ROZUCOR ASP

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

Abbreviated Prescribing information for Rozucor ASP (Rosuvastatin 5/10 mg and Aspirin 75 mg Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Rosuvastatin is a 3-hydroxy-3-methyl glutaryl coenzyme A (HMGCoA) reductase inhibitor indicated for the treatment of hyperlipidemia. Aspirin inhibits platelet aggregation by irreversibly acetylating platelet cyclo-oxygenase, thereby blocking the production of prostaglandin endoperoxides PGG2 and PGH2 which are precursors of the major platelet-aggregating material, thromboxane A2, which is also a powerful vasoconstrictor.

INDICATION: For the treatment of dyslipidemia associated with artherssclerotic arterial disease with risk of myocardial infarction, stroke or peripheral vascular disease.

DOSAGE AND ADMINISTRATION: The maximum dose rosuvastatin is 40mg once daily and for Aspirin for long term use is 75-150mg daily. In some circumstances a higher dose of Aspirin may be appropriate, especially in the short term, and up to 300 mg a day may be used on the advice of a doctor. Route of administration is oral and the capsules must not be chewed or crushed.

CONTRAINDICATION: Hypersensitivity to rosuvastatin, aspirin, other salicylates or any other NSAIDs or any of the excipients of this medicinal product, history of, or active peptic ulceration, haemophilia or other clotting disorders, gout, asthma, urticaria, rhinitis or other evidence of hyper sensitivity to aspirin or non-steroidal anti-inflammatory drugs, in patients with active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding 3 x the upper limit of normal (ULN), patients with severe renal impairment (creatinine clearance < 30 ml/min), patients with myopathy, patients receiving concomitant ciclosporin, during pregnancy and lactation and in women of childbearing potential not using appropriate contraceptive measures and in children under 12 years.

WARNINGS & PRECAUTIONS: Cases of myopathy and rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with HMG-CoA reductase inhibitors, including Rosuvastatin, caution should be exercised when anticoagulants are given in conjunction with rosuvastatin because of its potentiation of the effect of coumarin-type anticoagulants in prolonging the prothrombin time/INR, In the Rosuvastatin clinical trial program, dipstick-positive proteinuria and microscopic hematuria were observed among Rosuvastatin treated patients. Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including Rosuvastatin. There is a possible association between aspirin and Reye's syndrome when given to children. For this reason aspirin should not be given to children aged less than 12 years unless specifically indicated (e.g. Kawasaki's disease), Aspirin and other NSAIDs may cause salt and water retention and renal failure especially in patients with pre-existing renal impairment. Caution should be exercised in patients with asthma and other allergic conditions, bleeding tendencies, significant anemia, hypoprothrombinemia, impairmentof hepatic or renal function and dehydration.

DRUG INTERACTION: Rosuvastatin:-Cyclosporine, Gemfibrozil, Protease Inhibitors, Coumarin Anticoagulants, Niacin, Fenofibrate and Colchicine. **Aspirin: -** Alcohol, Metoclopramide, domperidone coumarin anticoagulant, clopidogrel, ticlopidine, oral hypoglycaemics, Phenytoin, sodium valproate, corticosteroids. methotrexate, spironolactone, acetazolamide, zafirlukast, mifepristone, antacids and absorbents. **ADVERSE REACTIONS: Rosuvastatin:**-Rhabdomyolysis with myoglobinuria and acute renal failure, myopathy (including myositis), liver enzyme abnormalities, headache, myalgia, abdominal pain, asthenia and nausea. **Aspirin:-** Fever, hypothermia, thirst, Dysrhythmias, hypotension, tachycardia, Agitation, Cerebral edema, coma, confusion, dizziness, headache, subdural or intracranial hemorrhage, lethargy, seizures., Dehydration, hyperkalemia, membolic acidosis, respiratory alkalosis., Dyspepsia, GI bleeding, ulceration and perforation, nausea, vomiting, heartburn, transient elevations of hepatic enzymes, hepatitis, Reye's syndrome, pancreatitis., Prolongation of the prothrombin time,, Acute anaphylaxis, angioedema,, Hypoglycemia (in children), hyperglycemia., pulmonary edema, Hearing loss, vertigo and Interstitial nephritis.

MARKETED BY:

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(Additional information is available on request)