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For abbreviations, symbols, and age group definitions show table

Brand Names: US Kerendia

Brand Names: Canada Kerendia

Pharmacologic Category Mineralocorticoid (Aldosterone) Receptor Antagonist; Nonsteroidal Mineralocorticoid (Aldosterone) Receptor Antagonist

**Dosing: Adult** Note: Prior to initiating therapy, verify serum potassium ≤5 mEq/L; do not initiate therapy if serum potassium >5 mEq/L. Patients with baseline serum potassium >4.8 to 5 mEq/L were excluded from clinical trials; initiation in this group may be considered according to manufacturer's labeling, but only with increased serum potassium monitoring during the first 4 weeks (Ref).

Chronic kidney disease associated with type 2 diabetes

#### Chronic kidney disease associated with type 2 diabetes: Oral:

Note: May be used as an adjunctive agent for patients with persistently elevated urinary albumin excretion (urine albumin-to-creatinine ratio ≥30 mg/g) who are receiving other preferred therapies (Ref).

#### Initial:

eGFR  $\geq$ 60 mL/minute/1.73 m<sup>2</sup>: 20 mg once daily. eGFR  $\geq$ 25 to <60 mL/minute/1.73 m<sup>2</sup>: 10 mg once daily.

eGFR <25 mL/minute/1.73 m<sup>2</sup>: Use not recommended.

Maintenance: Maintenance dose is determined by serum potassium measured 4 weeks after initiation of therapy or a dose adjustment and periodically during therapy.

### **Finerenone Maintenance Dose**

Current serum potassium (mEq/L)	Current finerenone dose		
	10 mg once daily	20 mg once daily	
≤4.8	Increase to 20 mg once daily. <sup>a</sup>	Continue 20 mg once daily.	
>4.8 to 5.5	Continue 10 mg once daily.	Continue 20 mg once daily.	
>5.5	Interrupt therapy. May consider restarting at 10 mg once daily when serum potassium ≤5 mEq/L.	Interrupt therapy. Restart at 10 mg once daily when serum potassium ≤5 mEq/L.	

<sup>a</sup> If eGFR has decreased by >30% compared to previous measurement, maintain 10 mg once daily dose.

Missed doses: If a dose is missed, administer as soon as possible but only on the same day. If not possible, skip the dose and continue with the next dose as scheduled.

Dosage adjustment for concomitant therapy: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

**Dosing: Kidney Impairment: Adult** Note: Prior to initiating therapy, verify serum potassium ≤5 mEq/L; do not initiate therapy if serum potassium >5 mEq/L. Patients with baseline serum potassium >4.8 to 5 mEq/L were excluded from clinical trials; initiation in this group may be considered according to the manufacturer's labeling, but only with increased serum potassium monitoring during the first 4 weeks (Ref).

### Altered kidney function:

### Initial:

eGFR ≥60 mL/minute/1.73 m<sup>2</sup>: 20 mg once daily.

eGFR ≥25 to <60 mL/minute/1.73 m<sup>2</sup>: 10 mg once daily.

eGFR <25 mL/minute/1.73 m<sup>2</sup>: Use not recommended.

Maintenance: Maintenance dose is determined by serum potassium measured 4 weeks after initiation of therapy or a dose adjustment and periodically during therapy.

## **Finerenone Maintenance Dose**

Current serum potassium (mEq/L)	Current finerenone dose		
	10 mg once daily	20 mg once daily	
≤4.8	Increase to 20 mg once daily. <sup>a</sup>	Continue 20 mg once daily.	
>4.8 to 5.5	Continue 10 mg once daily.	Continue 20 mg once daily.	
>5.5	Interrupt therapy. May consider restarting at 10 mg once daily when serum potassium ≤5 mEq/L.	Interrupt therapy. Restart at 10 mg once daily when serum potassium ≤5 mEq/L.	

<sup>&</sup>lt;sup>a</sup> If eGFR has decreased by >30% compared to previous measurement, maintain 10 mg once daily dose.

## **Dosing: Liver Impairment: Adult**

Mild to moderate impairment (Child-Pugh class A or B): No dosage adjustment necessary; consider increased serum potassium monitoring in patients with moderate impairment. Severe impairment: (Child-Pugh class C): Avoid use.

Dosing: Older Adult Refer to adult dosing.

## **Adverse Reactions (Significant): Considerations**

# Hyperkalemia

Hyperkalemia was common in clinical trials; however, it resulted in permanent therapy discontinuation or hospitalization infrequently (Ref).

Mechanism: Dose-related; related to the pharmacologic action. Blocks aldosterone from binding to the mineralocorticoid receptor, resulting in sodium reabsorption while conserving potassium ions (Ref).

Onset: Intermediate; occurs within 4 weeks of initiation (Ref).

Risk factors:

- Decreasing renal function. Note: Therapy initiation may cause an initial decrease in estimated GFR within the first 4 weeks and then stabilizes.
- Higher baseline potassium levels
- Known risk factors for hyperkalemia (eg, proteinuria, diabetes)
- Concomitant angiotensin-converting enzyme inhibitors, angiotensin-II receptor blockers, nonsteroidal anti-inflammatory drugs, and/or moderate CYP3A inhibitors

Adverse Reactions The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified. Adverse reactions reported in adults.

>10%: Endocrine & metabolic: Hyperkalemia (14%) (<u>table 1</u>)

# Finerenone: Adverse Reaction: Hyperkalemia

Drug (Finerenone)	Placebo	Number of Patients (Finerenone)	Number of Patients (Placebo)
14%	7%	6,510	6,489

1% to 10%:

Cardiovascular: Hypotension (5%)

Endocrine & metabolic: Hyponatremia (1%)

### Contraindications

Concomitant treatment with strong CYP3A4 inhibitors; adrenal insufficiency.

Canadian labeling: Additional contraindications (not in US labeling): Hypersensitivity to finerenone or any component of the formulation; Addison disease.

### Warnings/Precautions

#### Disease-related concerns:

- · Hepatic impairment: Consider increased serum potassium monitoring in patients with moderate hepatic impairment; avoid use in patients with severe hepatic impairment.
- · Renal impairment: Dose adjustment may be required.

Dosage Forms: US Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, Oral:

Kerendia: 10 mg, 20 mg

Generic Equivalent Available: US No

**Pricing: US** 

Tablets (Kerendia Oral)

10 mg (per each): \$27.47 20 mg (per each): \$27.47

**Disclaimer:** A representative AWP (Average Wholesale Price) price or price range is provided as reference price only. A range is provided when more than one manufacturer's AWP price is available and uses the low and high price reported by the manufacturers to determine the range. The pricing data should be used for benchmarking purposes only, and as such should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer. Medi-Span expressly disclaims all warranties of any kind or nature, whether express or implied, and assumes no liability with respect to accuracy of price or price range data published in its solutions. In no event shall Medi-Span be liable for special, indirect, incidental, or consequential damages arising from use of price or price range data. Pricing data is updated monthly.

Dosage Forms: Canada Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, Oral:

Kerendia: 10 mg, 20 mg

Administration: Adult Oral: Administer with or without food. If unable to swallow tablet whole, tablet may be crushed and mixed with water or soft foods (eg, applesauce); administer immediately after mixing.

Use: Labeled Indications Chronic kidney disease associated with type 2 diabetes: To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.

## **Medication Safety Issues**

### Older Adult: High-Risk Medication:

Beers Criteria: Diuretics (finerenone) are identified in the Beers Criteria as potentially inappropriate medications to be used with caution in patients ≥65 years of age due to the potential to cause or exacerbate syndrome of inappropriate antidiuretic hormone secretion (SIADH) or hyponatremia; monitor sodium concentration closely when initiating or adjusting the dose in older adults (Beers Criteria [AGS 2023]).

Metabolism/Transport Effects Substrate of CYP2C8 (Minor), CYP3A4 (Major); Note: Assignment of Major/Minor substrate status based on clinically relevant drug interaction potential;

### **Drug Interactions**

**Note**: Interacting drugs may **not be individually listed below** if they are part of a group interaction (eg, individual drugs within "CYP3A4 Inducers [Strong]" are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the drug interactions program by clicking on the "Launch drug interactions program" link above.

Aldesleukin: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Angiotensin II Receptor Blockers: May increase hyperkalemic effects of Finerenone. Risk C: Monitor

Angiotensin-Converting Enzyme Inhibitors: May increase hyperkalemic effects of Finerenone. Risk C: Monitor

Atazanavir: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk X: Avoid

Bulevirtide: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Clofazimine: May increase serum concentration of CYP3A4 Substrates (High risk with Inhibitors). Risk C: Monitor

CYP3A4 Inducers (Moderate): May decrease serum concentration of Finerenone. Risk X: Avoid

CYP3A4 Inducers (Strong): May decrease serum concentration of Finerenone. Risk X: Avoid

CYP3A4 Inhibitors (Moderate): May increase serum concentration of Finerenone. Risk C: Monitor

CYP3A4 Inhibitors (Strong): May increase serum concentration of Finerenone. Risk X: Avoid

CYP3A4 Inhibitors (Weak): May increase serum concentration of Finerenone. Risk C: Monitor

Dinutuximab Beta: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Elranatamab: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Epcoritamab: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Fludrocortisone: May decrease therapeutic effects of Mineralocorticoid (Aldosterone) Receptor Antagonists. Mineralocorticoid (Aldosterone) Receptor Antagonists may decrease therapeutic effects of Fludrocortisone. Risk C: Monitor

Fusidic Acid (Systemic): May increase serum concentration of CYP3A4 Substrates (High risk with Inhibitors). Management: Consider avoiding this combination if possible. If required, monitor patients closely for increased adverse effects of the CYP3A4 substrate. Risk D: Consider Therapy Modification

Gepotidacin: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk X: Avoid

Givinostat: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Glofitamab: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Grapefruit Juice: May increase serum concentration of Finerenone. Risk X: Avoid

Itraconazole: May increase serum concentration of Finerenone. Risk X: Avoid

Mosunetuzumab: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Potassium Salts: May increase hyperkalemic effects of Finerenone. Risk C: Monitor

Potassium-Sparing Diuretics: May increase hyperkalemic effects of Finerenone. Risk C: Monitor

Ritlecitinib: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Spironolactone: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Talquetamab: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Tarlatamab: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Teclistamab: May increase serum concentration of CYP Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Treosulfan: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Trofinetide: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Xanomeline: May increase serum concentration of CYP3A4 Substrates (Narrow Therapeutic Index/Sensitive with Inhibitors). Risk C: Monitor

Food Interactions Grapefruit juice increases finerenone concentrations. Management: Avoid concomitant use with grapefruit or grapefruit juice.

**Reproductive Considerations** In the Finerenone in Reducing Kidney Failure and Disease Progression in Diabetic Kidney Disease (FIDELIO-DKD) trial, patients who could become pregnant were required to have a negative pregnancy test prior to inclusion and use ≥2 effective methods of birth control (at least 1 being a physical barrier) during the study (Bakris 2020).

Pregnancy Considerations Developmental toxicity was observed in animal reproduction studies with doses equivalent to ~4 times those expected in humans.

### **Breastfeeding Considerations**

It is not known if finerenone is present in breast milk.

Due to the potential for serious adverse reactions in the breastfed infant, the manufacturer recommends that breastfeeding be avoided during therapy and for 1 day after the last finerenone dose.

**Monitoring Parameters** Serum potassium (at baseline, 4 weeks after initiation of therapy or dosage adjustments, and periodically during therapy with increased frequency in patients at risk for hyperkalemia); eGFR (at baseline and periodically during therapy).

**Mechanism of Action** Finerenone selectively blocks mineralocorticoid receptor–mediated sodium reabsorption and overactivation in both epithelial (eg, kidney) and nonepithelial (eg, blood vessels, heart) tissues reducing fibrosis and inflammation.

## Pharmacokinetics (Adult Data Unless Noted)

Distribution: V<sub>dss</sub>: 52.6 L.

Protein binding: 92%; primarily to albumin.

Metabolism: Primarily hepatic via CYP3A4 (90%) and to a lesser extent by CYP2C8 (10%) to inactive metabolites.

Bioavailability: 44%.

Half-life elimination: Terminal: 2 to 3 hours.

Time to peak: 0.5 to 1.25 hours.

Excretion: Urine (~80%; <1% as unchanged drug); feces (~20%; <0.2% as unchanged drug).

### Pharmacokinetics: Additional Considerations (Adult Data Unless Noted)

Altered kidney function: No clinically relevant differences in finerenone AUC or  $C_{max}$  values in patients with eGFR 15 to <90 mL/minute/1.73 m<sup>2</sup> compared to eGFR ≥90 mL/minute/1.73 m<sup>2</sup>.

Hepatic function impairment: No clinically significant effect on AUC and  $C_{max}$  in mild impairment (Child-Pugh class A). AUC increased by 38% and  $C_{max}$  was unchanged in moderate impairment (Child-Pugh class B) compared to healthy control subjects.

# **Brand Names: International**

International Brand Names by Country
For country code abbreviations (<a href="mailto:show table">show table</a>)

(QA) Qatar: Kerendia

#### **REFERENCES**

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