

NEW MODLIP ASG

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

Abbreviated Prescribing information for NEW MODLIP ASG [Atorvastatin 10mg and Aspirin 75mg or Atorvastatin 10mg and Aspirin 150 mg Capsules] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Atorvastatin: Serum-cholesterol reducers, HMG-CoA reductase inhibitor. Aspirin: An analgesic, non-steroidal anti-inflammatory, antipyretic, antirheumatic and antithrombotic agent.

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

DOSAGE AND ADMINISTRATION: The patient should be on an appropriate lipid-lowering diet and should continue on this diet during treatment with New Modlip ASG. Route of administration is oral. New Modlip ASG is administered once daily dose but the dosage should not be increased than maximum allowed dose for individual agents. The maximum dose Atorvastatin is 80mg once daily and for Aspirin for long term use is 75-150mg daily. Capsule should be swallowed whole, not to be opened, chewed or crushed.

CONTRAINDICATION: Contraindicated in patient with hypersensitivity to atorvastatin, aspirin, other salicylates or NSAIDs or any of the excipients, history of or active peptic ulceration, haemophilia or other clotting disorders, gout, asthma, urticaria, rhinitis, severe renal or hepatic impairment or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal and women who are pregnant or may become pregnant and in nursing mothers.

WARNINGS & PRECAUTIONS: **Atorvastatin:** Liver dysfunction, cognitive problems (memory loss, confusion), hyperglycemia, renal impairment, skeletal muscle problem, use with cyclosporine, HIV protease inhibitors (tipranavir plus ritonavir), hepatitis C protease inhibitor (telaprevir), avoid use; HIV protease inhibitor (lopinavir plus ritonavir), use lowest necessary dose, clarithromycin, itraconazole, HIV protease inhibitors: do not exceed 20mg dose; HIV protease inhibitors (nelfinavir): do not exceed 40mg dose and patients with stroke/recent transient ischemic stroke. **Aspirin:** Reye's syndrome if used on children, other NSAIDs use, asthma and other allergic conditions, bleeding tendencies, significant anemia, hypoprothrombinemia, impairment of hepatic or renal function and dehydration.

DRUG INTERACTIONS: **Atorvastatin:** Fibrin acid derivatives, lipid-modifying doses of niacin, cyclosporine, or strong CYP 3A4 inhibitors (e.g., clarithromycin, HIV protease inhibitors, and itraconazole), clarithromycin, erythromycin, azithromycin, combination of protease inhibitors, diltiazem, ezetimibe, itraconazole, grapefruit juice, cyclosporine, rifampin or other Inducers of Cytochrome P450 3A4, verapamil, amiodarone, gemfibrozil/fibrates, niacin, colchicine, colestipol, antacid, amlodipine, fusidic acid, digoxin, oral contraceptives and warfarin. **Aspirin:** Alcohol and corticosteroid, coumarin anticoagulant, oral hypoglycaemics, phenytoin, sodium valproate, methotrexate, clopidogrel, ticlopidine, spironolactone diuretics, zafirlukast, metoclopramide and domperidone and antacids and absorbents.

ADVERSE REACTIONS: **Atorvastatin:** Myopathy, rhabdomyolysis, abdominal pain, constipation, diarrhoea, dyspepsia, nausea, flatulence, nasopharyngitis, hyperglycemia, pharyngolaryngeal pain,

epistaxis, arthralgia, pain in extremity, musculoskeletal pain, muscle spasms, myalgia, joint swelling, liver function test abnormal, blood creatine phosphokinase increased, insomnia, headache, asthenia, hepatitis, anorexia, pancreatitis, eructation, thrombocytopenia, allergic reaction, alopecia, hyperglycemia/hypoglycemia, paresthesia, hypoesthesia, peripheral neuropathy, dysgeusia, vision blurred, visual disturbances, cholestasis, hepatic failure, skin rash, urticaria, pruritus, alopecia, angioneurotic oedema, bullous rashes, tinnitus, hearing loss, tendon rupture, impotence, gynecomastia, cognitive impairments, memory loss, confusion, pain (chest/back), malaise, weight gain, peripheral edema, pyrexia, sexual dysfunction, depression, interstitial lung disease, amnesia, forgetfulness. **Aspirin:** Allergic reaction, fever, hypothermia, thirst, dysrhythmias, hypotension, tachycardia, agitation, cerebral edema, coma, confusion, dizziness, headache, subdural or intracranial hemorrhage, lethargy, seizures, dehydration, hyperkalemia, metabolic 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, disseminated intravascular coagulation, coagulopathy, thrombocytopenia, anaemia, purpura, leukopenia, anaphylaxis, pruritus, skin eruptions, urticaria, hypoglycemia (in children), hyperglycemia, prolonged pregnancy and labor, stillbirths, lower birth weight infants, antepartum and postpartum bleeding, hyperpnea, pulmonary edema, tachypnea, Hearing loss, vertigo, tinnitus, hearing loss, tinnitus, salicylism, interstitial nephritis, papillary necrosis, proteinuria, renal insufficiency and failure.

MARKETED BY:



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(Additional information is available on request)