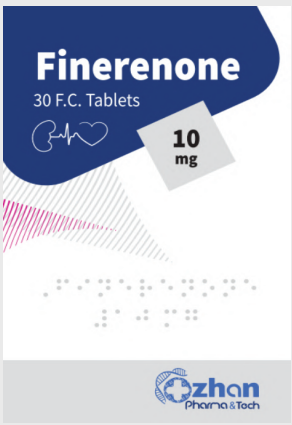
Finerenone

A New Growth for Cardiorenal Health



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Indication

Treatment of adults with:

- Chronic Kidney Disease (CKD) associated with Type 2 Diabetes (T2D) to reduce the risk of cardiovascular and kidney-related events.
- Heart Failure with preserved or mildly reduced Ejection Fraction (HFpEF/HFmrEF) to reduce the risk of heart failure events and cardiovascular outcomes.

Dosing and Administration

The recommended dose: 10 to 20 mg orally, once daily.

Finerenone's dose should be adjusted based on the patient's serum potassium levels and eGFR.

Initiation of Finerenone treatment and recommended dose

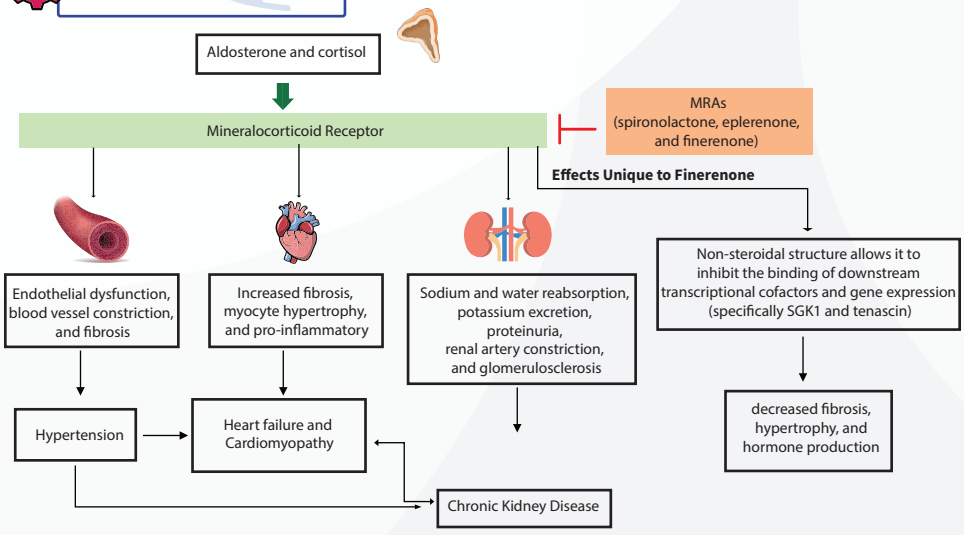
eGFR (mL/min/1.73 m^2)	Starting dose (once daily)
≥ 60	20 mg
25 to 60	10 mg
< 25	Not recommended

- Serum potassium and eGFR have to be remeasured 4 weeks after initiation or re-start of Finerenone treatment or increase in dose

		Current Finerenone dose (once daily)	
		10 mg	20 mg
Current serum potassium (mmol/L)	≤ 4.8	Increase to 20 mg Finerenone once daily*	Maintain 20 mg once daily
	> 4.8 to 5.5	Maintain 10 mg once daily	Maintain 20 mg once daily
	> 5.5	Withhold Finerenone. Consider re-starting at 10 mg once daily when serum potassium ≤ 5.0 mmol/L.	Withhold Finerenone. Re-start at 10 mg once daily when serum potassium ≤ 5.0 mmol/L.

* Maintain 10 mg once daily, if eGFR has decreased > 30% compared to the previous measurement

Mechanism of action

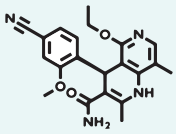


Key Features of Finerenone

01 Non-Steroidal Structure: Avoids steroid-related side effects

02 High Selectivity: Strong and stable binding to the MR receptor

03 Optimal Tissue Distribution: More effective impact on inflammation and fibrosis in the heart and kidneys



Safety Profile of Finerenone

- well-tolerated & low rate of side effects that lead to stopping treatment.
- Hyperkalemia: While the incidence of hyperkalemia was higher with Finerenone compared to a placebo, severe cases and the need to discontinue the drug were rare.
- Comparison with Other MRAs: Due to its unique non-steroidal structure, it has a lower risk of causing hyperkalemia compared to steroidal MRAs like Spironolactone and Eplerenone.

This makes it a safer option for patients with CKD, where other MRAs are often not used due to the high risk of severe hyperkalemia.

Comprehensive Clinical Evidence

FIDELITY program

- pooled analysis of data from two major trials: FIDELIO-DKD and FIGARO-DKD.
- designed to evaluate the efficacy & safety of finerenone in patients with both CKD & T2D.
- main purpose: Provide a more robust & comprehensive estimation of cardiorenal outcomes in this specific patient population.

Patient population

FIDELIO-DKD + FIGARO-DKD → FIDELITY

- N= 13026
- Age 18 years or older
- Stage 1-4 CKD and T2D
  mean eGFR: 57.7 ± 21.7 mL/min/1.73 m^2
  median UACR: 514.7 mg/g
- Serum potassium level at baseline: ≤ 4.8 mmol/L
- Maximum tolerated dose of a RAS inhibitor
- Finerenone VS Placebo

Results of FIDELITY program

CV composite outcome

- hospitalization for heart failure
- non-fatal myocardial infarction
- cardiovascular death

14% reduction in the risk of these events in the finerenone group

HR: 0.86 (95% CI, 0.78-0.95; P=0.0018)

Kidney composite outcome

- kidney failure
- a sustained decrease of ≥ 57% in eGFR from baseline
- death from renal causes

23% reduction in the risk of CKD progression in the finerenone group

HR: 0.77 (95% CI, 0.67-0.88; P=0.0002)

The FINEARTS-HF Trial

Study design: A randomized, double-blind, placebo-controlled trial in 6,001 patients with symptomatic heart failure and LVEF ≥ 40%.

This landmark study provided a **new indication for finerenone in heart failure with preserved or mildly reduced ejection fraction** (HFpEF/HFmrEF), a population with limited treatment options.

Primary outcomes

16% CV death and total worsening HF events compared to placebo

RR: 0.84
95% CI: 0.74-0.95
p-value: 0.007

Secondary outcomes

18% HF Events compared to placebo (RR: 0.82).

30% Renal Effects: decrease in the UACR

Increase In KCCQ Improved Quality of Life

composite kidney outcomes (such as eGFR decline or kidney failure).

Therapeutic Position: Recommended in Major Global Guidelines

- **KDIGO**: Finerenone is a recommended add-on therapy for adult patients with T2D & CKD who are at risk, even with standard treatment. This highlights its critical role in the latest guidelines.
- **ADA:** suggests considering Finerenone in patients with T2D & CKD to reduce CV & kidney risks. It is a key part of the comprehensive strategy for managing CV risk, alongside SGLT-2 inhibitors.