **with** or **without food**

Avoid taking KERENDIA with grapefruit or grapefruit juice

For patients who are unable to swallow whole tablets, KERENDIA **may be crushed and mixed with water or soft foods** such as applesauce immediately prior to use and administered orally.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Contraindications

KERENDIA is contraindicated in patients who…

- Are receiving concomitant treatment with strong CYP3A4 inhibitors
- Have adrenal insufficiency

CYP3A4, cytochrome P450 family 3 subfamily A member 4.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

FIDELIO-DKD

Study Design, Inclusion Criteria, and Endpoints

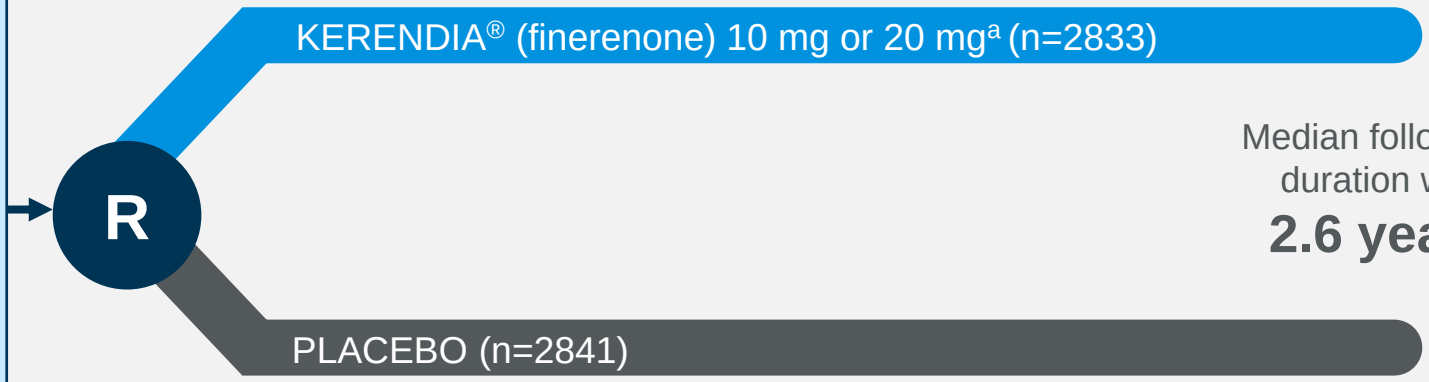
FIDELIO-DKD was a randomized, double-blind, placebo-controlled, multicenter study in adult patients with CKD associated with T2D

KEY INCLUSION CRITERIA

- UACR 30 to 300 mg/g, eGFR of 25 to 60 mL/min/1.73 m^2, and diabetic retinopathy OR UACR ≥300 mg/g and eGFR of 25 to 75 mL/min/1.73 m^2
- Serum potassium ≤4.8 mEq/L at screening
- Receiving SOC, including a maximum tolerated labeled dose of an ACEi or ARB

KEY EXCLUSION CRITERIA

- Known significant non-diabetic kidney disease
- Clinical diagnosis of chronic heart failure with reduced ejection fraction and persistent symptoms (New York Heart Association class II to IV)



Median follow-up duration was **2.6 years**

Primary composite endpoint

Time to first occurrence of a sustained decline in eGFR of ≥40%, kidney failure,[b] or renal death

Secondary composite endpoint

Time to first occurrence of CV death, nonfatal MI, nonfatal stroke, or hospitalization for HF

[a]The starting dose of KERENDIA was based on screening eGFR (10 mg once daily in patients with an eGFR of 25 to <60 mL/min/1.73 m^2 and 20 mg once daily in patients with an eGFR ≥60 mL/min/1.73 m^2).
[b]Kidney failure defined as chronic dialysis or kidney transplantation, or a sustained decrease in eGFR to <15 mL/min/1.73 m^2.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CKD, chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; HF, heart failure; MI, myocardial infarction; qd, once daily; R, randomization; SOC, standard of care; T2D, type 2 diabetes; UACR, urine albumin-to-creatinine ratio.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

FIDELIO-DKD

Baseline Characteristics

Baseline characteristics	Total (N=5674)
Race	
White	63%
Asian	25%
Black	5%
Mean age	66 years
Male	70%
Mean eGFR	44 mL/min/1.73 m^2
eGFR <45 mL/min/1.73 m^2	55%
Median UACR	852 mg/g
Mean HbA1c	7.7%
History of atherosclerotic CV disease	46%

CV, cardiovascular; eGFR, estimated glomerular filtration rate; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; HbA1c, glycated hemoglobin A1c; UACR, urine albumin-to-creatinine ratio.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

FIDELIO-DKD

Baseline Concomitant Medications

Baseline concomitant medications	Total (N=5674)
ACEi/ARB	99.8%
Antidiabetic medications	97%
Insulin	64.1%
Biguanides	44%
GLP-1 receptor agonists	7%
SGLT-2 inhibitors	5%
Statins	74%
Antiplatelet agent	57%

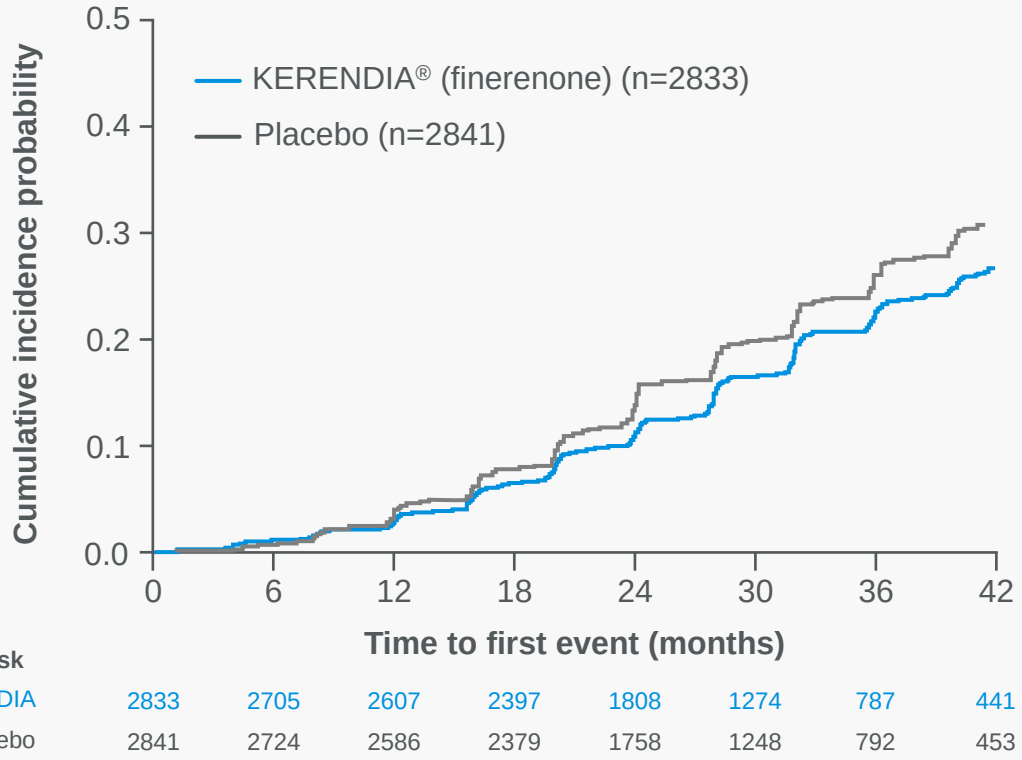
ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; GLP-1, glucagon-like peptide-1; SGLT-2, sodium-glucose cotransporter-2.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

FIDELIO-DKD

Primary Composite Endpoint

Time to First Occurrence of Kidney Failure, Sustained Decline in eGFR ≥40% From Baseline, or Renal Death in the FIDELIO-DKD Study



KERENDIA reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of ≥40%, kidney failure, or renal death (HR 0.82; 95% CI, 0.73-0.93, *P*=0.001). The treatment effect reflected a reduction in a sustained decline in eGFR of ≥40% and progression to kidney failure. There were few renal deaths during the trial.

CI, confidence interval; eGFR, estimated glomerular filtration rate; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; HR, hazard ratio.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

FIDELIO-DKD

Components of the Primary Composite Outcome

Analysis of the Primary Time-to-Event Endpoints (and Their Individual Components) in the Phase 3 Study FIDELIO-DKD[a]

	KERENDIA® (finerenone) n=2833		Placebo n=2841		Treatment effect KERENDIA/Placebo	
	n (%)	Event rate (100 pt-yr)	n (%)	Event rate (100 pt-yr)	Hazard ratio (95% CI)	*P* value[b]
Primary composite of kidney failure, sustained eGFR decline ≥40%, or renal death	504 (17.8)	7.6	600 (21.1)	9.1	0.82 (0.73-0.93)	0.001
Kidney failure	208 (7.3)	3.0	235 (8.3)	3.4	0.87 (0.72-1.05)	-
Sustained eGFR decline ≥40%	479 (16.9)	7.2	577 (20.3)	8.7	0.81 (0.72-0.92)	-
Renal death	2 (<0.1)	-	2 (<0.1)	-	-	-

The treatment effect reflected a reduction in a sustained decline in eGFR of ≥40% and progression to kidney failure, and there were few renal deaths during the trial.

[a]Time to first event was analyzed in a Cox proportional hazards model. For patients with multiple events, only the first event contributed to the composite endpoint. Sums of the numbers of first events for the single components do not add up to the numbers of events in the composite endpoint. [b]*P* value: two-sided *P* value from stratified logrank test.

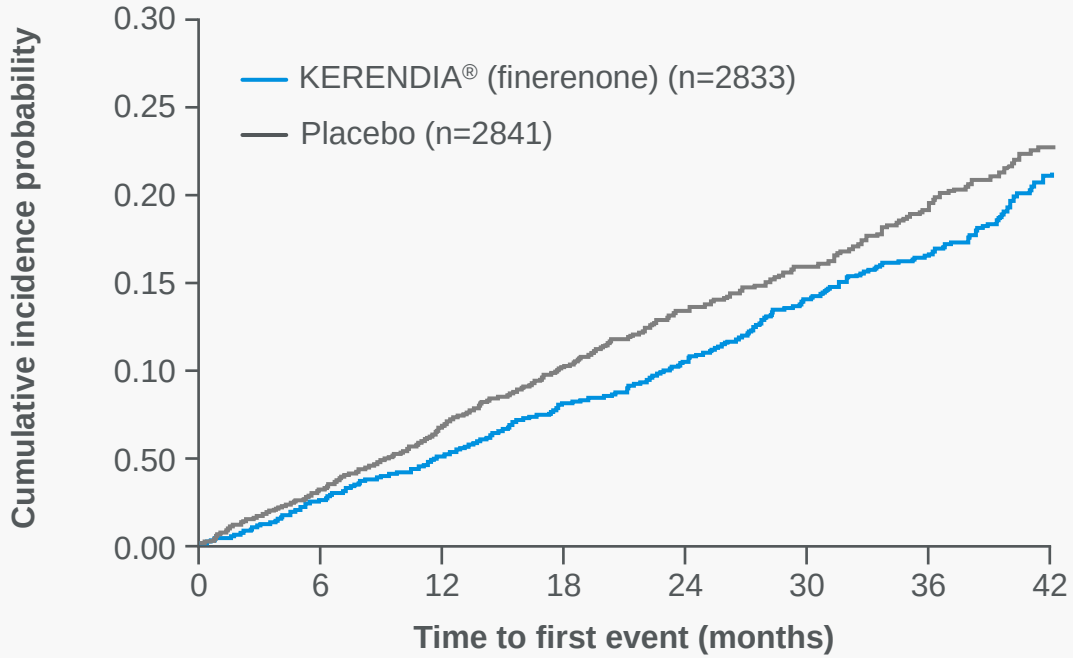
CI, confidence interval; eGFR, estimated glomerular filtration rate; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; pt-yr, patient year.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

FIDELIO-DKD

Secondary Composite Endpoint

Time to First Occurrence of CV Death, Nonfatal MI, Nonfatal Stroke, or Hospitalization for HF in the FIDELIO-DKD Study



No. at risk								
KERENDIA	2833	2760	2688	2582	2017	1488	984	537
Placebo	2841	2753	2653	2549	1969	1475	951	536

KERENDIA also reduced the incidence of the composite endpoint of CV death, nonfatal MI, nonfatal stroke, or hospitalization for HF (HR 0.86; 95% CI, 0.75-0.99, *P*=0.034).
The treatment effect reflected a reduction in CV death, nonfatal MI, and hospitalization for HF.

CI, confidence interval; CV, cardiovascular; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; HF, heart failure; HR, hazard ratio; MI, myocardial infarction.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

FIDELIO-DKD Components of the Secondary Composite Outcome

Analysis of the Secondary Time-to-Event Endpoints (and Their Individual Components) in the Phase 3 Study FIDELIO-DKD[a]

	KERENDIA® (finerenone) n=2833		Placebo n=2841		Treatment effect KERENDIA/Placebo	
	n (%)	Event rate (100 pt-yr)	n (%)	Event rate (100 pt-yr)	Hazard ratio (95% CI)	*P* value[b]
Secondary composite of CV death, nonfatal MI, nonfatal stroke, or hospitalization for HF	367 (13.0)	5.1	420 (14.8)	5.9	0.86 (0.75-0.99)	0.034
CV death	128 (4.5)	1.7	150 (5.3)	2.0	0.86 (0.68-1.08)	-
Nonfatal MI	70 (2.5)	0.9	87 (3.1)	1.2	0.80 (0.58-1.09)	-
Nonfatal stroke	90 (3.2)	1.2	87 (3.1)	1.2	1.03 (0.76-1.38)	-
Hospitalization for HF	139 (4.9)	1.9	162 (5.7)	2.2	0.86 (0.68-1.08)	-

The treatment effect reflected a reduction in CV death, nonfatal MI, and hospitalization for HF.

[a]Time to first event was analyzed in a Cox proportional hazards model. For patients with multiple events, only the first event contributed to the composite endpoint. Sums of the numbers of first events for the single components do not add up to the numbers of events in the composite endpoint. [b]*P* value: two-sided *P* value from stratified logrank test.

CI, confidence interval; CV, cardiovascular; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; HF, heart failure; HR, hazard ratio; MI, myocardial infarction; pt-yr, patient year.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Warnings and Precautions

Hyperkalemia

- KERENDIA can cause hyperkalemia
- The risk for developing hyperkalemia increases with decreasing kidney function and is greater in patients with higher baseline potassium levels or other risk factors for hyperkalemia
- Measure serum potassium and eGFR in all patients before initiation of treatment with KERENDIA and dose accordingly. Do not initiate KERENDIA if serum potassium is >5.0 mEq/L
- Measure serum potassium periodically during treatment with KERENDIA and adjust dose accordingly
- More frequent monitoring may be necessary for patients at risk for hyperkalemia, including those on concomitant medications that impair potassium excretion or increase serum potassium

eGFR, estimated glomerular filtration rate.

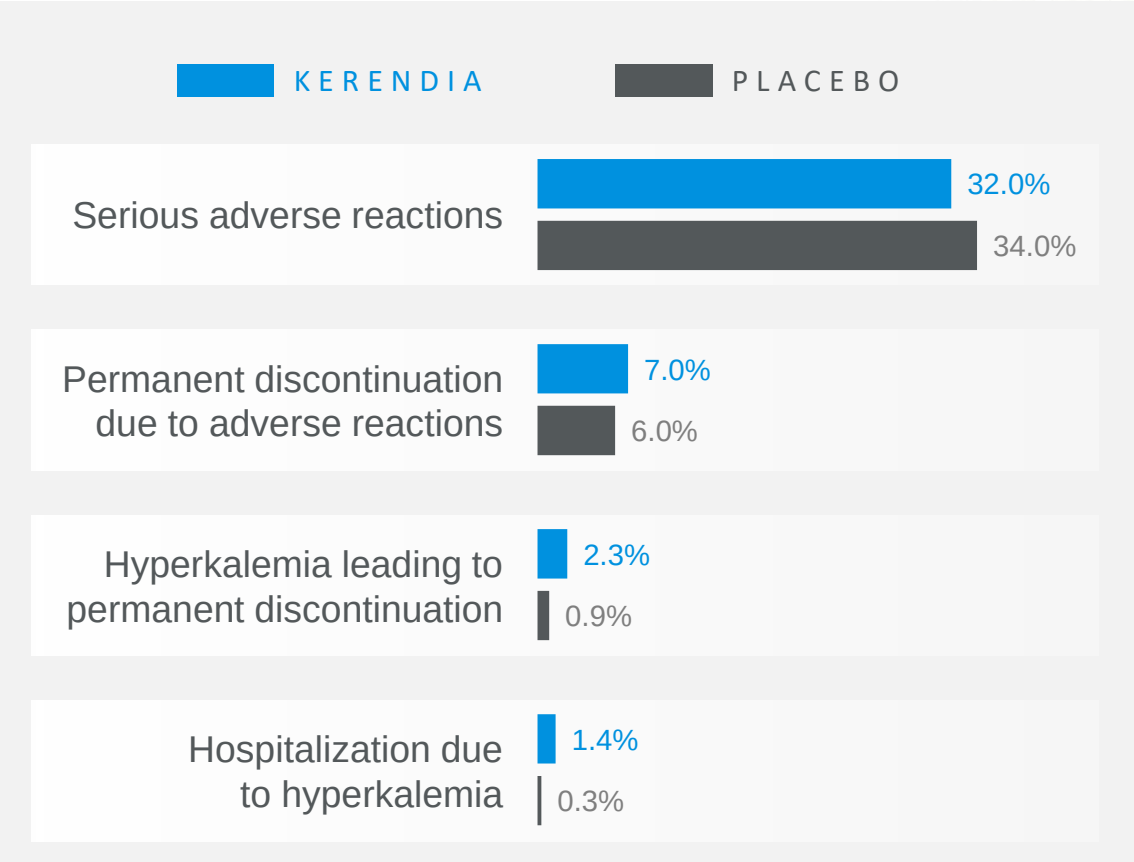
Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Adverse Reactions

Clinical Trials Experience

- Clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice
- The safety of KERENDIA was evaluated in the randomized, double-blind, placebo-controlled, multicenter pivotal phase 3 study FIDELIO-DKD. In this study, 2827 patients received KERENDIA (10 or 20 mg once daily) and 2831 received placebo. For patients in the KERENDIA group, the mean duration of treatment was 2.2 years
- The most frequently reported (≥10%) adverse reaction was hyperkalemia



FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Adverse Reactions (Continued)

Clinical Trials Experience

Adverse Reactions Reported in ≥1% of Patients on KERENDIA and More Frequently Than Placebo in the Phase 3 Study FIDELIO-DKD

Adverse reactions, n (%)	KERENDIA n=2827	Placebo n=2831
Hyperkalemia	516 (18.3)	255 (9.0)
Hypotension	135 (4.8)	96 (3.4)
Hyponatremia	40 (1.4)	19 (0.7)

Laboratory Test

- Initiation of KERENDIA may cause an initial small decrease in eGFR that occurs within the first 4 weeks of starting therapy that then stabilizes
- In a study that included patients with CKD associated with T2D, this decrease was reversible after treatment discontinuation

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease; T2D, type 2 diabetes.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Drug Interactions

CYP3A4 Inhibitors and Inducers

Strong CYP3A4 Inhibitors

- KERENDIA is a CYP3A4 substrate. Concomitant use with a strong CYP3A4 inhibitor increases KERENDIA exposure, which may increase the risk of KERENDIA adverse reactions. Concomitant use of KERENDIA with strong CYP3A4 inhibitors is contraindicated. Avoid concomitant intake of grapefruit or grapefruit juice

Moderate and Weak CYP3A4 Inhibitors

- KERENDIA is a CYP3A4 substrate. Concomitant use with a moderate or weak CYP3A4 inhibitor increases KERENDIA exposure, which may increase the risk of KERENDIA adverse reactions. Monitor serum potassium during drug initiation or dosage adjustment of either KERENDIA or the moderate or weak CYP3A4 inhibitor, and adjust KERENDIA dosage as appropriate

Strong and Moderate CYP3A4 Inducers

- KERENDIA is a CYP3A4 substrate. Concomitant use of KERENDIA with a strong or moderate CYP3A4 inducer decreases KERENDIA exposure, which may reduce the efficacy of KERENDIA. Avoid concomitant use of KERENDIA with strong or moderate CYP3A4 inducers

Drugs That Affect Serum Potassium

- More frequent serum potassium monitoring is warranted in patients receiving concomitant therapy with drugs or supplements that increase serum potassium

CYP3A4, cytochrome P450 family 3 subfamily A member 4.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Use in Specific Populations

Pregnancy

RISK SUMMARY

There are no available data on KERENDIA use in pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal studies have shown developmental toxicity at exposures about 4 times those expected in humans. The clinical significance of these findings is unclear.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Animal Data

In the embryo-fetal toxicity study in rats, finerenone resulted in reduced placental weights and signs of fetal toxicity, including reduced fetal weights and retarded ossification at the maternal toxic dose of 10 mg/kg/day corresponding to an $AUC_{unbound}$ of 19 times that in humans. At 30 mg/kg/day, the incidence of visceral and skeletal variations was increased (slight edema, shortened umbilical cord, slightly enlarged fontanelle), and one fetus showed complex malformations, including a rare malformation (double aortic arch) at an $AUC_{unbound}$ of about 25 times that in humans. The doses free of any findings (low dose in rats, high dose in rabbits) provided safety margins of 10 to 13 times for $AUC_{unbound}$ expected in humans.

When rats were exposed during pregnancy and lactation in the pre- and postnatal developmental toxicity study, increased pup mortality and other adverse effects (lower pup weight, delayed pinna unfolding) were observed at about 4 times the $AUC_{unbound}$ expected in humans. In addition, the offspring showed slightly increased locomotor activity, but no other neurobehavioral changes starting at about 4 times the $AUC_{unbound}$ expected in humans. The dose free of findings provides a safety margin of about 2 times for $AUC_{unbound}$ expected in humans.

AUC, area under the curve.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Use in Specific Populations (Continued)

Lactation

RISK SUMMARY

There are no data on the presence of KERENDIA or its metabolite in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. In a pre- and postnatal developmental toxicity study in rats, increased pup mortality and lower pup weight were observed at about 4 times the $AUC_{unbound}$ expected in humans. These findings suggest that KERENDIA is present in rat milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

Because of the potential risk to breastfed infants from exposure to KERENDIA, avoid breastfeeding during treatment and for 1 day after treatment.

Pediatric Use

RISK SUMMARY

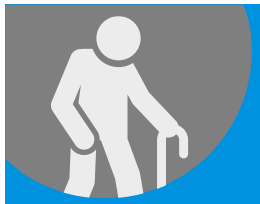
The safety and efficacy of KERENDIA have not been established in patients below 18 years of age.

AUC, area under the curve.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

KERENDIA® (finerenone)

Use in Specific Populations (Continued)



Geriatric Use

RISK SUMMARY

Of the 2827 patients who received KERENDIA in the FIDELIO-DKD study, 58% of patients were 65 years and older, and 15% were 75 years and older. No overall differences in safety or efficacy were observed between these patients and younger patients. No dose adjustment is required.

Hepatic Impairment

RISK SUMMARY

Avoid use of KERENDIA in patients with severe hepatic impairment (Child Pugh C).

No dosage adjustment is recommended in patients with mild or moderate hepatic impairment (Child Pugh A or B).

Consider additional serum potassium monitoring in patients with moderate hepatic impairment (Child Pugh B).

FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Click *i* *to view patient case studies*

Patient Case Studies

- **Bill**—62 years old; diagnosed with CKD associated with T2D
- **Mary**—67 years old; diagnosed with CKD associated with T2D

Patient Case Study 1

Bill—62 years old; diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | **TREATMENT** | **MANAGEMENT**

HbA1c, 7.6%

Blood pressure, 138/76 mmHg

eGFR, 62 mL/min/1.73 m^2

Serum potassium, 4.4 mEq/L

UACR, 315 mg/g

Maximum tolerated labeled dose of an ACEi/ARB and T2D standard of care

Hypothetical patient case

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin A1c; T2D, type 2 diabetes; UACR, urine albumin-to-creatinine ratio.

Test Your Knowledge

What is the recommended starting dose of KERENDIA® (finerenone) based on the patient's eGFR of 62 mL/min/1.73 m^2?

Click on an option.

A Not recommended

B 10 mg once daily

C 20 mg once daily

eGFR, estimated glomerular filtration rate.

Test Your Knowledge

What is the recommended starting dose of KERENDIA® (finerenone) based on the patient's eGFR of 62 mL/min/1.73 m^2?

A

Not recommended

B

10 mg once daily

C

20 mg once daily

The recommended starting dose of KERENDIA based on an eGFR of 62 mL/min/1.73 m^2 is 20 mg once daily.

eGFR, estimated glomerular filtration rate.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Patient Case Study 1

Bill—62 years old, diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

KERENDIA® (finerenone) Recommended Dosage in Adult Patients

Serum Potassium

≤4.8 mEq/L

Recommended to start KERENDIA treatment

>4.8 to 5.0 mEq/L

Initiation of KERENDIA treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on clinical judgement and serum potassium levels

>5.0 mEq/L

Do not initiate treatment

eGFR

≥60 mL/min/1.73 m^2

Starting dose:
20 mg once daily

≥25 to <60 mL/min/1.73 m^2

Starting dose:
10 mg once daily

<25 mL/min/1.73 m^2

Not recommended

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; K^+, potassium ion; T2D, type 2 diabetes.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Patient Case Study 1

Bill—62 years old, diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

Treatment Initiation

- 20 mg once daily of KERENDIA® (finerenone) was initiated

Assessment at 4 Weeks

- Serum potassium was 4.4 mEq/L
- eGFR was 60 mL/min/1.73 m^2

Dose Assessment

- Dose was maintained at 20 mg once daily of KERENDIA

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; T2D, type 2 diabetes.

Patient Case Study 1

Bill—62 years old, diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

KERENDIA® (finerenone) Dose Adjustment and Continuation (after 4 weeks and thereafter)

Current Serum potassium	Current dose: 10 mg once daily	Current dose: 20 mg once daily
≤4.8 mEq/L	Increase dose to 20 mg once daily.[a]	Maintain 20 mg once daily.
4.9-5.5 mEq/L	Maintain 10 mg once daily.	Maintain 20 mg once daily.
>5.5 mEq/L	Withhold KERENDIA. Restart at 10 mg once daily if serum potassium ≤5.0 mEq/L.	Withhold KERENDIA. Restart at 10 mg once daily if serum potassium ≤5.0 mEq/L.

[a]If eGFR has decreased by more than 30% compared to previous measurement, maintain 10 mg dose.

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; T2D, type 2 diabetes.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Patient Case Study 1

Bill—62 years old, diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

Assessment After 4 Weeks

- Serum potassium was 4.6 mEq/L
- eGFR was 60 mL/min/1.73 m^2

Monitoring

Bill continued to be assessed for eGFR and serum potassium according to local guidance.

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; T2D, type 2 diabetes.

Test Your Knowledge

What was the rate of discontinuation of KERENDIA® (finerenone) vs placebo due to hyperkalemia?

Click on an option.

A 2.3% vs 0.9%

B 4.2% vs 0.9%

C 6.7% vs 0.9%

D 9.0% vs 0.9%

Test Your Knowledge

What was the rate of discontinuation of KERENDIA® (finerenone) vs placebo due to hyperkalemia?

A 2.3% vs 0.9%

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D 9.0% vs 0.9%

In the FIDELIO-DKD study, the discontinuation rate of KERENDIA vs placebo due to hyperkalemia was 2.3% vs 0.9%.

FIDELIO-DKD, FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease.
Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Patient Case Study 2

Mary—67 years old; diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS	TREATMENT	MANAGEMENT

HbA1c, 7.0%

Blood pressure, 140/80 mmHg

- eGFR, 28 mL/min/1.73 m^2
- Serum potassium, 4.4 mEq/L
- UACR, 780 mg/g

Maximum tolerated labeled dose of an ACEi/ARB and T2D standard of care

Hypothetical patient case

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin A1c; T2D, type 2 diabetes; UACR, urine albumin-to-creatinine ratio.

Patient Case Study 2

Mary—67 years old; diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

KERENDIA® (finerenone) Recommended Dosage in Adult Patients

Serum Potassium

≤4.8 mEq/L

Recommended to start KERENDIA treatment

>4.8 to 5.0 mEq/L

Initiation of KERENDIA treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on clinical judgement and serum potassium levels

>5.0 mEq/L

Do not initiate treatment

eGFR

≥60 mL/min/1.73 m^2

Starting dose:
20 mg once daily

≥25 to <60 mL/min/1.73 m^2

Starting dose:
10 mg once daily

<25 mL/min/1.73 m^2

Not recommended

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; K^+, potassium ion; T2D, type 2 diabetes.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Patient Case Study 2

Mary—67 years old; diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

Treatment Initiation

- 10 mg once daily of KERENDIA® (finerenone) was initiated

Assessment at 4 Weeks

- Serum potassium was 4.7 mEq/L
- eGFR was 26 mL/min/1.73 m^2

Dose Adjustment

- Dose was increased to 20 mg once daily of KERENDIA

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; T2D, type 2 diabetes.

Patient Case Study 2

Mary—67 years old; diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

KERENDIA® (finerenone) Dose Adjustment Recommendations

	4 weeks later	After 4 weeks and thereafter	
Serum potassium		**Current dose: 10 mg once daily**	**Current dose: 20 mg once daily**
≤4.8 mEq/L		Increase dose to 20 mg once daily.[a]	Maintain 20 mg once daily.
4.9-5.5 mEq/L		Maintain 10 mg once daily.	Maintain 20 mg once daily.
>5.5 mEq/L		Withhold KERENDIA. Restart at 10 mg once daily if serum potassium ≤5.0 mEq/L.	Withhold KERENDIA. Restart at 10 mg once daily if serum potassium ≤5.0 mEq/L.

[a]If eGFR has decreased by more than 30% compared to previous measurement, maintain 10 mg dose.

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; T2D, type 2 diabetes.

Kerendia. Package insert. Bayer Healthcare Pharmaceuticals Inc; 2021.

Patient Case Study 2

Mary—67 years old; diagnosed with CKD associated with T2D

PRESENTATION AND DIAGNOSTICS | TREATMENT | MANAGEMENT

Assessment 8 Weeks After KERENDIA® (finerenone) Initiation

- Serum potassium was 4.6 mEq/L
- eGFR was 26 mL/min/1.73 m^2

Monitoring

Mary continued to be assessed for eGFR and serum potassium according to local guidance.

Hypothetical patient case

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; T2D, type 2 diabetes.