Fincard

Finerenone INN

Composition
Fincard 10 Tablet: Each film coated tablet contains Finerenone INN 10 mg.
Fincard 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.

Indication
Fincard is a non-steroidal mineralocorticoid receptor antagonist (nsMRA) indicated to reduce the risk of:
• Sustained estimated glomerular filtration rate (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 (T2DM).
• Cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF ≥40%).

Dosage and Administration

• Prior to Initiation of Fincard
Measure serum potassium levels and eGFR before initiation. Do not initiate treatment if serum potassium is >5.0 mEq/L.

• Recommended Starting Dosage
The recommended starting dosage is 10 mg or 20 mg orally once daily based on estimated glomerular filtration rate (eGFR) and serum potassium thresholds.

Table 1: Recommended Starting Dosage

eGFR (mL/min/1.73 m²)	Starting Dose
≥60	20 mg orally once daily
≥25 to <60	10 mg orally once daily
<25	Not recommended

• Increase dosage after 4 weeks to the target dose of 20 mg once daily for CKD and T2DM based on eGFR and serum potassium thresholds.

• Increase dosage after 4 weeks to the target dose of 20 mg or 40 mg once daily for HF with LVEF ≥40% based on eGFR and serum potassium thresholds.

• Tablets may be taken with or without food.

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

Monitoring and Dosage Adjustment
The target daily dose of **Fincard** is 20 mg orally. 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 **Fincard** treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on clinical judgment and serum potassium levels. Measure serum potassium 4 weeks after a dose adjustment and periodically throughout treatment and adjust the dose as needed.

Table 2: Dose Adjustment Based on Current Serum Potassium Concentration and Current Dose (CKD associated with T2DM)

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

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

Heart Failure with LVEF ≥40%
The target daily dose of **Fincard** for heart failure (LVEF ≥40%) is dependent on renal function (eGFR) at initiation of **Fincard** treatment.
• The target daily dose is 40 mg orally once daily if eGFR at initiation is ≥60 mL/min/1.73 m^2.
• The target daily dose is 20 mg orally once daily if eGFR at initiation is ≥25 to <60 mL/min/1.73 m^2.

Measure serum potassium and eGFR 4 weeks after initiating treatment and adjust dose. Measure serum potassium and eGFR 4 weeks after a dose adjustment and monitor periodically throughout treatment and adjust the dose as needed.

Table 3: Dose Adjustment Based on Current Serum Potassium Concentration, eGFR and Current Dose (Heart Failure (LVEF ≥40%)

Current Serum Potassium (mEq/L)	Current Fincard Dose		
	10 mg once daily	**20 mg once daily**	**40 mg once daily**
<5.0	Increase the dose to 20 mg once daily.*	Maintain 20 mg once daily if eGFR <60 mL/min/1.73 m² at initiation. Otherwise increase the dose to 40 mg once daily.*	Maintain 40 mg once daily.
≥5.0 - <5.5	Maintain 10 mg once daily.		
≥5.5 - <6.0	Withhold **Fincard**. Restart at 10 mg once daily when serum potassium <5.5 mEq/L.	Decrease to 10 mg once daily.	Decrease to 20 mg once daily.
≥6.0	Withhold **Fincard**. Restart at 10 mg once daily when serum potassium <5.5 mEq/L.**		

* If eGFR has decreased by more than 30% compared to previous measurement, maintain current dose.
** If repeated serum potassium measurements are ≥5.5 mEq/L, restart **Fincard** at 10 mg once daily when serum potassium <5.0 mEq/L.

Missed doses
Direct a patient to take a missed dose as soon as possible after it is noticed, but only on the same day. If this is not possible, the patient should skip the dose and continue with the next dose as prescribed.

Contraindication
Finerenone is contraindicated in patients-
• Who are hypersensitive to any component of this product
• Who are receiving concomitant treatment with strong CYP3A4 inhibitors
• 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. Measure serum potassium periodically during treatment with finerenone 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.

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
Use in pregnancy: There are no available data on finerenone use in pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.
Use in lactation: There are no data on the presence of finerenone or its metabolite in human milk, the effects on the breastfed infant or the effects of the drug on milk production. Because of the potential risk to breastfed infants from exposure to finerenone, avoid breastfeeding during treatment and for 1 day after treatment.
Pediatric Use: The safety and efficacy of finerenone have not been established in patients below 18 years of age.
Geriatric Use: No dose adjustment is required.
Hepatic Impairment: Avoid use of finerenone in patients with severe hepatic impairment. No dosage adjustment is recommended in patients with mild or moderate hepatic impairment. Consider additional serum potassium monitoring in patients with moderate hepatic impairment.

Other Interactions
Strong CYP3A4 Inhibitors: Use is contraindicated.
Moderate and Weak CYP3A4 Inhibitors: Monitor serum potassium during drug initiation or dosage adjustment of either finerenone or the moderate or weak CYP3A4 inhibitor and adjust finerenone dosage as appropriate.
Strong and Moderate CYP3A4 Inducers: Avoid concomitant use.
Grapefruit or Grapefruit Juice: Avoid concomitant intake.

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

Storage
Store below 30° C and dry place, protect from light. Keep out of the reach of children.

Packing
Fincard 10 Tablet: Each box contains 10's tablets in Alu-Alu blister pack.
Fincard 20 Tablet: Each box contains 10's tablets in Alu-Alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh