

MODLIP EZ

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

Abbreviated Prescribing information for MODLIP EZ [Atorvastatin 10 mg and Ezetimibe 10 mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Atorvastatin:** Serum-cholesterol reducers, HMG-CoA reductase inhibitor. **Ezetimibe:** Acts at the brush border of the small intestine and inhibit the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver.

INDICATION: For the treatment of patients with primary hypercholesterolemia.

DOSAGE AND ADMINISTRATION: Recommended starting dose is 1 tablet (Ezetimibe 10 mg and Atorvastatin 10 mg) once daily. The patient should be placed on a standard cholesterol-lowering diet that should continue during treatment.

CONTRAINDICATION: Contraindicated in patients with prior hypersensitivity to ezetimibe and / or atorvastatin, active liver disease or unexplained persistent elevations of serum transaminases, pregnant and nursing women and children.

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. **Ezetimibe:** Patients with 3 times UNL of transaminases.

DRUG INTERACTIONS: **Atorvastatin:** Fibric 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. **Ezetimibe:** Cyclosporin, antacids, cholestyramine, fibrates, statins and anticoagulants.

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, 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. **Ezetimibe:** Chest pain, dizziness, fatigue, headache, abdominal pain, diarrhea, pharyngitis, sinusitis, upper respiratory tract infection, arthralgia, back pain, myalgia, hypersensitivity reactions

(angioedema, rash), myalgia, increased CPK, elevations in liver transaminases, hepatitis, thrombocytopenia, pancreatitis, nausea, cholelithiasis, cholecystitis and very rarely myopathy.

MARKETED BY:



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(Additional information is available on request)