Fineron

Finerenone INN

Everest

COMPOSITION

Fineron 10 Tablet: Each film coated tablet contains Finerenone INN 10 mg.
Fineron 20 Tablet: 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. In patients treated with Finerenone, the mean systolic blood pressure decreased by 3 mmHg and the mean diastolic blood pressure decreased by 1-2 mmHg at month 1, remaining stable thereafter. At a dose 4 times the maximum approved recommended dose, Finerenone does not prolong the QT interval to any clinically relevant extent. Finerenone is completely absorbed after oral administration but undergoes metabolism resulting in absolute bioavailability of 44%. Finerenone C_{max} was achieved between 0.5 and 1.25 hours after dosing.

INDICATIONS

Fineron 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 AND ADMINISTRATION

- The recommended starting dosage is 10 mg or 20 mg orally once daily based on estimated glomerular filtration rate (eGFR) and serum potassium thresholds.
- Increase dosage after 4 weeks to the target dose of 20 mg once daily, based on eGFR and serum potassium thresholds.
- Tablets may be taken with or without food.

Recommended Dosage

eGFR (mL/min/1.73m²)	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, **Fineron** may be crushed and mixed with water or soft foods.

Dose Adjustment

Potassium (mEq/L)	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 Fineron. Consider restarting at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.	Withhold Fineron. Restart at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.

CONTRAINDICATIONS

Contraindicated in concomitant use with strong CYP3A4 inhibitors & patients with adrenal insufficiency.

WARNINGS & PRECAUTIONS

Patients with decreased kidney function and higher baseline potassium levels are at increased risk of Hyperkalemia. Monitor serum potassium levels and adjust dose as needed.

SIDE-EFFECTS

Adverse reactions occurring in ≥ 1% of patients on Finerenone and more frequently than placebo are hyperkalemia, hypotension, and hyponatremia.

USE IN SPECIFIC POPULATIONS

Pregnancy
No available safety data is found.
Lactation
Breastfeeding is not recommended.
Pediatric Use
Below 18 years of age is not recommended.
Geriatric Use
No dose adjustment is required.
Hepatic Impairment
Not recommended in severe hepatic impairment (Child Pugh C). No dosage adjustment is required in mild or moderate hepatic impairment (Child Pugh A & B).

DRUG INTERACTIONS

- Strong CYP3A4 Inhibitors: Use is contraindicated.
- Grapefruit or Grapefruit Juice: Avoid concomitant intake.
- Moderate or weak CYP3A4 Inhibitors: Monitor serum potassium during drug initiation or dosage adjustment.
- Strong or Moderate CYP3A4 Inducers: Avoid concomitant use.

OVERDOSAGE

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. Finerenone is unlikely to be efficiently removed by hemodialysis given its fraction bound to plasma proteins of about 90%.

STORAGE

Store below 30°C, in a cool & dry place. Keep away from light. Keep out of the reach of children.

HOW SUPPLIED

Fineron 10 Tablet: Each box contains 1×10 & 3×10 Tablets in a blister pack.
Fineron 20 Tablet: Each HDPE container contains 10 tablets.

Manufactured by
Everest Pharmaceuticals Ltd.
BSCIC I/A, Kanchpur, Narayanganj, Bangladesh

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