

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 have liver problems (acute liver failure or decompensated cirrhosis)
- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (listed in section 6). Stop using the medicine and get medical help right away you have signs of a serious allergic reaction including:
 - swelling of your face, lips, tongue or throat
 - difficulty breathing or swallowing
 - fainting or dizziness
 - very rapid heartbeat
 - severe skin rash or itching
 - flu-like symptoms including fever, sore throat, cough, tiredness, and joint pain

Special warnings regarding use of the medicine

Before treatment with Lipitor, tell your doctor if:

- you have unexplained 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 a stroke.
- you are pregnant or plan to become pregnant.
- you are breastfeeding or plan to breastfeed.
- you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as

statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

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.

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 for immune system (cyclosporine)
- medicines for cholesterol (gemfibrozil)
- medicines for infections (erythromycin, clarithromycin, itraconazole, ketoconazole, voriconazole, posaconazole and rifampin)
- birth control pills
- medicines for heart failure (digoxin)
- medicines for gout (colchicine)
- niacin
- fibrates
- medicines for viruses that treat HIV, AIDS, or hepatitis C (antivirals)
 - tipranavir in combination with ritonavir
 - ledipasvir in combination with sofosbuvir
 - saquinavir in combination with ritonavir
 - elbasvir in combination with grazoprevir
 - nelfinavir
 - glecaprevir in combination with pibrentasvir
 - simpravir
 - darunavir in combination with ritonavir
 - fosamprenavir in combination with ritonavir
 - letermovir
 - lopinavir in combination with ritonavir
 - fosamprenavir

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, since the medicine may harm the fetus.

Important information about some of this medicine's ingredients

This medicine contains lactose. If you have been told by your doctor that you are suffering from intolerance to certain sugars, consult your 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 serious side effects, including:

Muscle pain, tenderness and weakness (myopathy). Muscle problems, including rhabdomyolysis, may be serious in some people, and may rarely lead to kidney damage, which can lead to death.

Contact your doctor immediately if:

- You experience signs of a serious allergic reaction including:
 - swelling of your face, lips, tongue or throat
 - difficulty breathing or swallowing
 - fainting or dizziness
 - very rapid heartbeat
 - severe skin rash or itching
 - flu-like symptoms including fever, sore throat, cough, tiredness, and joint pain

- You have muscle pain, weakness and tenderness that appeared without a clear reason, especially if accompanied by fever or if you feel more tired than usual.
- 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.

Your chance of getting muscle problems is higher if you:

 - are taking certain other medicines during Lipitor treatment
 - drink large amounts of grapefruit juice
 - are 65 years of age or older
 - have thyroid problems (hypothyroidism) that are not controlled
 - have kidney problems
 - are taking high doses of Lipitor

- **Liver problems – Contact your doctor immediately** if you develop the following symptoms of liver problems:
 - sensation of tiredness or weakness
 - nausea or vomiting
 - loss of appetite

- pain in the upper abdomen
 - urine color becoming darker (amber color)
 - yellowing of the skin and the whites of the eyes.
- **The most common side effects are** nasal congestion, sore throat, runny nose, diarrhea, pain in extremities, urinary tract infection, nausea, muscle and joint pain, muscle spasms, abdominal pain, insomnia.

Additional side effects:

General effects: malaise, 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 phosphokinase 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.

Side effects reported during post-marketing follow-up (It is impossible to reliably estimate their frequency, since the effects are reported voluntarily by patients using the medicine, and the relevant population size cannot be estimated):

Gastrointestinal effects: pancreatitis

General effects: fatigue

Hepatobiliary effects: liver failure which may be life threatening

Immune system effects: anaphylaxis (severe hypersensitivity reaction to a foreign agent)

Injuries: tendon rupture

Musculoskeletal effects: myositis and rhabdomyolysis (muscle cell degradation)

Nervous system effects: dizziness, peripheral neuropathy, myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing)

There have been rare cases of cognitive impairment (e.g., memory loss, forgetfulness, memory impairment, confusion) associated with the use of statins. Cognitive impairment was generally non-serious and reversible upon statin discontinuation.

Psychiatric effects: depression

Respiratory system effects: interstitial lung disease

Dermatological effects: local edema, rash

Visual system effects: ocular myasthenia (a disease causing eye muscle weakness)

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

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:

Dexcel Pharma Technologies Ltd., 10 Hakidma St., Yokneam Illit 2069200, Israel

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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