Kerendia® (finerenone) tablets 10 mg • 20 mg

KERENDIA received level A recommendations in 2 chapters of the American Diabetes Association® (ADA) *Standards of Medical Care in Diabetes* (*Standards of Care*)[1]

Recommendations with A-level evidence are based on large, well-designed clinical trials or well-done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate.

Chapter 10: Cardiovascular Disease and Risk Management

For patients with CKD and T2D who are taking maximum tolerated doses of ACE inhibitors or ARBs, American Diabetes Association (ADA) recommends addition of KERENDIA to:

Improve CV outcomes and reduce the risk of CKD progression

See reverse side for additional recommendation

ACEi=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; CKD=chronic kidney disease; CV=cardiovascular; T2D=type 2 diabetes.

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 throughout and the provided full Prescribing Information.

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Chapter 11: Chronic Kidney Disease and Risk Management

The American Diabetes Association® (ADA) recommends treatment with nonsteroidal MR antagonist (ns-MRA) KERENDIA to reduce CKD progression and CV events in patients with CKD associated with T2D who are[1]:

at increased risk for CV events **or** at increased risk for CKD progression **or** unable to use an SGLT2i

MRA=mineralocorticoid receptor antagonist; SGLT2i=sodium-glucose cotransporter 2 inhibitor.

Learn more about KERENDIA ›

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 read additional Important Safety Information throughout and the provided full Prescribing Information.

Reference: 1. American Diabetes Association® (ADA) Professional Practice Committee; Draznin B, et al. Chronic kidney disease and risk management: standards of medical care in diabetes—2022. *Diabetes Care.* 2022;45(suppl 1):S175-S184. doi:10.2337/dc22-S011.

BAYER