

Finerenone INN

Composition

Fino 10: Each film-coated tablet contains Finerenone INN 10 mg.

Fino 20: Each film-coated tablet contains Finerenone INN 20 mg.

Pharmacology

Finerenone is a nonsteroidal, selective antagonist of the Mineralocorticoid Receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription. Finerenone blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation. Finerenone has a high potency and selectivity for the MR and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors.

Indication

Finerenone is indicated 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 (CKD) associated with Type 2 Diabetes (T2D).

Dosage & Administration

Route of administration: Oral.

Prior to Initiation of Fino: Measure serum potassium levels and estimated glomerular filtration rate (eGFR) before initiation. Do not initiate treatment if serum potassium is > 5.0 mEq/L.

The recommended starting dose of Fino is based on eGFR and is presented below-

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

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

The target daily dose of **Finerenone** is 20 mg. Measure serum potassium 4 weeks after initiating treatment and adjust dose; if serum potassium levels are > 4.8 to 5.0 mEq/L, initiation of **Finerenone** 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 below)-

Current Serum Potassium (mEq/L)	Current Finerenone Dose	
	10 mg once daily	20 mg once daily
≤ 4.8	Increase the dose to 20 mg once daily.	Maintain 20 mg once daily.
> 4.8 – 5.5	Maintain 10 mg once daily.	Maintain 20 mg once daily.
> 5.5	Withhold Finerenone. Consider restarting at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.	Withhold Finerenone. Restart at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.

* If eGFR has decreased by more than 30% compared to previous measurements, maintain 10 mg dose.

OR, AS DIRECTED BY REGISTERED PHYSICIAN

Contraindications

Finerenone is contraindicated in patients who are receiving concomitant treatment with strong CYP3A4 inhibitors and patients with adrenal insufficiency.

Warning & Precautions

Finerenone 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 **Finerenone** and dose accordingly. Do not initiate **Finerenone** if serum potassium is > 5.0 mEq/L.

Side Effects

Common Side Effects: The reported side effects were generally mild and seldom led to discontinuation of treatment. The most common side effects include peripheral edema, flushing, palpitations, dizziness. Other side effects that occurred in placebo-controlled clinical trials are orthostatic hypotension, diarrhea, rash, abdominal pain, fatigue, back pain, pruritus.

Rare side effects: Large purple or brown skin blotches, decreased blood platelets, low levels of white blood cells, depression, fluid in the lungs, pancreatitis.

Use in Pregnancy & Lactation

Pregnancy: There are limited data for the use of **Finerenone** in pregnant women.

Lactation: Data are unavailable on presence in human milk, effects on breastfed infants, or effects on milk production. Advise women that breastfeeding is not recommended at the time of treatment with **Finerenone** and for 1 day after treatment.

Drug Interactions

With medicine: Advise patients to avoid strong or moderate CYP3A4 inducers and to find alternative medicinal products with no or weak potential to induce CYP3A4.

With food & others: Avoid concomitant intake of grapefruit or grapefruit juice as it is expected to increase the plasma concentration of **Finerenone**.

Overdose

In the event of suspected overdose, immediately interrupt **Finerenone** treatment. The most likely manifestation of overdose is hyperkalemia. If hyperkalemia develops, standard treatment should be initiated.

Storage

Store below 30° C temperature and dry place, protected from light. Keep all medicines out of reach of children.

Packing

Fino 10: Each box contains 1x10 tablets in Alu-Alu blister strips.

Fino 20: Each box contains 1x10 tablets in Alu-Alu blister strips.

* Further information is available on request.



Manufactured by:

The ACME Laboratories Ltd.
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For Health, Vigour and Happiness

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