

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

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

For a list of inactive ingredients and allergens in this preparation, see section 2 "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for 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.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- To reduce blood lipid levels (cholesterol and triglycerides) and to increase HDL.
- To prevent cardiovascular diseases (such as myocardial infarction 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 THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (listed in section 6).
- you are suffering from an active liver disease or if you have persistent elevation of blood transaminase levels.
- you are pregnant, think that you are pregnant or are planning to become pregnant.
- you are breastfeeding.
- 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.

Special warnings regarding use of the medicine

Before treatment with Lipitor, tell your doctor if:

- you have muscle aches or weakness.
- you drink more than 2 glasses of alcohol daily.
- you have diabetes.
- you have thyroid problems.
- you have kidney problems.
- you have had liver problems.

Children and adolescents

This medicine is usually not intended for children below 10 years of age and for girls who have not yet started menstruating.

Tests and follow up

Before starting treatment with Lipitor, it is recommended to perform a liver function test. These tests may need to be repeated during treatment with the medicine.

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.

Before starting treatment with the medicine, try to control excess cholesterol with appropriate diet.

Drug interactions

If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Medicines that in combination with Lipitor increase its blood concentration and may increase the risk of muscle pain:

Clarithromycin (antibiotic), fusidic acid, protease inhibitors for treatment of AIDS: tipranavir, ritonavir, lopinavir, saquinavir, darunavir, fosamprenavir, nelfinavir. Protease inhibitors for treatment of hepatitis C: glecaprevir, pibrentasvir, simeprevir, elbasvir, ledipasvir plus sofosbuvir, grazoprevir, itraconazole (antifungal), cyclosporine, letermovir, gemfibrozil, cholesterol-lowering fibrates, niacin, colchicine (for gout)

- Medicines that in combination with Lipitor reduce its blood concentration:

Efavirenz, rifampin (antibiotic)

- Medicines whose blood concentration rises when administered in combination with atorvastatin:

Digoxin (for the heart), contraceptive pills containing norethindrone and ethinylestradiol

- Medicines that in combination with atorvastatin affect the activity of certain hormones in the body:

Ketoconazole, spironolactone and cimetidine

- Do not take Lipitor together with the following medicines: cyclosporine, telaprevir (for treatment of hepatitis C) or combination of the medicines tipranavir and ritonavir (for treatment of the AIDS virus).

Using this medicine and food

- The medicine can be taken with or without a meal.
- Do not drink large quantities of grapefruit juice (more than 1 liter per day) during the course of treatment with the preparation.
- Maintain a low-cholesterol diet during the course of treatment with the preparation.

Using this medicine and alcohol consumption

During the course of treatment with the medicine, do not drink more than 2 glasses of alcohol per day (see section 2, "**Before treatment with Lipitor, tell your doctor if:**")

Pregnancy, breastfeeding, and fertility

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

If you become pregnant while using the medicine, stop taking it and contact the doctor immediately.

Important information about some of this medicine's ingredients

This medicine contains lactose. If you have been told by the doctor that you are suffering from intolerance to certain sugars, consult the doctor before taking the medicine.

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by your doctor only.

Do not exceed the recommended dose.

Swallow the tablet whole with a small quantity of water. The tablet can be taken at any time of day, preferably at the same time.

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

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember. Do not take the dose if more than 12 hours have passed since you forgot the dose. Never take a double dose.

Adhere to the treatment regimen as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Lipitor may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects:

Use of Lipitor may cause the following serious side effects which usually disappear with dose reduction or treatment discontinuation:

- **Muscle problems** - Use of Lipitor can cause serious muscle problems that may lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking Lipitor in combination with other medicines (see section "Medicines that in combination with Lipitor increase its blood concentration and may increase the risk of muscle pain").
- **Liver problems – Contact your doctor immediately** if you develop symptoms of liver problems such as sensation of tiredness or weakness, loss of appetite, pain in the upper abdomen, urine color becoming darker (amber color), yellowing of your skin and the whites of your eyes.

Contact your doctor immediately if:

- You have muscle problems like weakness, tenderness, or pain that appeared without a clear reason, especially if accompanied by fever or if you feel more tired than usual. This may be a sign of a rare muscle problem.
- You have muscle problems that do not go away even after your doctor has instructed you to stop taking the medicine. Your doctor may refer you to further tests to diagnose the cause of your muscle problems.
- You develop an allergic reaction causing swelling of the face, lips, tongue and/or throat that may cause difficulties breathing or swallowing. Immediate treatment may be required.
- You suffer from nausea and vomiting.
- The color of urine becomes dark or brown.
- You feel more tired than usual.
- Your skin and whites of your eyes turn yellow.
- You suffer from abdominal pain.
- Allergic skin reaction.

Common side effects: nasopharyngitis, joint stiffness, diarrhea, pain in the extremities, urinary tract infection, indigestion, nausea, muscle and joint pain, muscle spasms, fibromyalgia (myalgia, pain in the connective tissue and muscles), insomnia and pharyngolaryngeal pain.

Additional side effects:

General effects: tiredness, fever.

Gastrointestinal effects: abdominal discomfort, flatulence, gas, hepatitis, cholestasis (a condition associated with blockade of bile flow within the liver, which can cause jaundice and damage to the liver).

Musculoskeletal effects: musculoskeletal pain, muscle weakness, neck pain, joint swelling, symptoms of lupus-like disease (including rash, joint disorders and effects on blood cells).

Changes in blood tests – increased transaminase levels, changes in liver enzyme levels, increased alkaline phosphatase level, increased creatine kinase level, increased blood sugar level (hyperglycemia).

Nervous system effects: nightmares.

Respiratory system effects: nosebleed.

Skin effects: urticaria.

Visual and auditory systems effects: blurred vision, tinnitus.
Urinary system effects: appearance of white blood cells in urine.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Calcium carbonate, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, Opadry white, hydroxypropyl cellulose, magnesium stearate, polysorbate 80, 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 the medicine looks like and contents of the pack:

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.

Registration holder and address:

Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach.

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

Lipitor 10 mg: 126-04-30587

Lipitor 20 mg: 126-05-30588

Lipitor 40 mg: 125-43-30440

Lipitor 80 mg: 125-44-30446

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