Taven®

Atorvastatin

Presentation

Taven® 10: Each film coated tablet contains Atorvastatin Calcium Trihydrate equivalent to Atorvastatin 10mg.
Taven® 20: Each film coated tablet contains Atorvastatin Calcium Trihydrate equivalent to Atorvastatin 20mg.
Taven® 40: Each film coated tablet contains Atorvastatin Calcium Trihydrate equivalent to Atorvastatin 40mg.

Indications

Hypercholesterolemia, Dyslipidemia, Hypertriglyceridemia

Mode of Action

Atorvastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic LDL receptors on the cell-surface to enhance uptake and catabolism of LDL.

However, Atorvastatin also increases the removal and reduces the secretion of very low-density lipoprotein (VLDL) and intermediate-density lipoprotein (IDL).

Dosage Guideline

Primary hypercholesterolemia and combined hyperlipidemia: Usually 10 mg once daily. Familial hypercholesterolemia: Initially 10 mg once daily, increased at intervals of at least 4 weeks to 40 mg; if necessary further increased up to 80 mg once daily.

Absorption

Atorvastatin is rapidly absorbed after oral administration; maximum plasma concentrations occur within 1 to 2 hours. Extent of absorption increases in proportion to atorvastatin dose. The absolute bioavailability of atorvastatin is approximately 14% and the systemic availability of HMG-CoA reductase inhibitory activity is approximately 30%.

Distribution

Mean volume of distribution of atorvastatin is approximately 381 liters. Atorvastatin is >98% bound to plasma proteins. A blood/plasma ratio of approximately 0.25 indicates poor drug penetration into red blood cells.

Metabolism

Atorvastatin is extensively metabolized after oral administration in the liver. Approximately 70% of circulating inhibitory activity for HMG-CoA reductase is attributed to active metabolites.

Excretion

Atorvastatin and its metabolites are eliminated primarily in bile following hepatic and/or extra-hepatic metabolism.

Side-effects

The commonest side-effects of Atovastatin are gastrointestinal disturbances. Other adverse effects include headache, skin rash, dizziness, blurred vision, insomnia. Hepatitis, pancreatitis, myopathy characterized by myalgia and muscle weakness have also been repoted.

Drug Interaction

Concurrent administration of Ciclosporin, Itrconazole, Ketoconazole, Erythromycin, Clarithromycin, HIV-protease inhibitors, fibric acid derivatives, nicotinic acid and Nefazodone might produce high plasma levels of Atorvastatin, thus increasing the risk of myopathy. Bleeding and increases in prothombin time have been reported in patients taking Atorvastatin with Coumarin anticoagulants.

Precaution

Atorvastatin should not be given to patients with acute liver disease or unexplained persistently raised serum-aminotransferase concentrations. It should be avoided during pregnancy since there is a possibility that it could interfere with fetal sterol synthesis; there have been few reports of congenital abnormalities associated with statins. It should be discontinued if marked or persistent increase in serum amino-transferase or creatine phosphokinase concentration occur. It should be used with caution in patient with severe renal failure.

Contraindication

Active liver disease or unexplained persistent elevations of serum transaminases. Hypersensitivity to any component of this medication.

Storage Condition

Store in a cool and dry place, away from direct light. Keep out of children's reach.

Use in Special groups

Neonates and Children

Adequate data are not available at the present time. From some references it has been concluded that use of atorvastatin after 12 years of age is not restricted.

Pregnant women

Safety of Atorvastatin in pregnant woman has not been studied.

Lactating mother

It is probably the best for mothers taking the drug to avoid breast feeding.

Adult

Safety & efficacy of atovastatin in this population were no different from that of patients <70 years.

Pack Size

Taven® 10: Each commercial pack contains 3 blister strips of 10 tablets.
Taven® 20: Each commercial pack contains 3 blister strips of 10 tablets.
Taven® 40: Each commercial pack contains 3 blister strips of 10 tablets.

Manufactured by
Renata Limited
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