Anzitor®

Atorvastatin

COMPOSITION

Anzitor® 10: Each film coated tablet contains Atorvastatin 10 mg as Atorvastatin Calcium USP.
Anzitor® 20: Each film coated tablet contains Atorvastatin 20 mg as Atorvastatin Calcium USP.
Anzitor® 40: Each film coated tablet contains Atorvastatin 40 mg as Atorvastatin Calcium USP.

PHARMACOLOGY

Anzitor® 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 (TG) and cholesterol in the liver are incorporated into 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 high affinity LDL receptor. **Anzitor®** lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and increases the number of hepatic LDL receptors on the cell surface for enhanced uptake and catabolism of LDL. **Anzitor®** reduces LDL production and the number of LDL particles. **Anzitor®** produces a profound and sustained increase in LDL receptor activity coupled with a beneficial change in the quality of circulating LDL particles.

INDICATIONS

Anzitor® is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B,and triglycerides in patients with-

- Primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia and mixed dyslipidemia (Fredrickson types lla and llb)
- Elevated serum TG levels (Fredrickson type IV)
- Primary dysbetalipoproteinemia (Fredrickson type III) who do not respond adequately to diet.
- Homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (eg, LDL apheresis) or if such treatments are unavailable.

DOSAGE & ADMINISTRATION

Patients should be placed on a standard cholesterol lowering diet before receiving **Anzitor®** and should continue on this diet during treatment with **Anzitor®**. The usual starting dose for all the indications is 10 mg once daily. The doses range is 10 to 80 mg once daily. Doses 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. Doses may be given at any time of day with or without food.
Children: Treatment experience in a paediatric population with dose of **Anzitor®** up to 80 mg/day is limited. Geriatric (>70 years) use:
The safety and efficacy of **Anzitor®** in this population is as similar as < 70 years of age patients with the dose upto 80 mg/day.
In patients with Renal Insufficiency: No dosage adjustment is required.

ADVERSE EFFECTS

Atorvastatin is generally well tolerated. Adverse reactions have usually been mild and transient. Reversible myositis is rare but significant side effect of the statins. The statins also cause headache, altered liver- function tests and gastro-intestinal effects including abdominal pain, flatulence, diarrhoea, nausea and vomiting. Thrombocytopenia, rash and hypersensitivity reactions have been reported rarely. Other side effects are reported with Atorvastatin therapy includes insomnia, angioedema, anorexia, asthenia, paraesthesia, peripheral neuropathy, alopecia, pruritus, rash, impotence, chest pain, hypoglycemia and hyperglycemia.

WARNINGS AND PRECAUTIONS

Liver effects: Liver function tests should be performed before the initiation of treatment and periodically thereafter. Should an increase in ALT or AST of greater than 3 times the upper limit of normal persist, reduction of dose or withdrawal of Atorvastatin is recommended. Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease.
Skeletal muscle effects: Uncomplicated myalgia has been reported in Atorvastatin-treated patients. Atorvastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Should significant increases in CPK persist, reduction of dose or withdrawal of Atorvastatin is recommended. Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with Atorvastatin and with other drugs in this class.

CONTRAINDICATIONS

Atorvastatin is contraindicated in patients with hypersensitivity to any component of this medication, active liver disease or unexplained persistent elevations of serum transaminases, during pregnancy, while breast-feeding, and in women of child-bearing potential not using appropriate contraceptive measures.

INTERACTIONS WITH OTHER MEDICATIONS

The risk of myopathy during treatment with other drugs in this class is increased with concurrent administration of cyclosporin, fibric acid derivatives, erythromycin, azole antifungals, or niacin (nicotinic acid). These risks may also occur when combining these drugs with Atorvastatin. No clinically significant interactions were seen when Atorvastatin was administered with anti hypertensives and or hypoglycemic agents. Caution should also be exercised when Atorvastatin is administered with inhibitors of P450 3A4 (macrolide antibiotics and azole antifungals). The effect of inducers of cytochrome P450 3A4 (rifampicin or phenytoin) on Atorvastatin is unknown. Patients should be closely monitored if Atorvastatin is added to digoxin, erythromycin, oral contraceptives, colestipol, antacid and warfarin. No interaction was found with cimetidine.

USE IN PREGNANCY AND LACTATION

Atorvastatin is contraindicated in pregnancy and while breast-feeding. Women of child bearing potential should use appropriate contraceptive measures. If the woman become pregnant while taking Atorvastatin, it should be discontinued.

OVERDOSAGE

Specific treatment is not available for Atorvastatin overdosage. If an overdose occurs, the patient should be treated symptomatically and supportive measures instituted, as required. Due to extensive drug binding to plasma proteins, haemodialysis is not expected to significantly enhance Atorvastatin clearance.

STORAGE

Store below 30° C. Protect from light and moisture, keep all medicines out of the reach of children.

HOW SUPPLIED

Anzitor® 10: Box containing 50 film coated tablets in Alu-Alu blister pack.
Anzitor® 20: Box containing 30 film coated tablets in Alu-Alu blister pack.
Anzitor® 40: Box containing 10 film coated tablets in Alu-Alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH