TIDE PLUS

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

Abbreviated Prescribing information for **Tide plus** [(1)Torsemide I.P. 10mg and Spironoloactone I.P. 25mg tablets, (2) Torsemide I.P 20mg and Spironoloactone I.P. 25mg tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Torsemide:** Torsemide is a diuretic of the pyridine-sulfonylurea class. Torasemide is a loop diuretic. It acts from within the lumen of the thick ascending portion of the loop of Henle, where it inhibits the Na+/K+/2Cl- carrier system. **Spironolactone:** Specific pharmacologic antagonist of aldosterone. Acting primarily through competitive binding of receptors at the aldosterone-dependent sodium-potassium exchange site in the distal convoluted renal tubule.

INDICATION: For treatment of resistant oedema associated with chronic cardic failure, hepatic cirrhosis; resistant hypertension and secondary hyperaldosteronism.

DOSAGE AND ADMINISTRATION: One or two tablets once daily. Maximum recommended dose of torasemide is 200mg/day and spironolcatone is 400mg/day.

CONTRAINDICATION: Torsemide: Contraindicated in patients with known hypersensitivity to torsemide or to sulfonylureas, in patients who are anuric. **Spironolactone:** It is contraindicated in patients with anuria, acute renal insufficiency, significant impairment of renal excretory function, hypercalcemia, hyperkalemia, Addison's disease or other conditions associated with hyperkalemia, and with concomitant use of eplerenone.

WARNINGS & PRECAUTIONS: **Torsemide**: Used with caution in patients with hepatic disease with cirrhosis and ascites, tinnitus and hearing loss, hypovolemia, or prerenal azotemi, laboratory values of electrolyte levels (calcium, magnesium), blood urea nitrogen, creatinine, uric acid, glucose, serum lipids levels were altered and should be monitored. **Spironolactone:** Caution should be exercise with simultaneous administration of medication or diet rich of potassium, ace inhibitors angiotensin II receptor antagonists, aldosterone blockers, non-steroidal anti-inflammatory drugs (NSAIDS), e.g., indomethacin, heparin and low molecular weight heparin and other drugs or conditions known to cause hyperkalemia. Observed for hypomagnesemia, hyponatremia, hypochloremic alkalosis, serum and urine electrolyte determinations and gynecomastia.

DRUG INTERACTIONS: **Torsemide**: Cholestyramine and probenecid. **Spironolactone:** Alcohol, barbiturates, or narcotics, antidiabetic drugs (e.g., oral agents, insulin), corticosteroids, ACTH, norepinephrine, skeletal muscle relaxants, lithium, NSAIDS, digoxin and cholestyramine.

ADVERSE REACTIONS: Torsemide: Water and electrolyte balance, Hypokalaemia, headache, dizziness, hypotension, weakness, drowsiness, confusional states, loss of appetite and cramps, Raised serum uric acid, glucose and lipids, aggravation of metabolic alkalosis. thromboembolic complications, vomiting, esophageal haemorrhage, dyspepsia, constipation, pancreatitis**,** increased serum urea and creatinine, increases in certain liver enzymes, pruritis, rash, angioedema, photosensitivity, visual disturbance, Dry mouth, excessive thirst, hypovolaemia, impotence, rhinitis, asthenia, ECG abnormality, cough increased, arthralgia, sore throat, myalgia, chest pain, insomnia, nervousness and edema. **Spironolactone:** Gastric bleeding, ulceration, gastritis, diarrhea and cramping, nausea, vomiting, inability to achieve or maintain erection, irregular menses or amenorrhea, postmenopausal bleeding, breast pain, carcinoma of the breast, leukopenia (including agranulocytosis), thrombocytopenia, fever, urticaria, maculopapular or erythematous cutaneous eruptions, anaphylactic reactions, vasculitis, leg cramps, lethargy, mental confusion, ataxia, dizziness, headache,drowsiness, mixed cholestatic/hepatocellular toxicity, renal dysfunction, stevens-johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug rash with eosinophilia and systemic symptoms (DRESS), alopecia and pruritis.

MARKETED BY:

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IN/ Tide plus 10,20,25mg/Oct-2015/01/Abpi
(Additional information is available on request)