MODLIP D

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

Abbreviated Prescribing information for MODLIP D [Atorvastatin 10mg and Vitamin D3 1000 I.U. tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Atorvastatin:** Serum-cholesterol reducers, HMG-CoA reductase inhibitor. **Vitamin D3**: Increasing intestinal calcium absorption, reducing parathyroid hormone levels and improving the amount and quality of bone, has a beneficial vascular effect.

INDICATION: Hypercholesterolaemia and prevention of cardiovascular disease.

DOSAGE AND ADMINISTRATION: Should be taken once daily. The maximum dose for atorvastatin is 80mg and 4000 IU for vitamin D3 once a day.

CONTRAINDICATION: **Atorvastatin:** Contraindicated in patient with hypersensitivity, active liver disease or unexplained persistent elevations of serum transaminases, in 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. **Vitamin D3**: Contraindicated in patients with diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria, renal failure and hypervitaminosis D.

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; patients with stroke/recent transient ischemic stroke. **Vitamin D3:** sarcoidosis, long term treatment, cardiac glycosides/diuretics use in elderly patients (calculus formation); hypercalciuria, impaired renal function; hereditary problems of galactose intolerance; lapp lactose deficiency; glucose-galactose malabsorption; fructose intolerance; glucose-galactose malabsorption and sucrase-isomaltase insufficiency.

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, warfarin. **Vitamin D3**: Thiazide diuretics, phenytoin/barbiturates, glucocorticoids, ion exchange resins or laxatives (paraffin oil) reduce GI absorption of vitamin D.

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. **Vitamin D3**: hypercalcaemia, hypercalciuria, constipation, flatulence, nausea, abdominal pain, diarrhea, pruritus, rash, urticarial.

MARKETED BY:

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(Additional information is available on request)