

MODLIP F

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

Abbreviated Prescribing information for MODLIP F [Atorvastatin 10mg and Fenofibrate 160mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Atorvastatin:** Serum-cholesterol reducers, HMG-CoA reductase inhibitor. **Fenofibrate:** Fenofibric acid, the active metabolite of fenofibrate, produces reductions in total-C, LDL-C, apo B, total triglycerides and VLDL in treated patients.

INDICATION: Combined hyperlipidemia (as an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in these patients).

DOSAGE AND ADMINISTRATION: As per the physician direction.

CONTRAINDICATION: Contraindicates in patient with hypersensitivity to any component of this medication, pre-existing gall bladder disease, Hepatic or severe renal dysfunction, including primary biliary cirrhosis, active liver disease or unexplained persistent elevations of serum transaminases, pregnancy, in breast feeding mothers and in women of childbearing potential not using adequate contraceptive measures. An interval of one month should be allowed from stopping atorvastatin treatment to conception in the event of planning a pregnancy. Safety and efficacy of atorvastatin in children have not yet been established.

WARNINGS & PRECAUTIONS: 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; patients with stroke/recent transient ischemic stroke, cholelithiasis and pancreatitis.

DRUG INTERACTIONS: Fibric acid derivatives, lipid-modifying doses of niacin, cyclosporine, or strong CYP 3A4 inhibitors (e.g., clarithromycin, HIV protease inhibitors, and itraconazole), strong inhibitors of CYP 3A4, 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, warfarin, other azole anti-fungal/niacin, oral 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, 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. **Fenofibrate:** decrease in haemoglobin and leukocytes, headache, peripheral neuropathy, vertigo,

thromboembolism (pulmonary embolism, deep vein thrombosis), interstitial pneumopathies, disorders digestive, gastric or intestinal disorders (abdominal pain, nausea, vomiting, diarrhoea, and flatulence), pancreatitis, gallstones, hypersensitivity/severe cutaneous skin reactions, photosensitivity reactions, alopecia, fatigue, asthenia.

MARKETED BY:



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(Additional information is available on request)