RANOLAZ 500

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

Abbreviated Prescribing information for RANOLAZ 500 (Ranolazine 500 mg Sustained Release Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Ranolazine has antianginal and anti-ischemic effects that do not depend upon reductions in heart rate or blood pressure. The mechanism of action of Ranolazine is unknown.

INDICATIONS: Indicated for the treatment of chronic angina.

DOSAGE AND ADMINISTRATION: Hypertension: Ranolazine dosing should be initiated at 500 mg b.i.d. and increased to 1000 mg b.i.d., as needed, based on clinical symptoms. The maximum recommended daily dose of Ranolazine is 1000 mg b.i.d.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients, severe renal impairment. Moderate or severe hepatic impairment, Concomitant administration of potent CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, voriconazol, posaconazol, HIV protease inhibitors, clarithromycin, telithromycin, nefazodone), Concomitant administration of potent CYP3A inducers, Concomitant administration of Class Ia (e.g. quinidine) or Class III (e.g. dofetilide, sotalol) antiarrhythmics other than amiodarone.

WARNINGS & PRECAUTIONS: QT Interval Prolongation. **Renal impairment**: Care should be taken while administering the ranolazine in mild to moderate renal impairment. Co-administration of CYP 3A4 inducers may leads to lack of efficacy of ranolazine. Blood pressure may be increased in patients with severe renal impairment and should be monitored regularly. Patients with problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product. Ranolazine may cause dizziness and blurred vision, which may affect the ability to drive and use machines. **Renal Failure:** Acute renal failure has been observed.

DRUG INTERACTIONS: CYP3A Inhibitors: Do not use ranolazine with strong CYP3A inhibitors, including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir. **P-gp Inhibitors:** Down-titrate ranolazine based on clinical response in patients. **CYP3A and P-gp Inducers:** decreases the plasma concentration of ranolazine**. CYP2D6 Inhibitors:** increases ranolazine concentrations**. Drugs Metabolized by CYP3A:** The plasma level of simvastatin and its metabolites plasma concentration increased. **Drugs Metabolized by CYP2D6:** lower doses of CYP2D6 substrates may be required.

ADVERSE REACTIONS: dizziness, headache, constipation, vomiting, nausea, asthenia, Bradycardia, Plapitation, disorientation, amnesia, depressed level of consciousness, loss of consciousness, parosmia, impaired hearing, peripheral coldness, orthostatic hypotension, throat tightness, pancreatitis, erosive duodenitis, oral hypoaesthesia, angioedema, allergic dermatitis, urticaria, cold sweat, rash, erectile dysfunction, elevated levels of hepatic enzyme, hypotension

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)