

#### Presentation:

Lipitin 10 : Each film-coated tablet contains Atorvastatin Calcium Trihydrate equivalent to Atorvastatin INN 10 mg. **Lipitin 20**: Each film-coated tablet contains Atorvastatin Calcium Trihydrate

equivalent to Atorvastatin INN 20 mg.

### Description:

Lipitin (Atorvastatin Calcium) is a lipid-lowering agent. It inhibits selectively and competitively the 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, an early and rate limiting step in the synthesis of cholesterol.

#### Indications:

Lipitin (Atorvastatin INN) is indicated for the treatment of

- Primary hypercholesterolaemia
   Heterozygous familial hypercholesterolaemia
   Homozygous familial hypercholesterolaemia
- Combined (mixed) hyperlipidaemia

in patients who have not responded adequately to diet and other appropriate

# Dosage & administration:

Primary hypercholesterolaemia and combined hyperlipidaemia, usually 10 mg once daily. Familial hypercholesterolaemia, initially 10 mg daily, increased at intervals of 4 weeks to 40 mg once daily; if necessary, further increased to max. 80 mg once daily.

# Contraindications:

Active liver diseases or unexplained persistent elevations of serum transaminases. Hypersensitivity to any component of this medication. Pregnancy and lactation.

## Adverse reactions:

Atorvastatin is generally well tolerated. Adverse reactions have usually been mild and transient. The most frequent adverse events thought to be related to Atorvastatin were constipation, flatulence, dyspepsia and abdominal pain, headache, nausea, myalgia, diarrhoea, asthenia and insomnia.

## Pregnancy & lactation:

Safety in pregnancy has not been established. HMG-CoA reductase inhibitors are not recommended for use during pregnancy. An interval of one month should be allowed from stopping atorvastatin treatment to conception in the

event of planning a pregnancy.

Use of HMG-CoA reductase inhibitors during breast feeding is not recommended, because of potential for serious adverse effects in nursing infants.

Paediatrics: Safety and efficacy of Atorvastatin has not been established in

Geriatrics: Efficacy and safety in older patients using recommended doses is similar to that seen in general population.

## Drug Interactions:

The risk of myopathy during treatment with other drugs of this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, niacin, erythromycin, azole antifungals.

Antacid: when atorvastatin and antacid suspension were coadministered,

Antacid: when atorvastatin and antacid suspension were coadministered, plasma concentration of atorvastatin decreased approximately 35% however, LDL-C reduction was not altered.

Digoxin: When multiple doses of atorvastatin and digoxin were coadministered, steady state plasma digoxin concentrations increased by approximately 20%.

Erythromycin: In healthy individuals, plasma concentration of atorvastatin increased approximately 40% with coadministration of atorvastatin and pathemycin.

erythromycin.

Oral Contraceptives: Coadministration of atorvastatin and an oral contraceptive increased AUC values for norethindrone and ethinyl estradiol by approximately 30% and 20%.

**Storage:** Store below 25°C, protected from moisture.

# Commercial pack :

**Lipitin 10:** Each box contains 3 blister strips of 10 tablets. Lipitin 20: Each box contains 1 blister strip of 10 tablets.

