

EPLINICE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for EPLINICE [Eplerenone Tablets 25 mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Eplerenone binds to the mineralocorticoid receptor and blocks the binding of aldosterone.

INDICATION: For the treatment of mild to moderate hypertension in adults.

DOSAGE AND ADMINISTRATION: Recommended dose is 50mg once daily and may be increased to 50mg twice daily. Dose higher than 100mg may leads to hyperkalemia. Reduce the starting dose to 25mg daily while used with mild to moderate CYP 3A4 inhibitors (like, erythromycin, saquinavir, amiodarone, diltiazem, verapamil, and fluconazole). Protect from light & moisture.

CONTRAINDICATION: Serum potassium >5.5 mEq/L at initiation; creatinine clearance ≤ 30 mL/min; concomitant administration of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, and nelfinavir); 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; concomitant administration of potassium supplements or potassium sparing diuretics (e.g., amiloride, spironolactone, or triamterene); strong CYP3A4 inducers (rifampicin, carbamazepine, phenytoin, phenobarbital, St John's Wort).

WARNINGS & PRECAUTIONS: Hyperkalemia; serum creatinine levels >2.0 mg/dL (males) or >1.8 mg/dL (females) or creatinine clearance ≤ 50 mL/min should not be treated with eplerenone; CHF post-MI who have serum creatinine levels >2.0 mg/dL (males) or >1.8 mg/dL (females) or creatinine clearance ≤ 50 mL/min; proteinuria; impaired hepatic function; impaired renal function.

DRUG INTERACTIONS: Eplerenone interacts with potassium-sparing diuretics and potassium supplements; lithium; cyclosporin; tacrolimus; NSAIDs; trimethoprim; ACE inhibitors, angiotensin-II receptors antagonists; Alpha 1 blockers; Tricyclic anti-depressants, neuroleptics, amifostine, baclofene; glucocorticoides, tetracosactide; digoxin; warfarin.

ADVERSE REACTIONS: Hyperkalemia, increased creatinine, headache, dizziness, angina pectoris/myocardial infarction, increased GGT, hypercholesterolemia, hypertriglyceridemia, diarrhea, abdominal pain, albuminuria, coughing, dizziness, fatigue, influenza-like syndrome, decrease sodium level, increase triglyceride/cholesterol level, increase ALT/GGT level, serum creatinine (dose related); increase uric acid level; angioneurotic edema; rash.

MARKETED BY:



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(Additional information is available on request)