

TIDE E

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TIDE E (Combikit of Tablet A: Eplerenone Tablets J.P. and Tablet B: Torsemide Tablets I.P)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Eplerenone has relative selectivity in binding to recombinant human mineralocorticoid receptors compared to its binding to recombinant human glucocorticoid, progesterone and androgen receptors. Eplerenone prevents the binding of aldosterone, a key hormone in the renin-angiotensin-aldosterone-system (RAAS). While, torsemide acts from within the lumen of the thick ascending portion of the loop of Henle, where it inhibits the Na⁺/K⁺/2Cl⁻ carrier system.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION:

Hypersensitivity to the active substance or to any of the excipients. In Patients with serum potassium level > 5.0 mmol/L at initiation. In Patients, taking groups of drugs, which helps to excrete excessive body fluid, (potassium sparing diuretics), strong inhibitors of CYP3A4, anti-fungal (ketoconazole or itraconazole), antiviral medication (nelfinavir or ritonavir), antibacterial (clarithromycin or telithromycin), anti-depressant (nefazodone). The combination of an angiotensin converting enzyme (ACE) inhibitor and an angiotensin receptor blocker (ARB) with eplerenone. Contraindicated in patients with severe renal insufficiency (eGFR < 30 mL per minute per 1.73 m²), hepatic insufficiency (Child-Pugh Class C), who are anuric and with hepatic coma.

WARNINGS & PRECAUTIONS: Hyperkalaemia, renal and hepatic impairment, hypotension and worsening renal Function, electrolyte and metabolic abnormalities, ototoxicity may occur. Co-administration with strong CYP3A4 inducers, lithium, cyclosporin, and tacrolimus is not recommended.

DRUG INTERACTION: Pharmacodynamic interactions: Potassium-sparing diuretics and potassium supplements, ACE inhibitors, ARB, Lithium, Cyclosporin, tacrolimus, NSAIDs, Trimethoprim, Alpha-1-blockers (e.g. prazosin, alfuzosine), Tricyclic anti-depressants, neuroleptics, amifostine, baclofen, Glucocorticoids, tetracosactide, Cytochrome P450 2C9 Inhibitors and Inducers, Cholestyramine, Organic Anion Drugs, Ototoxic Drugs, Renin-angiotensin Inhibitors, Radiocontrast Agents, Corticosteroids and ACTH. Pharmacokinetic interactions: can interact with digoxin, warfarin, CYP3A4 substrates, inducers and inhibitors and antacids.

ADVERSE REACTIONS: Pyelonephritis, infection, pharyngitis, eosinophilia, hypothyroidism, hyperkalaemia, hypercholesterolaemia, hyponatraemia, dehydration, hypertriglyceridaemia, Insomnia, hypoaesthesia, dizziness, syncope, headache, Left ventricular failure, atrial fibrillation, tachycardia, arterial thrombosis limb, orthostatic, Hypotension, Asthenia, Gynaecomastia, Cholecystitis, Musculoskeletal pain, Hyperhidrosis, angioedema, Rash, Pruritus, Flatulence, diarrhoea, nausea, constipation, vomiting, cough, hypotension and worsening renal function, electrolyte and metabolic abnormalities, ototoxicity may occur.

Marketed BY:

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IN/TIDE E 25, 10, 20 mg/OCT-20/01/ABPI

(Additional information is available on request)