

Lipistad[®] 10 Film-Coated Tablet

Active ingredient: Atorvastatin (calcium) 10 mg

What is in this leaflet

What Lipistad[®] 10 is used for.
How Lipistad[®] 10 works.
Before you use Lipistad[®] 10.
How to take Lipistad[®] 10.
While you are using Lipistad[®] 10.
Side effects.
After using Lipistad[®] 10.
Product description.
Manufacturer.
Marketing authorization holder.
Date of revision.

What Lipistad[®] 10 is used for

Lipistad[®] 10 is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are an increased risk of heart disease, Lipistad[®] 10 can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

How Lipistad[®] 10 works

The active ingredient, atorvastatin belong to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Before you use Lipistad[®] 10

When you must not take it

- If you are allergic to any component of this drug.
- If you have a disease which affects the liver.
- If you are in pregnancy and while breastfeeding.
- If you are women of child-bearing potential not using appropriate contraceptive measures.

Before you start to take it

If any of the situations mentioned below apply to you, you should tell your doctor before taking this drug:

- If you have liver dysfunction.
- If you have problems with skeletal muscle.
- If you are in pregnancy and while breastfeeding.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

You should tell your doctor if you receive other drugs that increase the risk of muscular disease (myopathy) such as cyclosporine, fibric acid derivatives, vitamin PP, erythromycin, azole antifungals; drugs that decrease plasma concentration of atorvastatin such as antacids, colestipol.

Other medicines known to interact with Lipistad[®] 10 include digoxin and oral contraceptives such as norethindrone and ethinyl estradiol.

There are no significant interactions with coadministration of Lipistad[®] 10 with antipyrine, cimetidine and warfarin.

How to take Lipistad[®] 10

How much to take

Always take Lipistad[®] 10 exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of Lipistad[®] 10 depending on your condition and whether you are taking other medicines.

- The dosage range is 10 to 80 mg once daily. Starting and maintenance dosage should be individualized according to prescription of your doctor.
- *Primary Hypercholesterolemia and Combined Hyperlipidemia* (commonly occurring form of high cholesterol levels characterised by increased bad cholesterol and triglyceride concentrations, often accompanied by decreased good cholesterol): 10 mg once a day. A therapeutic response is evident within two weeks, and the maximum response is usually achieved within four weeks. The response is maintained during long-term therapy.
- *Homozygous familial hypercholesterolemia*: 80 mg per day
- *Patients with kidney problems and elderly*: no adjustment of the dose is required.

When to take it

Lipistad[®] 10 is given any time of the day, with or without food.

How long to take it

It is important to continue taking Lipistad[®] 10 for as long as your doctor prescribes in order to maintain smooth control of your symptoms and signs. The duration of

treatment with Lipistad[®] 10 is determined by your doctor.

If you forget to take it

If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take a double dose to make up for a forgotten tablet. Just take the next dose at your regular time.

If you take too much (overdose)

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately.

While you are using Lipistad 10 mg

Things you must do

- Tell your doctor if you become pregnant.
- Tell your doctor if you have unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.
- Discontinued if markedly elevated CPK (creatine phosphokinase - an enzyme expressed by various tissues and cell types) levels occur, muscular disease (myopathy) is diagnosed or if you have a risk to the development of kidney failure secondary or rhabdomyolysis (abnormal muscle breakdown which can lead to kidney problem).
- Before starting treatment, your doctor will place you on a low-cholesterol diet, exercise and weight reduction in obese patients, which you should maintain also during therapy with Lipistad[®] 10.

Things you must not do

- Do not take too many tablets.
- Do not stop the treatment earlier than planned. Contact your doctor or pharmacist before stopping.

Things to be careful of

- Use with caution in patients who consume substantial amounts of alcohol and/ or have a history of liver disease.
- Use with caution in patients who have problems with skeletal muscle.

Side effects

Like all medicines, Lipistad[®] 10 can cause side effects, although not everybody gets them.

Side effects have usually been mild and transient. The most frequent side effects

are difficulty in sleeping (insomnia), headache, feeling sick (nausea), diarrhea, abdominal pain, indigestion (dyspepsia), constipation, flatulence, muscle pain (myalgia), feeling of weakness.

The following additional adverse effects have been reported in atorvastatin clinical trials: low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), loss of appetite (anorexia), disorder of the nerves which can cause weakness, tingling or numbness caused by disorder of the nerves (peripheral neuropathy), inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis), vomiting, inflammation of the liver (hepatitis), yellowing of the skin caused by thickening of bile, obstruction of hepatic ducts, or changes in liver cell function (cholestatic jaundice), hair loss (alopecia), itching (pruritus), rash, pain or weakness in muscles (myopathy), any of a group of

Date of version:

16 August 2012

muscle diseases in which inflammation and degenerative changes occur (myositis), prolonged painful contraction of a muscle (muscle cramps) and inability in a man to have sexual intercourse (impotence).

After using Lipistad® 10

Storage

The expiry date of this pack is printed on the box and blister foil. Do not use this pack after this date.

Do not store above 25°C. Protect from light.

Keep all medicines out of reach of children.

Disposal

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

Lipistad® 10 appears as a white, oval-shaped, biconvex, film-coated tablet, engraved with “10” on one side and plain on the other.

Ingredients

Active ingredient:

One tablet of Lipistad® 10 contains 10 mg of Atorvastatin (calcium).

The other ingredients are Calcium carbonate, Primellose, Lactose, Avicel, Povidone, Tween 80, Magnesium stearate, Hypromellose, Polyethylene glycol 6000, Purified talc, Titanium dioxide, Ethanol 96% and Purified water.

MAL No.: MAL07010915A

Manufacturer

STADA- VN J.V. Co., Ltd., K63/1 Nguyen Thi Soc St., My Hoa 2 Hamlet, Xuan Thoi Dong Village, Hoc Mon Dist., Ho Chi Minh City, Vietnam.

Marketing Authorisation Holder

STADPHARM SDN BHD
B05-05, 5th Floor, 3-Two Square,
Jalan 19/1, 46300 Petaling Jaya,
Selangor, Malaysia.