Kerendia® (finerenone) tablets 10 mg • 20 mg

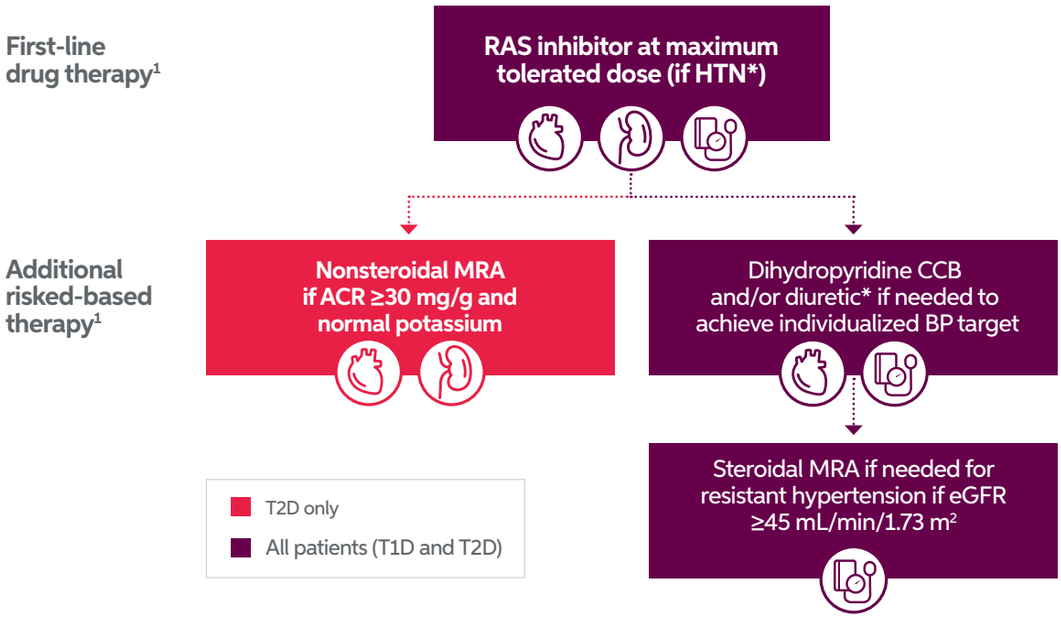
The American Diabetes Association® (ADA), Kidney Disease: Improving Global Outcomes® (KDIGO), and the American Association of Clinical Endocrinology® (AACE) include an ns-MRA in their recommendations for managing CKD associated with T2D[1-4]

KERENDIA is an approved ns-MRA[5]

The ADA/KDIGO consensus report is a series of consensus statements developed by the ADA and KDIGO to guide clinical care in diabetes and CKD[1]

To improve kidney and CV outcomes in patients with T2D and CKD, the ADA and KDIGO consensus report recommends an ns-MRA for T2D patients with eGFR ≥25 mL/min/1.73 m^2, albuminuria (UACR ≥30 mg/g), and normal serum potassium levels despite a maximum tolerated dose of an RAS inhibitor.[1]

KERENDIA is the first and only ns-MRA approved to slow CKD progression and reduce the risk of CV death, hospitalization for HF, and non-fatal MI in adult patients with CKD associated with T2D.[5]



For adult patients with CKD associated with T2D

KERENDIA is the first and only ns-MRA with proven clinical renal and CV benefits[1,5]

*ACEi or ARB (at maximum tolerated doses) should be first-line therapy for hypertension when albuminuria is present. Otherwise, dihydropyridine CCB or diuretic can also be considered; all 3 classes are often needed to attain BP targets.[1]

ACEi=angiotensin-converting enzyme inhibitor; ACR=albumin-to-creatinine ratio; ARB=angiotensin II receptor blocker; BP=blood pressure; CCB=calcium channel blocker; CKD=chronic kidney disease; CV=cardiovascular; eGFR=estimated glomerular filtration rate; HF=heart failure; HTN=hypertension; MI=myocardial infarction; MRA=mineralocorticoid receptor antagonist; ns-MRA=nonsteroidal mineralocorticoid receptor antagonist; RAS=renin-angiotensin system; T1D=type 1 diabetes; T2D=type 2 diabetes; UACR=urine albumin-to-creatinine ratio.

INDICATION:

- KERENDIA is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- Concomitant use with strong CYP3A4 inhibitors
- Patients with adrenal insufficiency

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

Please read additional Important Safety Information continued below and click here to see full Prescribing Information.

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For adult patients with CKD associated with T2D[1]

KDIGO suggests an ns-MRA for patients with CKD associated with T2D[3]

"We suggest an ns-MRA with proven kidney or CV benefit for patients with T2D, an eGFR ≥25 mL/min/1.73 m^2, normal serum potassium concentration, and albuminuria (≥30 mg/g) despite maximum tolerated dose of RAS inhibitor."

The ADA recommends an ns-MRA in 3 level A recommendations[2]*

"For people with T2D and CKD with albuminuria treated with maximum tolerated doses of an ACEi or ARB, addition of finerenone is recommended to improve CV outcomes and reduce risk of CKD progression."
—Chapter 10: Cardiovascular Disease and Risk Management

"In people with T2D and CKD, consider use of SGLT2 inhibitors (if eGFR is ≥20 mL/min/1.73 m^2), a GLP-1 agonist, or an ns-MRA (if eGFR is ≥25 mL/min/1.73 m^2) additionally for CV risk reduction."
—Chapter 11: Chronic Kidney Disease and Risk Management

"In people with CKD and albuminuria who are at increased risk for CV events or CKD progression, an ns-MRA shown to be effective in clinical trials is recommended to reduce CKD progression and CV events."
—Chapter 11: Chronic Kidney Disease and Risk Management

AACE Clinical Practice Guideline provides a grade A recommendation for the use of finerenone for persons with T2D, an eGFR ≥25 mL/min/1.73 m^2, normal serum potassium concentration, and albuminuria (UACR ≥30 mg/g) despite a maximum tolerated dose of an RAS inhibitor[4†]

For adult patients with CKD associated with T2D

KERENDIA is a fundamental pillar to improve CV and renal outcomes[5]

Scan code to learn more

*According to the ADA, recommendations with A-level evidence are based on large, well-designed randomized controlled trials or well-done meta-analyses of randomized controlled trials. Generally, these recommendations have the best chance of improving outcomes when applied to the population for which they are appropriate.[2]

† Recommendations that are granted a grade A recommendation are based on strong evidence proven through clinical trials per the AACE protocols.[4]

GLP-1=glucagon-like peptide 1; SGLT2=sodium-glucose cotransporter 2.

IMPORTANT SAFETY INFORMATION (cont'd)

MOST COMMON ADVERSE REACTIONS:

- From the pooled data of 2 placebo-controlled studies, the adverse reactions reported in ≥1% of patients on KERENDIA and more frequently than placebo were hyperkalemia (14% vs 6.9%), hypotension (4.6% vs 3.9%), and hyponatremia (1.3% vs 0.7%)

DRUG INTERACTIONS:

- ***Strong CYP3A4 Inhibitors:*** Concomitant use of KERENDIA with strong CYP3A4 inhibitors is contraindicated. Avoid concomitant intake of grapefruit or grapefruit juice
- ***Moderate and Weak CYP3A4 Inhibitors:*** 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:*** Avoid concomitant use of KERENDIA with strong or moderate CYP3A4 inducers

USE IN SPECIFIC POPULATIONS:

- ***Lactation:*** Avoid breastfeeding during treatment with KERENDIA and for 1 day after treatment
- ***Hepatic Impairment:*** Avoid use of KERENDIA in patients with severe hepatic impairment (Child Pugh C) and consider additional serum potassium monitoring with moderate hepatic impairment (Child Pugh B)

Please click here for full Prescribing Information for KERENDIA.

References: 1. de Boer IH, et al; Diabetes Management in Chronic Kidney Disease: A Consensus Report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO). *Diabetes Care*. 2022; 45(12):3075-3090. https://doi.org/10.2337/dci22-0027. **2.** American Diabetes Association® Professional Practice Committee; NA ElSayed, et al. *Diabetes Care*. 2023;46(suppl 1):S1-S202. **3.** Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. *Kidney Int*. 2022;102(5S):S1-S127. doi:10.1016/j.kint.2022.06.008. **4.** Blonde L, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update. *Endocr Pract*. 2022;28(10):923-1049. doi:10.1016/j.eprac.2022.08.002. **5.** KERENDIA (finerenone) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; September 2022.