KIVAS- 20 TABLET

Composition
Each Film Coated tablet contains:
Atorvastatin USP 20 mg.
(as Calcium Trihydrate)

Properties & Uses
Atorvastatin, a 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitor (a statin), is a lipid regulating drug with actions on plasma lipids similar to those of simvastatin. It is used to reduce LDL-cholesterol, apolipoprotein B, and triglycerides, and to increase HDL-cholesterol in the treatment of hyperlipidaemias, including hypercholesterolaemias and combined (mixed) hyperlipidaemia (type IIa or IIb hyperlipoproteinaemias), hypertriglyceridaemia (type IV), and dysbetalipoproteinaemia (type III).

Atorvastatin can also be effective as adjunctive therapy in patients with homozygous familial hypercholesterolaemia who have some LDL-receptor function. The effects of statins on plasma lipids are well established. Their primary action is to increase the expression of low-density lipoprotein (LDL)-receptors in the liver, which occurs in response to inhibition of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, the rate-limiting enzyme in cholesterol synthesis. This leads to increased clearance of LDL-cholesterol from the plasma, with a subsequent reduction in both LDL and total cholesterol. Triglycerides are also decreased, due to decreased synthesis of very-low-density lipoprotein (VLDL), while high-density lipoprotein (HDL)-cholesterol is either modestly increased or unchanged, leading to an improvement in the LDL-HDL ratio. Patients with homozygous familial hypercholesterolaemia have no functioning LDL receptors and statins are therefore less effective; however, some statins have been shown to lower LDL-cholesterol in these patients, suggesting that inhibition of LDL synthesis also plays a role in their action.

Pharmacokinetics
Atorvastatin is rapidly absorbed from the gastrointestinal tract. It has low absolute bioavailability of about 12% due to presystemic clearance in the gastrointestinal mucosa and first-pass metabolism in the liver, its primary site of action. Atorvastatin is metabolised by the cytochrome P450 isoenzyme CYP3A4 to a number of active metabolites. It is 98% bound to plasma proteins. The mean plasma elimination half-life of atorvastatin is about 14 hours although the half-life of inhibitory activity for HMGCoA reductase is about 20 to 30 hours due to the contribution of the active metabolites. Atorvastatin is excreted as metabolites, primarily in the bile.

Adverse Effects
The commonest adverse effects of therapy with statins are gastrointestinal disturbances. Other adverse effects reported include headache, skin rashes, dizziness, blurred vision, insomnia, and dysgeusia. Reversible increases in serum-aminotransferase concentrations may occur and liver function should be assessed before treatment is initiated and then monitored periodically until one year after the last elevation in dose. Hepatitis and pancreatitis have been reported. Hypersensitivity reactions including anaphylaxis and angioedema have also occurred. Myopathy, characterised by myalgia and muscle weakness and associated with increased creatine phosphokinase concentrations, has been reported, especially in patients taking statins concurrently with ciclosporin, furosemide derivatives, or nifedipine. Rarely, rhabdomyolysis with acute renal failure may develop.

Interactions
The most serious consequence of drug interactions with statins is the development of myopathy or rhabdomyolysis. Drugs that can cause myopathy when given alone increase the risk of myopathy with all statins; these drugs include fibrin acid derivatives (fibrates or gemfibrozil), and nicotinic acid. The risk of myopathy is also increased by drugs that increase the plasma levels of statins by inhibiting the microsomal cytochrome P450 isoenzyme CYP3A4, as are simvastatin and lovastatin, and interactions may occur with drugs that inhibit this enzyme, including ciclosporin, itraconazole, ketoconazole, erythromycin, clarithromycin, HIV-protease inhibitors, nefazodone, amidodarone, and verapamil; there may also be a similar interaction with grapefruit juice. Statins may also have effects on other drugs. Bleeding and increases in prothrombin time have been reported in patients taking simvastatin or other statins with coumarin anticoagulants.

Dose
Primary hypercholesterolaemia and combined hyperlipidaemia,
Usually 10 mg once daily; if necessary, may be increased at intervals of at least 4 weeks to max. 80 mg once daily; CHILD 10–17 years usually 10 mg once daily
Familial hypercholesterolaemia, Initially 10 mg daily, increased at intervals of at least 4 weeks to 40 mg once daily; if necessary, further increased to max. 80 mg once daily (or 40 mg once daily combined with anion-exchange resin in heterozygous familial hypercholesterolaemia); CHILD 10–17 years initially 10 mg daily, increased if necessary after at least 4 weeks to 20 mg once daily (limited experience with higher doses)

Precautions
Statins should not be given to patients with active liver disease or unexplained persistently raised serum-aminotransferase concentrations. They should be avoided during pregnancy since there is a possibility that they could interfere with fetal sterol synthesis; there have been a few reports of congenital abnormalities associated with statins. Statins are generally contra-indicated in pregnancy since there is a possibility than they might affect fetal sterol synthesis. They should be discontinued if marked or persistent increases in serum-aminotransferase or creatine phosphokinase concentrations occur, or if myopathy is diagnosed. Some statins, such as fluvastatin, pravastatin, rosuvastatin, and simvastatin, should be used with caution in patients with severe renal impairment. In children older than 10 years, there are concerns about the potential adverse effects of statins on growth and sexual development, because these patients require lifelong therapy. Toxic epidermal necrolysis apparently caused by atorvastatin has been reported.

Presentation; Three blister sheets each of 15 film coated tablets in pack.

Storage; Store below 30 °C, protected from sunlight and moisture

This is a Medicament:
Medicine is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription and the instructions of the pharmacist who sold the medicament.
The doctor and pharmacist are experts in medicine, its benefit & risk.
Don’t by yourself interrupt the period of treatment prescribed.
Don’t repeat the same prescription without consulting your doctor.
Keep this medicament out of reach of children.
Council of Arab Health Ministers Arab Pharmacists Association