For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Atorvastatin Tablets IP
(Brand Name: LIPONORM® 5 mg / 10 mg / 20 mg / 40 mg Tablets)

2. Qualitative and Quantitative Composition

Each Film-Coated Tablet Contains:
Atorvastatin Calcium IP equivalent to Atorvastatin …… 5 mg / 10 mg / 20 mg
Excipients …… q.s.
Colour: Titanium Dioxide

Each Film-Coated Tablet Contains:
Atorvastatin Calcium IP equivalent to Atorvastatin …… 40 mg
Excipients …… q.s.
Colours: Red Oxide of Iron, Yellow oxide of Iron and Titanium Dioxide

3. Dosage Form and Strength

Dosage Form: Tablets.
Dosage Strength: Atorvastatin 5 mg, 10 mg, 20 mg, 40 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

LIPONORM Tablets are indicated in the treatment of following:

1) **Hypercholesterolemia and Hyperlipidemia/Dyslipidemia:** Atorvastatin therapy is recommended as an adjunct to diet to reduce risk of atherosclerotic vascular diseases due to hypercholesterolemia. Atorvastatin is indicated in the management of primary hypercholesterolemia, heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia/dyslipidemia in patients who have not responded adequately to diet and other non-pharmacological measures.

2) **Primary Prevention of Cardiovascular Diseases (CVDs):** In adult patients with or without type 2 diabetes and without clinically evident coronary heart disease (CHD), but with multiple risk factors for it such as age, smoking, hypertension, retinopathy, albuminuria, decreased levels of high density lipoprotein-cholesterol (HDL-C), or a family history of premature CVD, LIPONORM Tablets are indicated to:
    - Reduce the risk of myocardial infarction.

- Reduce the risk of stroke.
- Reduce the risk for revascularization procedures and angina.

3) **Secondary Prevention of CVDs:** In adult patients with clinically evident CHD, LIPONORM Tablets are indicated to:
    - Reduce the risk of non-fatal myocardial infarction.
    - Reduce the risk of fatal and non-fatal stroke.
    - Reduce the risk for revascularization procedures.
    - Reduce the risk of hospitalization for congestive heart failure (CHF).
    - Reduce the risk of angina.

4.2Posology and Method of Administration

For oral administration.

1) **Primary Hypercholesterolemia and Mixed Dyslipidemia:** The recommended starting dose of atorvastatin in adults is 10 or 20 mg once daily. Patients who require a large reduction in low density lipoprotein-cholesterol (LDL-C) (more than 45%) may be started at 40 mg once daily. The effective dosage range of atorvastatin is 10 to 80 mg once daily.

2) **Homozygous Familial Hypercholesterolemia:** The effective dose of atorvastatin in adult patients is 10 to 80 mg daily. Only limited data is available. In these patients, atorvastatin should be used as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis).

3) **Heterozygous Familial Hypercholesterolemia.**
    Adults: Initially 10 mg of atorvastatin to be administered once daily, increased at intervals of at least 4 weeks to 40 mg once daily. If necessary, dose may be further increased to maximum of 80 mg once daily or a bile acid sequestrant may be combined with 40 mg atorvastatin once daily.
    Pediatric Patients (10 to 17 Years of Age): The recommended starting dose of atorvastatin is 10 mg per day; the usual dose range is 10 to 20 mg once daily.

4) **Prevention of CVDs.**
    Adults: Usually 10 mg of atorvastatin to be administered once daily. Higher doses may be required in order to achieve cholesterol goals.

The starting dose and maintenance doses of atorvastatin should be individualized according to patient characteristics such as goal of therapy and therapeutic response. After initiation and/or upon titration of atorvastatin, lipid levels should be analyzed within 2 to 4 weeks and dosage adjusted accordingly.
LIPONORM Tablets may be administered at any time of day with or without food. The tablet should be swallowed whole with water and not to be cut, crushed or chewed.
Or, as prescribed by the physician.

4.3Contraindications

LIPONORM Tablets are contraindicated in following conditions:

- Hypersensitivity to atorvastatin or to any component of the formulation.
- Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels.
- Pregnancy.
- Lactation.

4.4Special Warnings and Precautions for Use

Skeletal Muscle: Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with atorvastatin. A history of renal impairment may be a risk factor for the development of rhabdomyolysis. Thus, in such patients, closer monitoring for skeletal muscle effects is required. Atorvastatin, like other statins, occasionally causes myopathy (muscle aches or muscle weakness) in conjunction with increase in creatinine phosphokinase (CPK) values >10 times upper limit of normal (ULN).

Concurrent administration of atorvastatin with certain drugs such as cyclosporine, fibrates, macrolide antibiotics including erythromycin, azole antifungals, HIV-protease inhibitors, or niacin increases the risk of myopathy. On rare occasions, this results in rhabdomyolysis with renal dysfunction secondary to myoglobinuria. In cases where co-administration of these medications with atorvastatin is necessary, the benefit and the risk of concurrent treatment should be carefully considered.

Atorvastatin therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., severe acute infection, hypotension, major surgery, trauma, severe endocrine and electrolyte disorders, and uncontrolled seizures).

Liver Dysfunction: Statins have been associated with biochemical abnormalities of liver function. It is recommended that liver function tests be performed prior to and at 12 weeks following both the initiation of therapy and any elevation of dose, and periodically (as clinically indicated) thereafter. There have been rare post-marketing reports of fatal and non-fatal hepatic failure in patients taking statins, including atorvastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with atorvastatin, promptly interrupt therapy. If an alternate etiology is not found, do not restart atorvastatin. Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Active liver disease or unexplained persistent transaminase elevations are contraindications for the use of atorvastatin.

Endocrine Function: Increase in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including atorvastatin. Statins interfere with cholesterol synthesis and theoretically might blunt adrenal and/or gonadal steroid production. Clinical studies have shown that atorvastatin does not reduce basal plasma cortisol concentration or impair adrenal reserve. Caution should be exercised if a statin is

administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones such as ketoconazole, spironolactone, and cimetidine.

Interstitial Lung Disease: Exceptional cases of interstitial lung disease have been reported with some statins, especially with long term therapy. Presenting features can include dyspnoea, non-productive cough and deterioration in general health (fatigue, weight loss and fever). If it is suspected a patient has developed interstitial lung disease, statin therapy should be discontinued immediately.

4.5Drug Interactions

CYP3A4 Inhibitors: Potent CYP3A4 inhibitors have been shown to lead to markedly increased concentrations of atorvastatin. Co-administration of potent CYP3A4 inhibitors (e.g., cyclosporine, telithromycin, clarithromycin, delavirdine, stiripentol, ketoconazole, voriconazole, itraconazole, posaconazole and HIV protease inhibitors including ritonavir, lopinavir, atazanavir, indinavir, darunavir, etc.) should be avoided if possible. In cases where co-administration of these drugs with atorvastatin cannot be avoided lower starting dose of atorvastatin should be considered and appropriate clinical monitoring of the patient is recommended.

Moderate CYP3A4 inhibitors (e.g., erythromycin, diltiazem, verapamil and fluconazole) may increase plasma concentrations of atorvastatin. An increased risk of myopathy has been observed with the use of erythromycin in combination with statins. Therefore, a lower dose of atorvastatin should be considered and appropriate clinical monitoring of the patient is recommended when concomitantly used with moderate CYP3A4 inhibitors.

CYP3A4 Inducers: Concomitant administration of atorvastatin with inducers of cytochrome P4503A (e.g., efavirenz, rifampin, St. John's Wort) can lead to variable reductions in plasma concentrations of atorvastatin. Due to the dual interaction mechanism of rifampin (cytochrome P4503A induction and inhibition of hepatocyte uptake transporter OATP1B1), simultaneous co-administration of atorvastatin with rifampin is recommended, as delayed administration of atorvastatin after administration of rifampin has been associated with a significant reduction in atorvastatin plasma concentrations. The effect of rifampin on atorvastatin concentrations in hepatocytes is, however, unknown and if concomitant administration cannot be avoided, patients should be carefully monitored for efficacy.

Combination of Protease Inhibitors: Atorvastatin AUC was significantly increased with concomitant administration with several combinations of HIV protease inhibitors, as well as with the hepatitis C protease inhibitor (e.g., telaprevir), compared to that of atorvastatin alone. Therefore, in patients taking the HIV protease inhibitor tipranavir plus ritonavir, or the hepatitis C protease inhibitor telaprevir, concomitant use of atorvastatin should be avoided. In patients taking the HIV protease inhibitor lopinavir plus ritonavir, caution should be used when prescribing atorvastatin and the lowest dose necessary should be used. In patients taking the HIV protease inhibitors saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, or fosamprenavir plus ritonavir, the dose of atorvastatin should not exceed 20 mg and should be used with caution. In patients taking the HIV protease inhibitor nelfinavir or the hepatitis C protease inhibitor boceprevir, the dose of atorvastatin should not exceed 40 mg and close clinical monitoring is recommended.

Grapefruit Juice: Grapefruit juice contains one or more components that inhibit CYP 3A4 and can increase plasma concentration of drugs metabolised by CYP3A4 such as atorvastatin. Intake of 240 ml of grapefruit juice also resulted in a decreased AUC of 20.4% for the active orthohydroxy metabolite. Large quantities of grapefruit juice (> 1.2 liter daily for 5 days) increased AUC of atorvastatin 2.5 fold and AUC of active (atorvastatin and metabolites) HMG-CoA reductase inhibitors 1.3 fold. Thus, concomitant intake of large quantities of grapefruit juice and atorvastatin is not recommended.

Digoxin: When multiple doses of atorvastatin and digoxin were co-administered, steady state plasma digoxin concentrations increased by approximately 20%. Patients taking digoxin should be monitored appropriately.

Oral Contraceptives: Co-administration of atorvastatin and an oral contraceptive increased AUC values for norethindrone and ethinyl estradiol. These increases should be considered when selecting an oral contraceptive for a woman taking atorvastatin.

Warfarin: Atorvastatin had no clinically significant effect on prothrombin time when administered to patients receiving chronic warfarin treatment.

Colchicine: Cases of myopathy, including rhabdomyolysis, have been reported when atorvastatin is co-administered with colchicine, thus, caution should be exercised when prescribing atorvastatin with colchicine.

Niacin: The risk of skeletal muscle effects may be enhanced when atorvastatin is used in combination with niacin. Thus, dosage reduction should be considered in this setting.

Gemfibrozil and Other Fibrates: Due to an increased risk of myopathy/rhabdomyolysis when HMG-CoA reductase inhibitors are co-administered with gemfibrozil, concomitant administration of atorvastatin with gemfibrozil should be avoided. Because it is known that the risk of myopathy during treatment with HMG-CoA reductase inhibitors is increased with concurrent administration of other fibrates, atorvastatin should be administered with caution when used concomitantly with other fibrates.

Itraconazole: Atorvastatin AUC was significantly increased with concomitant administration of itraconazole 200 mg. Therefore, in patients taking itraconazole, caution should be exercised when the atorvastatin dose exceeds 20 mg.

Clarithromycin: Atorvastatin AUC was significantly increased with concomitant administration of clarithromycin (500 mg twice daily). Therefore, in patients taking clarithromycin, caution should be exercised when the atorvastatin dose exceeds 20 mg.

Ezetimibe: The use of ezetimibe alone is associated with muscle-related events, including rhabdomyolysis. The risk of these events may therefore be increased with concomitant use of ezetimibe and atorvastatin. Appropriate clinical monitoring of these patients is recommended.

Cyclosporine: Atorvastatin and atorvastatin-metabolites are substrates of the OATP1B1 transporter. Inhibitors of the OATP1B1 (e.g., cyclosporine) can increase the bioavailability of atorvastatin. Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin 10 mg and cyclosporine 5.2 mg/kg/day compared to that of atorvastatin alone. The co-administration of atorvastatin with cyclosporine should be avoided.

Colestipol: Plasma concentrations of atorvastatin and its active metabolites were lower when colestipol was co-administered with atorvastatin. However, lipid effects were greater when atorvastatin and colestipol were co-administered than when either drug was given alone.

Fusidic Acid: The risk of myopathy including rhabdomyolysis may be increased by the concomitant administration of systemic fusidic acid with statins. There have been reports of rhabdomyolysis (including some fatalities) in patients receiving this combination. If treatment with systemic fusidic acid is necessary, atorvastatin treatment should be discontinued throughout the duration of the fusidic acid treatment.

4.6Use in Special Populations

Pregnant Women

Pregnancy Category X. LIPONORM Tablets are contraindicated in women who are or may become pregnant. Serum cholesterol and triglycerides increase during normal pregnancy. Lipid lowering drugs offer no benefit during pregnancy because cholesterol and cholesterol derivatives are needed for normal fetal development. There are no adequate and well-controlled studies of atorvastatin use during pregnancy. There have been rare reports of congenital anomalies following intrauterine exposure to statins. Atorvastatin has the potential to cause hazards to the fetus, thus, it should be administered to women of childbearing potential only when such patients are highly unlikely to conceive. If the woman becomes pregnant while taking atorvastatin, atorvastatin should be discontinued immediately.

Atorvastatin may cause fetal harm when administered to a pregnant woman. Females of reproductive potential are advised to use effective contraception during treatment with atorvastatin.

Lactating Women

LIPONORM Tablets are contraindicated during breastfeeding. There is no available information on the effect of atorvastatin on the breastfed infant or effect on milk production. It is not known whether atorvastatin is excreted in human milk, but a small amount of another drug from the statin class does pass into breast milk. Because statins have a potential to cause serious adverse reactions in nursing infants, women requiring atorvastatin treatment should be advised not to nurse their infants. Accordingly, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Patients

The safety and efficacy of atorvastatin has not been established in paediatric patients younger than 10 years of age. Thus, LIPONORM Tablets are not recommended in children below 10 years old. For dosage in children above 10 years, please refer ‘Posology and Method of Administration’ section.

Geriatric Patients

No overall differences in safety or effectiveness were observed between geriatric subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older adults cannot be ruled out. Since advanced age (≥65 years) is a predisposing factor for myopathy, atorvastatin should be prescribed with caution in the elderly.

Renal Impairment Patient
Renal disease does not affect the plasma concentrations of atorvastatin. Thus, adjustment of atorvastatin dosage is not required in patients with renal dysfunction.

Hepatic Impairment Patients
Atorvastatin and its metabolites are eliminated primarily in bile following hepatic and/or extra-hepatic metabolism. Thus, atorvastatin should be used with caution in patients with hepatic impairment. LIPONORM Tablets are contraindicated in patients with active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels.

4.7Effect on Ability to Drive and Use Machines
Atorvastatin has negligible influence on the ability to drive and use machines.

4.8Undesirable Effects
The two most commonly reported adverse reactions with the use of atorvastatin are:

- Rhabdomyolysis and myopathy.
- Liver enzyme abnormalities.

Clinical Trials Experience
The commonly reported adverse reactions (incidence ≥ 2% and greater than placebo) regardless of causality, in patients treated with atorvastatin in placebo-controlled trials were nasopharyngitis (8.3%), arthralgia (6.9%), diarrhea (6.8%), pain in extremity (6.0%), urinary tract infection (5.7%), dyspepsia (4.7%), nausea (4%), musculoskeletal pain (3.8%), muscle spasm (3.6%), myalgia (3.5%), insomnia (3%), and pharyngolaryngeal pain (2.3%).
Other adverse reactions reported in placebo-controlled studies include:

- Body as a Whole: Malaise, pyrexia.
- Digestive System: Abdominal discomfort, eructation, flatulence, hepatitis, cholestasis.
- Musculoskeletal System: Musculoskeletal pain, muscle fatigue, neck pain, joint swelling.
- Metabolic and Nutritional System: Increase in transaminases (ALT and AST), abnormal liver function test, increase in blood alkaline phosphatase, increase in creatine phosphokinase, hyperglycemia.
- Nervous System: Nightmares.
- Respiratory System: Epistaxis.
- Skin and Appendages: Urticaria.
- Special Senses: Blurred vision, tinnitus.
- Urogenital System: Urine test positive for white blood cells (WBCs).

Post-Marketing Experience
The following adverse reactions have been identified during post-approval use of atorvastatin. Because these reactions are reported voluntarily from a population of uncertain

size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions associated with atorvastatin therapy include the following: Anaphylaxis, angioneurotic edema, bullous rashes (including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), rhabdomyolysis, myositis, fatigue, tendon rupture, fatal and non-fatal hepatic failure, dizziness, depression, peripheral neuropathy, pancreatitis and interstitial lung disease. There have been rare reports of immune-mediated necrotizing myopathy associated with statin use. There has been rare post-marketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, confusion) associated with statin use. These cognitive issues have been reported for all statins. The reports are generally non serious, and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks).

4.9Overdose

An overdose of atorvastatin is not expected to produce life-threatening symptoms. Symptoms of an atorvastatin overdose are unknown. There is no specific treatment for atorvastatin overdose. In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required. Due to extensive drug binding to plasma proteins, hemodialysis is not expected to significantly enhance atorvastatin clearance.

5. Pharmacological Properties

5.1 Mechanism of Action

Atorvastatin is a synthetic lipid-lowering agent. Atorvastatin is a selective, competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase enzyme. This enzyme catalyzes the conversion of HMG-CoA to mevalonate (a precursor of sterols, including cholesterol), an early and rate-limiting step in cholesterol biosynthesis.

Atorvastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase enzyme and thereby reducing cholesterol biosynthesis in the liver. The liver is the primary site of action and the principal site of cholesterol synthesis and lipoprotein clearance. Atorvastatin reduces low density lipoprotein (LDL) production and the number of LDL particles. Atorvastatin increases the number of hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL.

5.2Pharmacodynamic Properties

Cholesterol and triglycerides (TG) circulate in the bloodstream as part of lipoprotein complexes. Elevated plasma levels of total cholesterol (total-C), low density lipoprotein-cholesterol (LDL-C), and apolipoprotein B (apo B) promote atherosclerosis and are risk factors for developing cardiovascular diseases (CVDs), while increased levels of high density lipoprotein-cholesterol (HDL-C) are associated with a decreased cardiovascular risk.

Atorvastatin reduces total-C, LDL-C, VLDL-C, apo B, and TGs and increases HDL-C in patients with hyperlipidemia (heterozygous familial and non-familial) and mixed dyslipidemia (Fredrickson Types IIa and IIb). Therapeutic response of atorvastatin is seen

within 2 weeks, and maximum response is usually achieved within 4 weeks and maintained during chronic therapy.

5.3Pharmacokinetic Properties

Absorption: Atorvastatin is rapidly absorbed after oral administration. Maximum plasma concentrations occur within 1 to 2 hours. Extent of absorption increases in proportion to atorvastatin dose. The absolute bioavailability of atorvastatin is approximately 14% and the systemic availability of HMG-CoA reductase inhibitory activity is approximately 30%. The low systemic availability is attributed to presystemic clearance in gastrointestinal mucosa and/or hepatic first-pass metabolism. Although food decreases the rate and extent of drug absorption, efficacy is similar whether atorvastatin is given with or without food.

Distribution: Mean volume of distribution of atorvastatin is approximately 381 liters. Atorvastatin is ≥98% bound to plasma proteins.

Metabolism: Atorvastatin is extensively metabolized to ortho- and parahydroxylated derivatives and various beta-oxidation products. *In vitro* inhibition of HMG-CoA reductase by ortho- and parahydroxylated metabolites is equivalent to that of atorvastatin. Approximately 70% of circulating inhibitory activity for HMG-CoA reductase is attributed to active metabolites.

Excretion: Atorvastatin and its metabolites are eliminated primarily in bile following hepatic and/or extra-hepatic metabolism; however, the drug does not appear to undergo enterohepatic recirculation. Mean plasma elimination half-life of atorvastatin in humans is approximately 14 hours, but the half-life of inhibitory activity for HMG-CoA reductase is 20 to 30 hours due to the contribution of active metabolites. Less than 2% of a dose of atorvastatin is recovered in urine following oral administration.

6. Nonclinical Properties

6.1 Animal Toxicology

Atorvastatin was negative for mutagenic and clastogenic potential in a battery of 4 *in vitro* tests and 1 *in vivo* assay. Atorvastatin was not found to be carcinogenic in rats, but high doses in mice (resulting in 6-11 folds the $AUC_{0\text{-}24h}$ reached in humans at the highest recommended dose) showed hepatocellular adenomas in males and hepatocellular carcinomas in females.

There is evidence from animal experimental studies that HMG-CoA reductase inhibitors may affect the development of embryos or foetuses. In rats, rabbits and dogs atorvastatin had no effect on fertility and was not teratogenic, however, at maternally toxic doses foetal toxicity was observed in rats and rabbits. The development of the rat offspring was delayed and post-natal survival reduced during exposure of the dams to high doses of atorvastatin. In rats, there is evidence of placental transfer. In rats, plasma concentrations of atorvastatin are similar to those in milk.

7. Description

LIPONORM 5 Tablets are White, circular, biconvex, film coated tablets, plain on both sides.

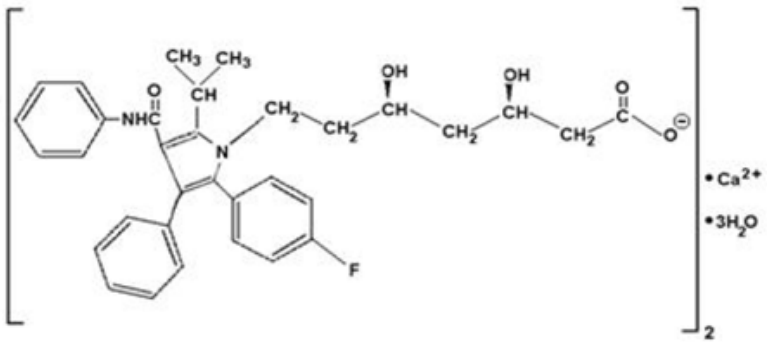
LIPONORM 10 Tablets are White, circular, biconvex, film coated tablets with ‘10’ engraved on one side and plain on other side.

LIPONORM 20 Tablets are White, circular, biconvex, film coated tablets with ‘L’ and ‘20’ engraved on either side of the breakline on one side and other side plain.

LIPONORM 40 Tablets are Light orange colour, circular, biconvex, film coated tablets, plain on both sides.

Each tablet of LIPONORM 5 contains 5 mg of atorvastatin for oral administration.
Each tablet of LIPONORM 10 contains 10 mg of atorvastatin for oral administration.
Each tablet of LIPONORM 20 contains 20 mg of atorvastatin for oral administration.
Each tablet of LIPONORM 40 contains 40 mg of atorvastatin for oral administration.

Atorvastatin calcium is the calcium salt of atorvastatin, a synthetic lipid-lowering agent. Atorvastatin competitively inhibits 3-hydroxy, 3-methylglutaryl-coenzyme A (HMG-CoA) reductase enzyme and thereby reduces cholesterol biosynthesis in the liver.
Atorvastatin calcium is a white to off-white crystalline powder that is insoluble in aqueous solutions of pH 4 and below. Atorvastatin calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer, and acetonitrile; slightly soluble in ethanol; and freely soluble in methanol.
Molecular Weight: 1209.42 g/mol.
Molecular Formula: C33H34FN2O5)2Ca•3H2O.
Chemical Name: Calcium;(3R,5R)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-propan-2-ylpyrrol-1-yl]-3,5-dihydroxyheptanoate;trihydrate.
Structural Formula:



Inactive ingredients (excipients) of LIPONORM 5 mg / 10 mg / 20 mg Tablets contain Lactose, Microcrystalline Cellulose, Calcium Carbonate, Sodium Starch Glycollate, Starch, Talc, Colloidal Silicon Dioxide, Magnesium Stearate & Instacoat aqua III – white.

Inactive ingredients (excipients) of LIPONORM 40 Tablet contain Lactose, Microcrystalline Cellulose, Calcium Carbonate, Sodium Starch Glycollate, Starch, Talc, Colloidal Silicon Dioxide, Magnesium Stearate & Instacoat aqua III – Yellow.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 Months

8.3Packaging Information

LIPONORM 5 mg / 10 mg / 20 mg Tablets : 15 tablets per blister.
LIPONORM 40 mg Tablets : 15 tablets per strip.

8.4Storage and Handling Instructions

Store protected from moisture at a temperature not exceeding 30°C.
Keep out of reach of children.

9. Patient Counseling Information

- Take LIPONORM Tablets exactly as prescribed by your doctor. Do not change your dose or stop therapy without talking to your doctor.
- Take LIPONORM Tablets once daily at any time of day at about the same time each day. LIPONORM Tablets can be taken with or without food.
- If you miss a dose of LIPONORM Tablets, take it as soon as you remember. Do not take the drug if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time; do not take 2 doses to make up for the missed doses.
- Do not take LIPONORM Tablets if you are pregnant or think you may be pregnant, or are planning to become pregnant. Atorvastatin may harm your unborn baby. If you get pregnant, stop taking this medicine and consult your doctor immediately.
- Do not take LIPONORM Tablets if you are breast feeding. Atorvastatin can pass into your breast milk and may harm your baby.
- Do not take LIPONORM Tablets if you have liver dysfunction.
- LIPONORM Tablets are not recommended in children under 10 years of age.
- Consult your doctor immediately if you suffer from any muscle problems like weakness, tenderness, pain, or more tiredness than usual after taking drug therapy.
- Talk to your doctor before you start any new medicines and also inform them about all the medicines that you are taking currently. This includes prescription and nonprescription medicines, vitamins, and herbal supplements. LIPONORM Tablets and certain other medicines can interact with each other causing serious side effects.

- Do not give LIPONORM Tablets to other people, even if they have the same problem you have. It may harm them.

10. Details of Manufacturer

BLUE CROSS LABORATORIES PVT LTD.
A-12, M.I.D.C., AMBAD, NASHIK – 422 010.

11. Details of Permission or License Number with Date

LIPONORM 5 mg / 10 mg / 20 mg / 40 mg Tablets Mfg. Lic. No. : BD/25.
LIPONORM 5 mg / 10 mg / 20 mg / 40 mg Tablets Date of FDA Product Permission: 01/01/2013

12. Date of Revision

May 2021.

Marketed by:
EXCEL
Division of BLUE CROSS
MADE IN INDIA BY
BLUE CROSS LABORATORIES PVT LTD.
A-12, M.I.D.C., NASHIK-422 010.
Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.