DIVASTIN

Tablet

DRUG INTERNATIONAL LTD.

Composition : **Divastin-10 :** Each film coated tablet contains Atorvastatin 10mg as Atorvastatin Calcium Trihydrate USP.

Divastin-20 : Each film coated tablet contains Atorvastatin 20mg as Atorvastatin Calcium Trihydrate USP.

Divastin-40 : Each film coated tablet contains Atorvastatin 40mg as Atorvastatin Calcium Trihydrate USP.

Description : Atorvastatin is a synthetic lipid lowering agent. Atorvastatin is an inhibitor of 3-hydroxy-3 methyl glutaryl coenzyme A (HMG-Co A) reductase.

Pharmacology : Atorvastatin is rapidly absorbed from the gastro-intestinal tract. It has low absolute bioavailability of about 12% due to presystemic clearance in the gastro-intestinal mucosa. The mean plasma elimination half-life of Atorvastatin is about 14 hours although the half-life of inhibitory activity for HMG-CoA reductase is approximately 20 to 30 hours due to the contribution of the active metabolites. It is 98% bound to plasma proteins. Atorvastatin is excreted as metabolites, primarily in the bile.

Indications : Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL cholesterol, apolipoprotein B and triglycerides in patients with primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia or combined hyperlipidaemia when response to diet and other nonpharmacological measures are inadequate.

Dosage & 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 usual starting dose is 10mg once a day. Dosages should be individualized according to baseline LDL-C levels, the goal of therapy and patient response. Adjustment of dosage should be made at intervals of 4 weeks or more. The maximum dose is 80mg once a day. Dosages may be given at any time of day with or without food. Or, as directed by the registered physician.

Contraindication : Atorvastatin is contra-indicated in patients with hypersensitivity to any component of this medication, active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal and in women of child bearing potential not using appropriate contraceptive measures.

Precautions : Liver function tests should be perfomed before the initiation of treatment and periodically thereafter. Patients who develop any signs or symptoms suggestive of liver injury should have liver function tests performed. Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease.

Side effects : Atorvastatin is generally well tolerated. Adverse reactions have usually been mild and transient. The most frequent adverse effects are constipation, flatulence, dyspepsia, abdominal pain, headache, nausea, myalgia, asthenia, diarrhoea and insomnia.

Use in pregnancy and lactation : Atorvastatin should be administered to women of child bearing age only when such patients are highly unlikely to conceive and have been informed of potential hazards. If the women becomes pregnant while taking Atorvastatin, it should be discontinued and the patient advised again as to the potential hazards to the fetus. The potential for adverse reaction in nursing infants, women taking Atorvastatin should not breast feed.

Use in Child : There is no data available.

Drug interactions : Digoxin : Administration of multiple dosages of Atorvastatin with digoxin increased steady state plasma digoxin concentrations by approximately 20%. Antacid : administration of Atorvastatin with an oral antacid suspension containing magnesium and aluminium hydroxides decreased Atorvastatin plasma concentrations approximately 35%. Warfarin : Patients receiving warfarin should be closely monitored when Atorvastatin is added to their therapy.

Storage : Store below 30°C in a dry place.

Packing : **Divastin-10 :** Each box contains 2 x 14's tablets in blister pack.

Divastin-20 : Each box contains 2 x 14's tablets in blister pack.

Divastin-40 : Each box contains 2 x 14's tablets in blister pack.