Atorvastatin calcium
Atorvast-Ratiopharm®

Film-coated tablets
10 mg, 20 mg, 40 mg, 80 mg
Atorvastatin calcium

Rx

COMPOSITION

Each film-coated tablet contains:
Active ingredient: atorvastatin calcium trihydrate
Equivalent to atorvastatin 10 mg / 20 mg / 40 mg / 80 mg
Excipients: calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, simethicone, magnesium stearate
Film coat: hypromellose, macrogol 6000, titanium dioxide (E171), talc

PHARMACOLOGY

Pharmacodynamics

Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme in the formation of cholesterol in the liver. Cholesterol is a precursor of the lipoprotein fraction in which cholesterol is transported in the blood. Atorvastatin reduces cholesterol in the liver and increases the number of hepatic LDL receptors available for the uptake of LDL. Atorvastatin also reduces the production of LDL and the number of circulating LDL particles.

Pharmacokinetics

Atorvastatin is rapidly absorbed after oral administration; maximum plasma concentrations are reached within 1–2 hours. Absorption increases in proportion to the dose administered. Bioavailability is approx. 12%. Systemic availability of HMG-CoA reductase activity is approx. 30%. Atorvastatin is extensively bound to plasma proteins (>98%). Atorvastatin is metabolized in the liver by cytochrome P450 3A4 to ortho- and parahydroxylated derivatives and various beta-oxidation products. Atorvastatin and its metabolites are excluded from the blood stream by hepatic uptake. Atorvastatin is not a substrate for transporter proteins. Atorvastatin and its metabolites are excreted primarily in the bile. Atorvastatin is also excreted in the urine and in the milk of nursing mothers. Atorvastatin is not a substrate for OATP1B1 transporter protein. Atorvastatin and its metabolites do not undergo significant enterohepatic circulation.

INDICATIONS

Atorvastatin is indicated as an adjunct to diet for the treatment of elevated cholesterol levels in hypercholesterolemia, including familial hypercholesterolemia, when the response to diet and other measures is inadequate.

Atorvastatin is indicated to reduce the risk of cardiovascular events in patients with coronary heart disease, with a history of myocardial infarction, and/or stable angina pectoris.

CONTRAINDICATIONS

- Hypersensitivity to the active substance or any of the excipients
- Liver disease
- Pregnancy
- Breastfeeding
- Women of childbearing age
- Children
- Adolescents
- Adult men
- Elderly patients
- Patients with a history of myopathy/rhabdomyolysis
- Patients with a history of liver disease
- Patients with a history of muscle disorder
- Patients with a history of cerebrovascular disease
- Patients with a history of stroke
- Patients with a history of myocardial infarction
- Patients with a history of angina pectoris
- Patients with a history of coronary heart disease
- Patients with a history of diabetes
- Patients with a history of hypertension
- Patients with a history of cancer
- Patients with a history of kidney disease
- Patients with a history of gallstones
- Patients with a history of alcohol abuse
- Patients with a history of drug abuse
- Patients with a history of smoking
- Patients with a history of obesity
- Patients with a history of hypertriglyceridemia
- Patients with a history of hypercholesterolemia
- Patients with a history of hypertension
- Patients with a history of diabetes