

Aditor[®]

Atorvastatin

Composition:

Aditor 10mg: Each film coated tablet contains 10mg Atorvastatin as Atorvastatin Calcium Trihydrate.

Aditor 20mg: Each film coated tablet contains 20mg Atorvastatin as Atorvastatin Calcium Trihydrate.

Properties:

Atorvastatin is a selective, competitive inhibitor of (HMG-CoA reductase). This enzyme catalyzes the conversion of HMG-CoA to mevalonate, the rate limiting step in cholesterol biosynthesis.

Pharmacokinetics:

Atorvastatin is rapidly absorbed after oral administration.

Atorvastatin is more than 98% bound to plasma proteins.

It undergoes extensive metabolism to active ortho- and parahydroxylated metabolites which account for approximately 70% of the circulating (HMG-CoA reductase) inhibitory effect.

Elimination of Atorvastatin and its metabolites occurs primarily in the bile following hepatic and/or extrahepatic metabolism.

The mean plasma elimination half-life of Atorvastatin in human is approximately 14 hours, however, the half-life of HMG-CoA reductase inhibitory activity is 20-30 hours, due to the contribution of active metabolites.

Indications:

Reduction of elevated cholesterol and triglyceride values which do not respond to other measures of reduction (such as diet, physical exercises, weight loss) in patients with:

Elevated total-C, LDL-C, apo B, and TG.

Elevated blood cholesterol values (hypercholesterolemia).

Concurrently elevated cholesterol and triglyceride values in the blood (mixed hyperlipidemia).

Genetically determined elevated blood cholesterol values in familial hypercholesterolemia.

Contraindications:

Hypersensitivity to Atorvastatin.

Liver diseases or unclear and persistent elevations of hepatic function test values (serum transaminases).

Skeletal muscle disease.

Pregnancy and lactation.

Warnings/Precautions:

Liver function should be tested prior to the initiation of therapy then at regular intervals. If the liver function values showed increase to more than triple the normal level and persist over longer period, dose reduction or withdrawal of Atorvastatin is recommended.

Muscle pain has occasionally been reported. The increase of muscle enzyme (CPK) in blood should be examined, if it remains clearly elevated over a longer period, the dose should be reduced or withdrawn.

Drug interactions:

The risk of myopathy during treatment with related drugs of this substance class (HMG-CoA reductase inhibitors) is increased with concurrent administration of cyclosporin, fibric acid derivatives, niacin, erythromycin, and azole antifungals.

Concurrent use of Atorvastatin and digoxin may increase digoxin serum concentrations.

Concurrent use of Atorvastatin and colestipol decrease plasma concentration of Atorvastatin.

Coadministration of Atorvastatin and oral contraceptives increase AUC values for norethindrone and ethinyl estradiol.

Atorvastatin plasma concentrations were not significantly altered by coadministration of antacid.

Concurrent use of Atorvastatin with grapefruit juice can increase plasma concentrations of Atorvastatin since grapefruit juice contains one or more components that inhibit CYP3A4. Concomitant intake of large quantities of grapefruit juice and Atorvastatin is therefore not recommended.

Adverse effects:

Atorvastatin is generally well tolerated, and its adverse reactions are mild and transient.

The most frequent adverse events were constipation, flatulence, dyspepsia, abdominal pain, headache, nausea, muscle pain, feeling of weakness, diarrhea and insomnia.

Dosage and administration:

The patient should be placed on a diet before and during treatment.

The recommended starting dose is 10mg once daily taken at any time of the day (independent of mealtimes) and can be increased up to the maximum daily dose which is 80mg.

Presentations available:

Aditor is available as 10mg film coated tablet in 30 tablets pack.

Aditor is available as 20mg film coated tablet in 30 tablets pack.

This is a Medicament :

- Keep all medicaments away from children.
- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the treatment before consulting your doctor.
- Do not repeat the same prescription without consulting your doctor.