MODLIP 40

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

Abbreviated Prescribing information for MODLIP 40 [Atorvastatin Tablets 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. Triglycerides and cholesterol in the liver are incorporated into very low-density lipoproteins (VLDL) and released into the plasma for delivery to peripheral tissues. Low-density lipoprotein (LDL) is formed from VLDL and is catabolised primarily through the receptor with high affinity to LDL (LDL receptor).

INDICATIONS: It is indicated as an adjunct diet to reduce elevated total cholesterol and triglyceride levels in patients with primary hypercholesterolemia and mixed dyslipidemia (type IIa & IIb).

DOSAGE AND ADMINISTRATION: The patient should be placed on a standard cholesterol-lowering diet before receiving Atorvastatin and should continue on this diet during treatment with Atorvastatin. The dose should be individualised according to baseline LDL-C levels, the goal of therapy, and patient response. The usual starting dose is 10 mg once a day. Adjustment of dose should be made at intervals of 4 weeks or more. The maximum dose is 80 mg once a day. *Primary hypercholesterolaemia and combined (mixed) hyperlipidaemia*: The majority of patients are controlled with atorvastatin 10 mg once a day. A therapeutic response is evident within 2 weeks, and the maximum therapeutic response is usually achieved within 4 weeks.

CONTRAINDICATION: Atorvastatin is contraindicated in patients: with hypersensitivity to the active substance or to any of the excipients, 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 and treated with the hepatitis C antivirals glecaprevir/pibrentasvir.

WARNINGS & PRECAUTIONS: Patients who develop increased transaminase levels should be monitored until the abnormality(ies) resolve. Should an increase in transaminases of greater than 3 times the upper limit of normal (ULN) persist, reduction of dose or withdrawal of atorvastatin is recommended. Atorvastatin, like other HMG-CoA reductase inhibitors, may in rare occasions affect the skeletal muscle and cause myalgia, myositis, and myopathy that may progress to rhabdomyolysis, a potentially life-threatening condition characterised by markedly elevated creatine kinase (CK) levels (> 10 times ULN), myoglobinaemia and myoglobinuria which may lead to renal failure. In few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia. Atorvastatin should be discontinued in case of aggravation of symptoms. Atorvastatin should be prescribed with caution in patients with pre-disposing factors for rhabdomyolysis. Risk of rhabdomyolysis is increased when atorvastatin is administered concomitantly with certain medicinal products that may increase the plasma concentration of atorvastatin such as potent inhibitors of CYP3A4 or transport proteins. The risk of myopathy and/or rhabdomyolysis may be increased by concomitant administration of HMG-CoA reductase inhibitors (e.g. atorvastatin) and daptomycin. Consideration should be given to temporarily suspend. There have been reports of rhabdomyolysis (including some fatalities) in patients receiving fusidic acid and statins in combination.

DRUG INTERACTIONS: Concomitant administration of medicinal products that are inhibitors of CYP3A4 or transport proteins may lead to increased plasma concentrations of atorvastatin and an increased risk of myopathy. The risk might also be increased at concomitant administration of atorvastatin with other medicinal products that have a potential to induce myopathy, such as fibric acid

derivates and ezetimibe. The use of fibrates alone is occasionally associated with muscle related events, including rhabdomyolysis. The risk of these events may be increased with the concomitant use of fibric acid derivatives and atorvastatin. When multiple doses of digoxin and 10 mg atorvastatin were co-administered, steady state digoxin concentrations increased slightly.

ADVERSE REACTIONS: nasopharyngitis, thrombocytopenia, allergic reactions, anaphylaxis, hyperglycaemia, hypoglycaemia, weight gain, anorexia, nightmare, insomnia, headache, dizziness, paraesthesia, hypoesthesia, dysgeusia, amnesia, peripheral neuropathy, myasthenia gravis, vision blurred, visual disturbance, ocular myasthenia, tinnitus, hearing loss, vasculitis, pharyngolaryngeal pain, epistaxis, constipation, flatulence, dyspepsia, nausea, diarrhoea, vomiting, abdominal pain upper and lower, eructation, pancreatitis, hepatitis, cholestasis, hepatic failure, urticaria, skin rash, pruritus, alopecia, angioneurotic oedema, dermatitis bullous including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis, lichenoid drug reaction, myalgia, arthralgia, pain in extremity, muscle spasms, joint swelling, back pain, neck pain, muscle fatigue, myopathy, myositis, rhabdomyolysis, muscle rupture, tendinopathy, sometimes complicated by rupture, lupus-like syndrome, immune-mediated necrotising myopathy, gynaecomastia, malaise, asthenia, chest pain, peripheral oedema, fatigue, pyrexia, liver function test abnormal, blood creatine kinase increased, white blood cells urine positive.

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(Additional information is available on request)