Composition: Erutic-25: Each film coated tablet contains Eplerenone BP 25 mg.

Erutic-50: Each film coated tablet contains Eplerenone BP 50 mg.

Indication: It is indicated for improving survival of stable patients with symptomatic heart failure with reduced ejection fraction (HFrEF) after an acute myocardial infarction, and the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Dosage and Administration: Heart failure with reduced ejection fraction (HFrEF) post an acute myocardial infarction: Initiate treatment with 25 mg once daily. Titrate to maximum of 50 mg once daily within 4 weeks, as tolerated. Dose adjustments may be required based on potassium levels. **Hypertension:** 50 mg once daily, alone or combined with other antihypertensive agents. For inadequate response, increase to 50 mg twice daily. Or, as directed by the registered physician.

Precaution: Hyperkalemia: Patients with decreased renal function, diabetes, proteinuria or patients who are taking ACEs and ARBs, NSAIDs or moderate CYP3A inhibitors are at increased risk. Monitor serum potassium levels and adjust dose as needed.

Side Effects: Most common adverse reactions hyperkalemia and increased creatinine.

Drug Interaction: CYP3A Inhibitors: Eplerenone metabolism is predominantly mediated via CYP3A. Do not use Eplerenone with drugs that are strong inhibitors of CYP3A. In post-MI HFrEF patients taking a moderate CYP3A inhibitor, do not exceed 25 mg once daily. In patients with hypertension taking a moderate CYP3A inhibitor, initiate at 25 mg once daily. For inadequate blood pressure response, dosing may be increased to a maximum of 25 mg twice daily. **ACE Inhibitors and Angiotensin II Receptor Antagonists:** The risk of hyperkalaemia increase when eplerenone is used in combination with an ACE inhibitor and/or an ARB.

Contraindication: For all patients: Eplerenone is contraindicated in all patients with:

*serum potassium >5.5 mEq/L at initiation,

*creatinine clearance ≤30 mL/min, or

*concomitant administration of strong CYP3A

Erutic

Eplerenone BP
25mg & 50mg Tablet

DRUG INTERNATIONAL LTD.

inhibitors (e.g., ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, and nelfinavir).

For patients treated for hypertension: It is contraindicated for the treatment of hypertension in patients with:

*type 2 diabetes with microalbuminuria,

*serum creatinine >2.0 mg/dL in males or >1.8 mg/dL in females,

*creatinine clearance <50 mL/min, or

*concomitant administration of potassium supplements or potassium-sparing diuretics (e.g., amiloride, spironolactone, or triamterene).

Use in pregnancy and lactation : Pregnancy : There are no adequate and well-controlled studies in pregnant women. Eplerenone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers :** The concentration of Eplerenone in human breast milk after oral administration is unknown, because many drugs are excreted in human milk and because of the unknown potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Use in Child : The safety and effectiveness of Eplerenone has not been established in pediatric patients.

Geriatric use : No differences in overall incidence of effectivity of safety was observed in elderly patients.

Overdosage : No cases of human overdosage with Eplerenone have been reported.

Storage : Keep away from sunlight. Store below 30° C in a dry & cool place.

Packing : Erutic-25: Each box contains 28's tablets in blister pack.

Erutic-50: Each box contains 98's tablets in blister pack.