

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Keep this leaflet. You may need to read it again. If you have more questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.



LIPTIN film-coated tablets 10 mg
LIPTIN film-coated tablets 20 mg
LIPTIN film-coated tablets 40 mg
Atorvastatin

What is in this leaflet

1. What **Liptin** is and what it is used for
2. What you need to know before you take **Liptin**
3. How to take **Liptin**
4. Possible side effects
5. How to store **Liptin**
6. Contents of the pack and other information

1. What **Liptin** is and what it is used for

Liptin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. **Liptin** is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and lifestyle changes on their own have failed. If you are at an increased risk of heart disease, **Liptin** 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.

2. What you need to know before you take **Liptin** Do not take **Liptin** Tablets:

- If you are hypersensitive (allergic) to atorvastatin or to any similar medicines used to lower blood lipids or to any of the other ingredients of the medicine - see Section 6 for details.
- If you have or have ever had a disease which affects the liver.
- If you have had any unexplained abnormal blood tests for liver function.
- If you are a woman able to have children and not using reliable contraception.
- If you are pregnant or trying to become pregnant.
- If you are breast-feeding.

Warning and precautions

Ask your doctor or pharmacist before you take **Liptin**. The following are reasons why **Liptin** may not be suitable for you:

- If you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- If you have kidney problems
- If you have an under-active thyroid gland (hypothyroidism)
- If you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- If you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines)
- If you regularly drink a large amount of alcohol
- If you have a history of liver disease, if you are older than 70 years

Check with your doctor or pharmacist before taking **Liptin**

- If you have severe respiratory failure (breathing problems)
- If you have diabetes or risk for developing diabetes, your doctor will monitor you carefully during this treatment. You are likely to be at risk of developing diabetes.
- If you have high levels of sugar and lipid in blood, excessive weight and high blood pressure. If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your **Liptin** treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g. rhabdomyolysis is known to increase when certain medicines are taken at the same time (see Section 2 "Other medicines and **Liptin**").

Other medicines and **Liptin**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription. There are some medicines that may change the effect of **Liptin** film-coated tablets, or their effect may be changed by **Liptin**. This type of interaction could

make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in Section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin.
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampicin, fusidic acid.
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol.
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem.
- Medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone.
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, tipranavir/ritonavir combination, etc
- Some medicines used to treat hepatitis C, eg telaprevir
- Other medicines known to interact with **Liptin** film-coated tablets include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicin (for gut treatment) and antacids (indigestion products containing aluminium or magnesium)
- Medicines obtained without a prescription: St John's Wort

Liptin with food and drink

See Section 3 for instructions on how to take **Liptin**. Please note the following:

Grapefruit juice

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of **Liptin**.

Alcohol

Avoid drinking too much alcohol while taking this medicine. See Section 2 "Warnings and precautions" for details.

Pregnancy and breast-feeding

Do not take **Liptin** if you are pregnant, or if you are trying to become pregnant. Do not take **Liptin** if you are able to become pregnant unless you use reliable contraceptive measures. Do not take **Liptin** if you are breast-feeding. The safety of **Liptin** during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Normally this medicine does not affect your ability to drive or operate machines. However, do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

Important information about some of the substances of **Liptin**

The medicine **Liptin** film-coated tablets contain lactose (a type of sugar). If your doctor tells you to have some sugary intolerance, talk to your doctor before you start taking this medicine. **Liptin** 10 mg film-coated tablets contain 55 mg lactose per dose. **Liptin** 20 mg film-coated tablets contain 110 mg lactose per dose. **Liptin** 40 mg film-coated tablets contain 220 mg lactose per dose. This should be taken into account in patients with diabetes mellitus.

3. How to take **Liptin**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also

during therapy with **Liptin** film-coated tablets. The usual starting dose of **Liptin** film-coated tablets is 10 mg once a day in adults and children aged 10 years or older. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of **Liptin** is 80 mg once daily for adults and 20 mg once daily for children. **Liptin** film-coated tablets should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

Always take **Liptin** film-coated tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The duration of treatment with **Liptin** film-coated tablets is determined by your doctor. Please ask your doctor if you think that the effect of **Liptin** film-coated tablets is too strong or too weak.

If you take more Liptin than you should:

If you accidentally take too many **Liptin** film-coated tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

If you forget to take Liptin:

If you forget to take a dose, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Liptin

If you have any further questions on the use of this medicine or wish to stop your treatment, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.

Rare (affects 1 in 1000 users) include:

- serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing.
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems.

Very rare (affect less than 1 user in 10,000) include:

- if you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.

Other possible side effects with **Liptin** film-coated tablets:

Common side effects (affects 1 to 10 users in 100) include:

- inflammation of the nasal passages, pain in the throat, nose bleed
- allergic reactions
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase
- headache
- nausea, constipation, wind, indigestion, diarrhoea
- joint pain, muscle pain and back pain
- blood test results that show your liver function can become abnormal

Uncommon side effects (affects 1 to 10 users in 1000) include:

- anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels)
- having nightmares, insomnia
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory
- blurred vision
- ringing in the ears and/or head
- vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of the pancreas leading to stomach pain)
- hepatitis (liver inflammation)
- rash, skin rash and itching, hives, hair loss
- neck pain, muscle fatigue
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised

temperature

- urine tests that are positive for white blood cells

Rare side effects (affects 1 to 10 users in 10,000) include:

- visual disturbance
- unexpected bleeding or bruising
- cholestasis (yellow of the skin and whites of the eyes)
- tendon injury

Very rare side effects (affects less than 1 user in 10,000) include:

- an allergic reaction – symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- hearing loss
- gynecomastia (breast enlargement in men and women).

Possible side effects reported with some statins (medicines of the same type):

- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

5. How to store Liptin

Do not store above 30°C. Store in the original package. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

LIPTIN 10 mg: 1 film-coated tablet contains 10 mg atorvastatin in the form of atorvastatin calcium as active substance.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, calcium carbonate, copovidone, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, polydextrose, talc, titanium dioxide, triglycerides, maltodextrin, hypromellose.

LIPTIN 20 mg: 1 film-coated tablet contains 20 mg of atorvastatin in the form of atorvastatin calcium as the active substance.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, calcium carbonate, copovidone, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, polydextrose, talc, titanium dioxide, triglycerides, maltodextrin, hypromellose.

LIPTIN 40 mg: 1 film-coated tablet contains 40 mg of atorvastatin calcium as an active substance.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, calcium carbonate, copovidone, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, polydextrose, talc, titanium dioxide, triglycerides, maltodextrin, hypromellose.

What Liptin looks like and contents of the pack

A box of 30 (3 x 10) film-coated tablets (round shape, with brake line on one side) of 10 mg atorvastatin as atorvastatin calcium, in blister packs.

A box of 30 (3 x 10) film-coated tablets (round shape) of 20 mg atorvastatin as atorvastatin calcium, in blister packs.

A box of 30 (3 x 10) film-coated tablets (round shape) of 40 mg atorvastatin as atorvastatin calcium, in blister packs.

Marketing Authorisation Holder and Manufacturer

ZADA Pharmaceuticals Ltd.
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75300 Lukavac, Bosnia and Herzegovina.

This leaflet was last revised in: 01.2016.

Data of first authorisation / renewal of the authorisation in Bosnia and Herzegovina:

LIPTIN, film-coated tablets, 30 x 10 mg:

Date: 11.01.2016. **Number:** 04-07.3-2-5193/15

LIPTIN, film-coated tablets, 30 x 20 mg:

Date: 11.03.2015. **Number:** 04-07.3-2-325/15

LIPTIN, film-coated tablets, 30 x 40 mg:

Date: 11.03.2015. **Number:** 04-07.3-2-326/15

ENUP00004 V2