FINOTAB

FINERENONE

Compositions:
Each flim-coated tablet contains Finerenone INN 10 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.

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.

Contraindications:
It is contraindicated in patients Who are receiving concomitant treatment with strong CYP3A4 inhibitors and With adrenal insufficiency. Hypersensitivity to any of its components.

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

Side Effects:
Side effects of Finerenone include: High blood potassium (hyperkalemia) Low blood pressure (hypotension) Low blood sodium (hyponatremia)

Use in Pregnancy and Lactation:
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. 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.

Drug Interaction:
Strong CYP3A4 Inhibitors: Use is contraindicated. Grapefruit or Grapefruit Juice: Avoid concomitant use. Moderate or 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 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 in a cool (below 30° C) and dry place, protected from light and moisture. Keep out of the reach of children.

Packing:
Each box contains 3×10’s, 5×10’s, 10x10’s film coated tablet in Alu-Alu blister strip.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.