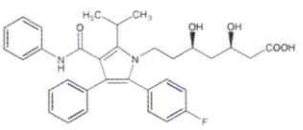
ATORVASTATIN
SAATIN® 10
SAATIN® 20
SAATIN® 40

Film-coated Tablet
HMG CoA Reductase Inhibitor

Rx



(atorvastatin)

FORMULATION:
Each film-coated tablet contains:
Atorvastatin (as Calcium) ..... 10 mg / 20 mg / 40 mg

PRODUCT DESCRIPTION:
10 mg Tablet: White to off-white, oblong, biconvex, film-coated tablet, plain on both sides.
20 mg Tablet: White to off-white, oval, biconvex, film-coated tablet, plain on both sides.
40 mg Tablet: White to off-white, oval, biconvex, film-coated tablet, plain on both sides.

PHARMACODYNAMICS AND PHARMACOKINETICS:
Atorvastatin, a 3-hydroxy-3-methylglutaryl coenzyme A (HMG CoA) reductase inhibitor (or statin), is a lipid regulating drug with actions on plasma lipids.
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/or first pass metabolism in the liver, its primary site of action. Atorvastatin is metabolized 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 HMG CoA reductase is about 20 to 30 hours due to contribution of the active metabolites. Atorvastatin is excreted as metabolites, primarily in the bile.

INDICATIONS:
It is used to reduce LDL-Cholesterol, apolipoprotein B, and triglycerides and to increase HDL-Cholesterol in the treatment of hyperlipidaemias (type IIa or IIb hyperlipoproteinaemias), hypertriglyceridaemia (type IV), and dysbetalipoproteinaemia (type III).

DOSAGE AND ADMINISTRATION:
The usual initial dose is 10 mg to 20 mg of atorvastatin once daily; an initial dose of 40 mg daily may be used in patients who require a large reduction in LDL-Cholesterol. The dose may be adjusted at intervals of 4 weeks up to a maximum of 80 mg daily.

PRECAUTIONS:
It should not be given to patients with active liver disease. Liver function should be assessed before starting treatment and subsequently when clinically indicated; additional assessment after 3 months and before and after dosage increases has been advised for some statins, particularly when high doses are given.
It should be used with caution in patients with renal impairment as the risk of myopathy is increased.
It should be stopped if creatine phosphokinase increases significantly or if myopathy is diagnosed.

CONTRAINDICATIONS:
Atorvastatin should be avoided during pregnancy since there is possibility that it could interfere with fetal sterol synthesis.

PREGNANCY:
Atorvastatin should be avoided during pregnancy since there is possibility that it could interfere with fetal sterol synthesis; there have been a number of reports of congenital abnormalities associated with statins.

ADVERSE DRUG REACTIONS:
The most common adverse effects of therapy with atorvastatin and other statins are gastrointestinal disturbances. Other adverse effects reported include headache, skin rashes, dizziness, blurred vision, insomnia and dysgeusia. Hypersensitivity reactions including anaphylaxis and angioedema have also occurred.

OVERDOSE AND TREATMENT :
There is no specific treatment for atorvastatin overdosage. In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required.

DRUG INTERACTIONS:
Interactions may occur with drugs that inhibit the cytochrome P450 isoenzyme CYP3A4 including ciclosporin, itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin, HIV-protease inhibitors, nefazodone, danazol, amiodarone and verapamil; there may also be similar interaction with grapefruit juice.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY:
10 mg: Alu/Alu Blister Pack x 10's; Box of 100 Film-coated Tablets
20 mg: Alu/Alu Blister Pack x 10's; Box of 100 Film-coated Tablets
40 mg: Alu/Alu Blister Pack x 10's; Box of 100 Film-coated Tablets

REGISTRATION NUMBER:
10 mg Film-coated Tablet: DRP-5589-01
20 mg Film-coated Tablet: DRP-5155-01
40 mg Film-coated Tablet: DRP-6540-01

DATE OF FIRST AUTHORIZATION:
10 mg Film-coated Tablet: 02 November 2015
20 mg Film-coated Tablet: 07 November 2014
40 mg Film-coated Tablet: 19 September 2017

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Manufactured by:
HIZON LABORATORIES, INC.
Assumption Road, Sumulong Highway,
Antipolo City

Distributed by:
GX INTERNATIONAL, INC.
RMG Corporate Center
Lot 60 Block 11, Buencamino St.,
Cupang, Muntinlupa City

DATE OF REVISION:
March 2023

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