

# Atovex™

Atorvastatin

## Composition:

**Atovex™ 10** Tablet: Each film-coated tablet contains Atorvastatin Calcium INN equivalent to Atorvastatin 10 mg.

## Description:

**Atovex™** is a preparation of Atorvastatin, which acts as a lipid lowering agent. **Atovex™** competitively inhibits HMG-CoA (3-hydroxy-3-methyl-glutaryl-coenzyme A) reductase, an enzyme that catalyzes the biosynthesis of cholesterol. The enzyme catalyzes the conversion of HMG-CoA to mevalonate, a rate limiting step in cholesterol biosynthesis. It reduces LDL- cholesterol, apolipoprotein B & triglycerides and increases HDL cholesterol in the treatment of hyperlipidemia.

## Indications:

Primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia, homozygous familial hypercholesterolaemia or combined (mixed) hyperlipidaemia in patients who have not responded adequately to diet & other appropriate measures. Prevention of cardiovascular events in patients with type 2 diabetes & at least one additional risk factor for cardiovascular disease.

## Dosage & Administration:

Adult:

**Primary hypercholesterolaemia and combined hyperlipidaemia:** Usually 10 mg daily, if necessary, may be increased at intervals of at least 4 weeks to max. 80mg 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.

**Prevention of cardiovascular events in type 2 diabetes:** 10 mg once daily.

Children:

**Primary hypercholesterolaemia and combined hyperlipidaemia:** 10-17 years usually 10 mg once daily. Limited experience with doses above 20 mg daily.

**Familial hypercholesterolaemia:** 10-17 years up to 20 mg once daily. Limited experience with higher doses.

**OR AS DIRECTED BY THE PHYSICIAN.**

## Side Effects:

Side effects reported commonly include gastrointestinal disturbances, constipation, flatulence, dyspepsia, abdominal pain,

headache, nausea, insomnia etc. Others include myopathy, peripheral neuropathy, anorexia, rash, hyperglycaemia and hypoglycaemia etc. Chest pain, dizziness, angina have been reported in isolated cases.

## Precautions:

Liver function tests to be carried out before starting treatment & such tests should be repeated at intervals of 6 months for about 1 year.

**Pregnancy:** Atorvastatin is not recommended during pregnancy. If any patient becomes pregnant while taking this drug, therapy should be discontinued.

**Lactation:** Not recommended.

**Pediatric use:** Not recommended in children below 10 years of age.

## Contraindications:

This drug is contraindicated in patients with known hypersensitivity to Atorvastatin or any other components of this medication, active liver disease or unexplained persistent elevations of serum transaminases.

## Drug Interactions:

The risk of myopathy during treatment with statins is increased with concurrent administration of fibric acid derivatives, lipid-modifying doses of Niacin, Cyclosporine, or strong CYP 3A4 inhibitors (e.g., Clarithromycin, HIV protease inhibitors and Itraconazole). Atorvastatin and atorvastatin-metabolites are substrates of the OATP1B1 transporter. Inhibitors of the OATP1B1 (e.g., Cyclosporine) can increase the bioavailability of Atorvastatin. Concomitant administration of Atorvastatin with inducers of cytochrome P450 3A4 (e.g., Efavirenz, Rifampin) can lead to variable reductions in plasma concentrations of Atorvastatin. When multiple doses of Atorvastatin and Digoxin were co-administered, steady state plasma Digoxin concentration increased by approximately 20%. Co-administration of Atorvastatin and an oral contraceptive increased AUC values for Norethindrone and Ethinyl estradiol. Atorvastatin had no clinically significant effect on prothrombin time when administered to patients receiving chronic Warfarin treatment.

## Storage Condition:

Store in a cool & dry place, protect from light. Keep out of the reach of children.

## Presentation:

**Atovex™ 10** Tablet: Each box contains 3x10's tablets in blister pack.

Manufactured by:

**Julphar Bangladesh Ltd.**

Sreepur, Gazipur, Bangladesh.