**New Modlip-ASG 75**

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

Abbreviated Prescribing information for NEW MODLIP-ASG 75 [Aspirin Gastro-resistant and Atorvastatin Capsules I.P.]

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

## PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION**: Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate limiting enzyme responsible for the conversion of 3-hydroxy-3-methyl-glutaryl coenzyme A to mevalonate, a precursor of sterols, including cholesterol. Chemically, aspirin is acetylsalicylic acid. Aspirin inhibits prostaglandin synthesis resulting in inhibition of platelet aggregation for their lifespan of about 7 to 10 days. The acetyl group of aspirin binds with a serine residue of cyclooxygenase-1 (COX-1), resulting in irreversible inactivation of the enzyme.

**INDICATIONS:** It is indicated for the treatment of dyslipidemia associated with atherosclerotic arterial disease with risk of myocardial infarction, stroke, or peripheral vascular disease.

**DOSAGE AND ADMINISTRATION:** Usual dose is 1 capsule to be administered once daily. If required, doses may be increased, but should not exceed the recommended maximum daily doses. Maximum recommended dose of atorvastatin is 80 mg per day while aspirin can be administered up to 300 mg per day. These capsules may be preferably administered with food. The capsule should be swallowed whole with water and not be cut, crushed, or chewed.

**CONTRAINDICATION:** Atorvastatin is contraindicated in patients: with hypersensitivity to the active substance or to any of the excipients of this medicinal product, with active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal, during pregnancy, while breast-feeding and in women of child-bearing potential not using appropriate contraceptive measures. Aspirin is contraindicated in patients: Hypersensitivity to aspirin. Hypoprothrombinaemia, haemophilia and active peptic ulceration or a history of peptic ulceration.

**WARNINGS & PRECAUTIONS:** A history of renal impairment may be a risk factor for the development of rhabdomyolysis. Caution should be exercised if a statin is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones such as ketoconazole, spironolactone, and cimetidine. Aspirin may precipitate bronchospasm or induce attacks of asthma in susceptible subjects or other hypersensitivity reactions, particularly in individuals with bronchial asthma, hay fever, nasal polyps, or chronic respiratory disease.

**DRUG INTERACTIONS:** Potent CYP3A4 inhibitors have been shown to lead to markedly increased concentrations of atorvastatin. Concomitant administration of atorvastatin with inducers of cytochrome P4503A (e.g., efavirenz, rifampin, St. John's Wort) can lead to variable reductions in plasma concentrations of atorvastatin. Co-administration of atorvastatin and an oral contraceptive increased AUC values for norethindrone and ethinyl estradiol. These increases should be considered when selecting an oral contraceptive for a woman taking atorvastatin. The use of ezetimibe alone is associated with muscle-related events, including rhabdomyolysis. Atorvastatin AUC was significantly increased with concomitant administration of clarithromycin (500 mg twice daily). Therefore, in patients taking clarithromycin, caution should be exercised when the atorvastatin dose exceeds 20 mg. he risk of skeletal muscle effects may be enhanced when atorvastatin is used in combination with niacin.

Salicylates can inhibit renal clearance (displacing methotrexate from protein binding sites) of methotrexate, leading to bone marrow toxicity, especially in the elderly or renal impaired patients. Therefore, the concomitant use of methotrexate (at doses >15 mg/week) with aspirin is contraindicated. Salicylates antagonize the uricosuric action of uricosuric agents. Thus, concurrent use of probenecid and sulfinpyrazone with aspirin should be avoided. Diuretics in combination with aspirin at higher doses leads to decreased glomerular filtration via decreased prostaglandin synthesis. As a result, sodium excretion may be decreased. The risk of GI bleeding and ulceration may be increased when aspirin and corticosteroids are co-administered. In patients who are elderly, volume-depleted (including those on diuretic therapy), or who have compromised renal function, co-administration of NSAIDs, including aspirin, with RAAS inhibitors may result in deterioration of renal function,

including possible acute renal failure.

**ADVERSE REACTIONS:** Nausea, vomiting, diarrhea, dyspepsia, heartburn, abdominal discomfort or pain, flatulence, eructation, GI bleeding or ulceration, and rarely GI inflammation, with pancreatitis also reported, hepatitis, cholestasis, transient hepatic impairment, abnormal liver function tests to increases in ALT, AST, alkaline phosphatase, even fatal or non-fatal hepatic failure, arthralgia, joint swelling, myalgia, muscle fatigue, musculoskeletal pain, muscle spasm, neck pain, rhabdomyolysis, myositis, and tendon rupture, dizziness, vertigo, headache, insomnia, nightmares, depression, agitation, seizures, cerebral edema, coma, lethargy, and cognitive impairment such as memory loss, forgetfulness, amnesia, and confusion, with peripheral neuropathy also noted, nasopharyngitis, pharyngolaryngeal pain, epistaxis, tinnitus, asthma, rhinitis, nasal congestion, interstitial lung disease, urticaria, pruritus, and skin eruptions to bullous rashes such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, along with anaphylaxis, angioneurotic edema, edema, urinary tract infection, urine positive for WBCs, proteinuria, interstitial nephritis, papillary necrosis, renal insufficiency or failure, hyperkalemia, metabolic acidosis, respiratory alkalosis, leukopenia, thrombocytopenia, purpura, anemia, and hemolysis or hemolytic anemia in patients with severe G6PD deficiency, malaise, fatigue, pyrexia, sweating, and thirst are also reported.

**MARKETED BY:**

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

**IN/New Modlip-ASG 75/MAR-2026/02/ABPI**

(Additional information is available on request)