

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Name, form and strength of the preparation

Lipitor® 10 mg

Lipitor® 20 mg

Lipitor® 40 mg

Lipitor® 80 mg

Film-coated tablets



Atorvastatin (as calcium) 10 mg, 20 mg, 40 mg, 80 mg

A list of inactive and allergenic ingredients in the preparation can be found in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours. **This medicine is not intended for children below 10 years of age.**

WHAT DO I HAVE TO KNOW ABOUT THE MEDICINE?

- This medicine contains lactose and therefore should not be used in patients suffering from a sensitivity to lactose and/or impaired ability to break down lactose and/or impaired ability to absorb glucose or galactose.
- Be sure to maintain a low-cholesterol diet and to perform physical activity in addition to use of this medicine.

For information on side effects, please see section 4.

1. WHAT IS THE MEDICINE INTENDED FOR?

- To reduce elevated blood lipid levels (cholesterol and triglycerides) and increase HDL.
- To prevent cardiovascular diseases (such as: myocardial infarction and/or stroke) in patients at high risk for a primary event.
- In patients with a coronary heart disease, Lipitor® reduces the risk of myocardial infarction, stroke, hospitalization due to heart failure, angina pectoris and/or need for catheterization.

Therapeutic group:

Statins – HMG-CoA reductase enzyme inhibitors.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- * you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine or to other medicines from this family.
- * you are suffering from an active liver disease or if you have persistent elevation of blood transaminase levels.
- * you are pregnant or breastfeeding, planning to become pregnant or to breastfeed.
- * you are a woman of child-bearing age and you do not use reliable contraception.
- * do not use the medicine in children below 10 years of age and in girls who have not yet started menstruating.
- * you are taking cyclosporine, telaprevir (for the treatment of hepatitis C), or combination of tipranavir and ritonavir (for the treatment of the AIDS virus).
- * you are suffering from a disease of the skeletal muscles.

❗ Do not use the medicine without consulting a doctor before commencing treatment:

- if you are suffering, or have suffered in the past, from impaired function of the liver or kidneys or from a brain hemorrhage.
- if you regularly consume large quantities of alcoholic beverages.

❗ Special warnings regarding use of the medicine

! If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

! **Before commencing treatment** with the medicine, a liver function test should be performed.

! **During treatment** with the medicine, liver function and cholesterol level tests should be performed.

! Inform the doctor that you are taking this medicine before undergoing any kind of surgery (including dental surgery).

! Statins may increase the risk of diabetes in patients who are in a risk group; these patients require blood sugar level monitoring.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

• **medicines that in combination with atorvastatin increase its blood concentration and may increase the risk of muscle pain:**

Antibiotics, such as: erythromycin, clarithromycin, fusidic acid, other cholesterol-lowering preparations (e.g., fibric acid derivatives, nicotinic acid), antifungal preparations from the azole group (e.g., itraconazole), boceprevir (for treatment of hepatitis C), colchicine (for gout), anti-HIV medicines (protease inhibitors) such as: saquinavir, ritonavir, darunavir, fosamprenavir, lopinavir and nelfinavir.

• **medicines that in combination with atorvastatin increase its blood concentration:**

diltiazem (for the heart and blood vessels), rifampin (antibiotic) (when taken simultaneously with atorvastatin), amlodipine (for treatment of high blood pressure).

• **medicines that in combination with atorvastatin lower its blood concentration:**

efavirenz (e.g., Stocrin), rifampin (antibiotic) when not administered in proximity to atorvastatin, antacids (containing magnesium or aluminum).

• **medicines whose blood concentration rises when administered in combination with atorvastatin:**

oral contraceptives containing norethindrone or ethinylestradiol, digoxin (for the heart) – you should be monitored.

• If you are taking anticoagulants (warfarin) – coagulation factors should be monitored.

• Do not eat grapefruit or drink grapefruit juice during the course of treatment with the preparation.

Do not take Lipitor® together with the following medicines:

• Cyclosporine, telaprevir (for treatment of hepatitis C) or a combination of tipranavir and ritonavir (for treatment of the AIDS virus).

❗ Use of the medicine and food

Swallow the tablet whole with a small amount of water. The medicine can be taken with or without a meal.

Maintain a low-cholesterol diet during the course of treatment with this medicine.

Do not eat grapefruit or drink grapefruit juice during the course of treatment with the preparation.

❗ Use of the medicine and alcohol

During the course of treatment with the medicine, do not drink excessive amounts of alcohol (see section 2, subsection "Do not use the medicine without consulting a doctor before commencing treatment").

❗ Pregnancy and breastfeeding

Do not use the medicine if you are pregnant or breastfeeding, planning to become pregnant or breastfeed.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions!

The dosage and treatment regimen will be determined by the doctor only.

This medicine is not intended for children below 10 years of age.

Complete the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting a doctor.

Reduction of the dosage should generally be done gradually.

Attention:

Wait at least two hours between taking this medicine and taking antacids.

Do not exceed the recommended dose!

The tablet must not be crushed/halved/chewed, since it is film-coated.

If you took an overdose or if a child has accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine at the required time, take a dose as soon as you remember, but never take a double dose! Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Lipitor® may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue use of the medicine and refer to a doctor immediately if:

you develop a severe allergic reaction which causes swelling of the face, tongue and throat and you suffer from breathing difficulties (rare).

you develop a severe skin reaction, including peeling and swelling of the skin, blisters on the skin, mouth, eyes, or genitals and fever (rare).

you develop a rash with pink-red spots on the palms of the hands and soles of the feet (rare).

you develop muscle weakness, muscle tenderness or pain, and if you simultaneously feel bad and have a high fever. This may result from muscle tissue breakdown which can be life-threatening and cause kidney problems (rare).

you suffer from sudden bleeding or bruises – this may indicate liver problems. Refer to the doctor immediately for advise (very rare).

Additional side effects:

Common side effects – inflammation of the nasal passages, sore throat, nose bleed, allergic reaction, increased blood sugar levels (if you have diabetes, continue to strictly monitor blood sugar levels), increase in blood creatine kinase, headache, nausea, constipation, flatulence, indigestion, diarrhea, joint and muscle pains, back pain, blood test results that indicate impaired liver function.

Uncommon side effects – loss of appetite, weight gain, decreased blood sugar levels (if you have diabetes, continue to strictly monitor blood sugar levels), nightmares, insomnia, dizziness, numbness or tingling in the fingers and toes, decreased sensation of pain or touch, altered sense of taste, memory loss, blurred vision, ringing in the ears/head, vomiting, hiccups, abdominal pain, pancreatitis (which may cause severe abdominal pain), liver inflammation, rash, itching, urticaria, hair loss, neck pain, muscle fatigue, fatigue, feeling unwell, weakness, chest pain, swelling of the ankles (edema), fever, white blood cells in the urine.

Rare side effects – visual disturbances, unexpected bleeding and bruising, yellowing of the skin and whites of the eyes, tendon injury.

Very rare side effects – hearing loss, enlargement of the breasts in men and women.

Side effects reported with use of other statins – sexual function difficulties, depression, shortness of breath, persistent cough, fever, diabetes.

- If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Store the medicine in a dry place, below 25°C.

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Calcium carbonate, Microcrystalline cellulose, Lactose monohydrate, Croscarmellose sodium, Polysorbate 80, Hydroxypropyl cellulose, Magnesium stearate, Opadry white, Simethicone emulsion.

The preparation contains lactose:

Lipitor® 10 mg: 27.25 mg lactose monohydrate.

Lipitor® 20 mg: 54.5 mg lactose monohydrate.

Lipitor® 40 mg: 109 mg lactose monohydrate.

Lipitor® 80 mg: 218 mg lactose monohydrate.

What does the medicine look like and what are the contents of the package:

Lipitor® 10 mg: a round, white, film-coated tablet, with "ATV" imprinted on one side and "10" on the other side.

Lipitor® 20 mg: a round, white, film-coated tablet, with "ATV" imprinted on one side and "20" on the other side.

Lipitor® 40 mg: a round, white, film-coated tablet, with "ATV" imprinted on one side and "40" on the other side.

Lipitor® 80 mg: a round, white, film-coated tablet, with "ATV" imprinted on one side and "80" on the other side.

License holder: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Manufacturer: Pfizer GmbH, Germany.

This leaflet was checked and approved by the Ministry of Health in October 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Lipitor® 10 mg: 126.04.30587.00/01

Lipitor® 20 mg: 126.05.30588.00/01

Lipitor® 40 mg: 125.43.30440.05/06

Lipitor® 80 mg: 125.44.30446.11/12