

# Epleron®

Eplerenone tablet

## Presentation

Epleron® 25: Each tablet contains Eplerenone INN 25 mg.  
Epleron® 50: Each tablet contains Eplerenone INN 50 mg.

## Description

Eplerenone is a blocker of aldosterone binding at the mineralocorticoid receptor. Eplerenone binds to the mineralocorticoid receptor and blocks the binding of aldosterone, a component of the renin-angiotensin-aldosterone-system (RAAS). Aldosterone synthesis, which occurs primarily in the adrenal gland, is modulated by multiple factors, including angiotensin II and non-RAAS mediators such as adrenocorticotrophic hormone and potassium. Aldosterone binds to mineralocorticoid receptors in both epithelial (e.g. kidney) and nonepithelial (e.g. heart, blood vessels, and brain) tissues and increases blood pressure through induction of sodium reabsorption and possibly other mechanisms. Eplerenone has been shown to produce sustained increases in plasma renin and serum aldosterone, consistent with inhibition of the negative regulatory feedback of aldosterone on renin secretion. The resulting increased plasma renin activity and aldosterone circulating levels do not overcome the effects of Eplerenone.

## Indications and Uses

- Congestive Heart Failure after an acute Myocardial Infarction
- Hypertension

## Dosage and Administration

*Congestive Heart Failure after an acute Myocardial Infarction:*

The recommended dose of Eplerenone is 50 mg once daily. Treatment should be initiated at 25 mg once daily and titrated to the target dose of 50 mg once daily preferably within 4 weeks as tolerated by the patient. Eplerenone may be administered with or without food.

*Hypertension:*

Eplerenone may be used alone or in combination with other antihypertensive agents. The recommended starting dose of Eplerenone is 50 mg administered once daily. For patients with an inadequate blood pressure response to 50 mg once daily the dosage of Eplerenone should be increased to 50 mg twice daily. Higher dosages of Eplerenone are not recommended either because they have no greater effect on blood pressure than 100 mg or because they are associated with an increased risk of hyperkalemia.

## Precautions

Eplerenone should be used with caution in hyperkalemia, severe kidney disease, diabetic patients with Congestive Heart Failure after an acute Myocardial Infarction including those with proteinuria.

## Side effects

Headache, dizziness, diarrhea, stomach pain, nausea, cough or flu-like symptoms may occur. Symptoms of a serious allergic reaction like: rash, itching, swelling, severe dizziness, trouble breathing can occur.

## Contraindications

Eplerenone is contraindicated in-

- Hyperkalaemia
- Severe renal impairment (creatinine clearance less than 30 ml/min)
- Severe hepatic impairment

Concomitant use with potent CYP3A4 inhibitors like Ketoconazole, Itraconazole, Nefazodone, Troleandomycin, Clarithromycin, Ritonavir, and Nelfinavir or other potassium-sparing diuretics are also contraindicated.

## Overdosage

No cases of human overdosage with Eplerenone have been reported.

## 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.

## Pediatric use

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

## Geriatric use

No differences in overall incidence of effectivity or safety was observed in elderly patients.

## Commercial Pack

Epleron® 25: Each box contains 2 blister strips of 10 tablets.  
Epleron® 50: Each box contains 1 blister strip of 10 tablets.

Manufactured by  
 **Incepta Pharmaceuticals Ltd**  
Savar, Dhaka, Bangladesh  
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PTG : EN2

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