

Patient Information Leaflet for DIVATOR 40 MG FILM-COATED TABLET

(Atorvastatin)

Please read this leaflet carefully before you start taking/using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

- 1 What DIVATOR is and what it is used for
- 2 What you need to know before you take DIVATOR
- 3 How to take DIVATOR
- 4 Possible side effects
- 5 How to store DIVATOR
- 6 Further information

1. WHAT IS DIVATOR AND WHAT IS IT USED FOR?

DIVATOR belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

DIVATOR 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 at an increased risk of heart disease, DIVATOR 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 DIVATOR

Do not take DIVATOR:

- if you are hypersensitive (allergic) to DIVATOR 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 a children and not using reliable contraception.
- if you are pregnant or trying to become pregnant.
- if you are breast-feeding.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Lipitor:

- if you have severe respiratory failure
- 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 are older than 70 years.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Lipitor 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 Lipitor”).

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Other medicines and Lipitor

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of Lipitor or their effect may be changed by Lipitor. 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. cyclosporine
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, 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, etc.
- Other medicines known to interact with DIVATOR 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) and antacids (indigestion products containing aluminium or magnesium)
- Medicines obtained without a prescription: St John's Wort

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

Taking DIVATOR with food and drink

See Section 3 for instruction on how take DIVATOR. 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 DIVATOR.

Alcohol

Avoid drinking too much alcohol while taking this medicine. See Section 2 "Take special care with DIVATOR" for details.

Pregnancy and breast-feeding

Do not take DIVATOR if you are pregnant, or if you are trying to become pregnant.

Do not take DIVATOR if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take DIVATOR if you are breast-feeding.

The safety of DIVATOR 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 a machine. 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 ingredients of DIVATOR

DIVATOR contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

DIVATOR contains sodium. If you are on a controlled sodium diet please consider sodium content.

3. HOW TO TAKE DIVATOR

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with DIVATOR.

The usual starting dose of DIVATOR 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 DIVATOR is 80 mg once daily for adults and 20 mg once daily for children.

DIVATOR 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 DIVATOR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The duration of your treatment with DIVATOR is determined by your doctor.

Please ask your doctor if you think that the effect of DIVATOR is too strong or too weak.

If you take more DIVATOR than you should

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

If you forget to take DIVATOR

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

If you stop taking DIVATOR

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, DIVATOR 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 to 10 users in 10,000:

- Serious allergic reactions 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:

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

Other possible side effects with DIVATOR:

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 you should continue careful monitoring of your blood sugar levels), increase in blood creatine kinase
- headache
- nausea, constipation, wind, indigestion, diarrhea
- joint pain, muscle pain, 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 to sensation of 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 (edema), raised temperature
- urine test 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 (yellowing 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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DIVATOR

Keep out of the reach and sight of children.

Keep in dry place, at room temperature below 25°C

This medicine does not require any special storage conditions.

Do not use DIVATOR after the expiry date which is stated on the container and outer packaging after

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

6. FURTHER INFORMATION

What DIVATOR contains

- The active substance is atorvastatin

Each film-coated tablet contains 40 mg atorvastatin (as atorvastatin calcium)

- The other ingredients are Calcium carbonate, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxy propyl cellulose, polysorbate 80, magnesium stearate, polyvinyl alcohol, titanium dioxide, PEG 3350, talc.

What DIVATOR looks like and contents of the pack

Primary package: PVC/Alu/PA-Al blisters containing 30 film-coated tablets.

Secondary package: Carton box.

Marketing Authorization Holder

Drogsan İlaçları San. ve Tic. A.Ş.,
Oğuzlar Mah. 1370. Sok. 7/3 Balgat
Ankara / TURKEY

Manufacturer:

Drogsan İlaçları San. ve Tic. A.Ş.,
Çubuk
Ankara / TURKEY

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