

## PATIENT INFORMATION LEAFLET

**Patient Information Leaflet for  
DÍVATOR 10 mg film tablet  
Oral.**

- **Drug Substance:** Atorvastatin calcium equivalent to 10 mg atorvastatin
- **Excipients:** Calcium carbonate, lactase monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxy propyl cellulose, Polysorbate 80, magnesium stearate, purified water, film coating (Polyvinyl alcohol, Titanium dioxide, PEG 3350 Pulvis, Talk).

**Before start using this medicine, first you read carefully this INSTRUCTION MANUAL, because it contains important information for you.**

- *Keep this leaflet. Later you may need to read it again.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine is prescribed for you personally, you should not give to others.*
- *During the use of this medicine if you go to doctor or hospital, say to your doctor that you use this medicine.*
- *Please abide exactly by what it is written in this instruction. Except from the dose that recommended for you about the medicine, do not use **high or low** dose.*

**In this leaflet:**

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**Titles include.**

## **1. What is DÍVATOR and what it is used for?**

Each film tablet put into use in 30 and 90 tablets blister packages containing titanium dioxide as atorvastatin calcium equivalent to 10 mg atorvastatin and coloring agent.

DÍVATOR is white film coated tablets.

DÍVATOR belongs to drug group named lipid (fat) regulators known as statins. It is used for lower the fat based substances known as cholesterol and triglyceride. Cholesterol is a naturally occurring substance necessary for normal growth process. However the blood cholesterol rises too much, it may cause narrowing the arteries by stored at blood vessel wall and in conclusion can lead to blockage. This is the most common causes of heart diseases. High cholesterol levels are accepted to raise the risk of heart disease.

DÍVATOR is used for lowering the lipids which are known as cholesterol and triglyceride in blood when singly the low fat diet or life style changes fail to succeed. Despite being normal your cholesterol levels; if you have increased risk for heart disease, DÍVATOR can be used for lowering this risk. During the treatment you must continue the standard cholesterol lowering diet.

## **2. Points to take into account before using DÍVATOR**

**DO NOT USE DÍVATOR in the following cases.**

If;

- You have the potential of child bearing or do not use the proper birth control method,
- You are pregnant, trying to get pregnant or breast feed,
- You plan to have a baby approximately 1 month ago your doctor will suggest you to cut the usage of DÍVATOR.
- You react previously against the DÍVATOR or similar drugs lowering the blood lipids or its aid ingredients,
- You have a disease affecting your liver or had an illness,
- You have abnormal results that cannot be explained in your liver function tests,
- You had excessive alcohol.

**USE CAUTIOUSLY DÍVATOR in the following cases**

If;

- You have kidney problems or history of kidney problem,
- You or your family have myopathy,
- You have previously myopathy (muscle pain, muscle weakness etc. ) during the treatment with other lipid lowering drugs (for example; statins or fibrats),
- You have high amounts of alcohol consistently,
- You have intolerance against some sugars,
- You have important dyspnoea,
- You have hypothyroidism (producing underrate thyroid hormone in body ),
- You are older than 70 years,

- You have risk factors from the point of diabetes. If you have diabetes or the risk of diabetes; while you use this drug your doctor will monitor you closely. If you have high sugar or fat in your blood, if you are overweight and have high blood pressure; you may have risk of developing diabetes.

If any of these are valid for you, your doctor will need to make blood tests before and during the treatment of DÍVATOR to predict your risks from the point of adverse effects relative to muscular system.

If you had paralysis before, say it to your doctor; your doctor will take into account this deciding the most appropriate treatment and dose for you.

If these warnings valid for you even in any period in the past, please consult to your doctor.

### **Using DÍVATOR with food and drink**

When using DÍVATOR, do not drink grapefruit juice more than one or two small cup. Because drinking excessive grapefruit juice can change the effects of DÍVATOR.

### **Pregnancy**

*Before using the drug, consult your doctor or pharmacist.*

If you are pregnant or trying to get pregnant do not use DÍVATOR.

*If you realize that you are pregnant during the treatment consult immediately to your doctor or pharmacist.*

### **Breast-Feeding**

*Before using the drug, consult your doctor or pharmacist.*

If you do breast-feed do not use DÍVATOR.

### **Vehicle and machine use**

It is not expected to have any negative effects using DÍVATOR on the ability to use vehicle and machine. If you think that this drug affects your ability to use device and machine, do not use them.

### **Important information about some aid ingredient that is in the content of DÍVATOR**

DÍVATOR consist lactose. If you had said before you had intolerance to some sugars by your doctor, contact your doctor before taking this medical product.

DÍVATOR consist sodium. If you are in controlled sodium diet take into account.

### **Using DÍVATOR with other drugs**

Some drugs can change the DÍVATOR'S effectiveness or the effectiveness of some drugs can be changed by DÍVATOR. This kind of interaction can change the effectiveness one of or both of the drugs. It can raise the adverse effects risk or seriousness and also, including muscle weakness situation which is important but rarely seen and known as rhabdomyolysis. When your doctor deciding the dose of DÍVATOR take into account this.

Some drugs that may interact with DÍVATOR

- Drugs that change the work of the immune system; for example, effective drugs against allergic diseases like cyclosporine or terfenadine, astemizole
- Effective drugs against certain infection diseases or fungus diseases; for example, erythromycin, clarithromycin, ketoconazole, itraconazole, rifampin, fucidic acid
- Other drugs that regulates lipid; for example, gemfibrozile, fenofibrat, cholestipol
- Some channel blockers using for hypertension or angina (Chest pain generated with stricture/ obstruction of vessels of coronary); for example, verapamil, diltiazem
- Defibrillator drugs; for example, digoxin, amiodarone
- Drugs used in the treatment of AIDS (HIV) like ritonavir, lopinavir, atazanavir, indinavir, darunavir, nelfinavir (protease inhibitors)
- Boceprevir used in the treatment of Hepatitis C (protease inhibitor)
- Other drugs known to interact with DĪVATOR; ezetimibe (cholesterol lowering), warfarin (lower the blood clotting), birth control pills, stiripentol (inhibitor of epileptic seizure), cimetidine (used for ulcer and epigastric burning), phenazone (pain killer), antacids (indigestion drugs consisting aluminum and magnesium) and hypericum perforatum (St. John's Wort)

*Now if you are using any drug prescriptive or unprescribed or you have used lately please give information about these to your doctor or pharmacist.*

### **3. How to use DĪVATOR?**

#### **Instructions for proper use and dose/application frequency:**

- DĪVATOR'S daily starting dose for adults, 10 years and above age's children is 10 mg.
- This dose can be increased by your doctor until it is determined that you get the amount you need. Your doctor will make the dose for you suitable by checking 4 weeks or much longer intervals. DĪVATOR'S maximum dose for adults is 80 mg and for children is 20 mg.
- Before starting the DĪVATOR treatment, cholesterol lowering diet should be entered and this diet should be continued during the DĪVATOR treatment.
- Take DĪVATOR like your doctor said. If you are not sure check with your doctor and pharmacist.

#### **Application way and method:**

- DĪVATOR tablets must be swallowed whole with water.
- Doses can be taken any time of the day with feed or separately.
- Despite this, you should try taking your dose at the same times of the day.

#### **Various age groups:**

##### **Use in Childs:**

Recommended starting dose for 10 years and above child is 10 mg, recommended maximum dose in a day is 20 mg.

##### **Use in Elders:**

No differences have been observed between the elderly patients and population in achieving the DĪVATOR'S safety, efficiency and lipid treatment purposes.

#### **Exclusive use situations**

##### **Renal failure:**

Patients with renal failure, no dosage adjustment is required.

**Liver failure:**

DĪVATOR should not be used in patients with active liver diseases. In patients who have history of liver disease should be used carefully. Before or after starting the treatment with DĪVATOR, liver function tests should be done periodically.

*If you have impression concerning the DĪVATOR'S effect is very strong or weak, talk with your doctor or pharmacist.*

**If you used DĪVATOR more than you should use:**

*If you used DĪVATOR more than you should use talk with your doctor or pharmacist.*

**If you forget to use DĪVATOR:**

If you remember that you forget to take your dose before your next dose time has arrived, take it as soon as you remember.

*To balance your forgotten doses do not take double dose.*

Effects that may occur when the treatment ended with DĪVATOR; if you have further questions about using this drug or if you want to end up your treatment, consult to your doctor or pharmacist.

**4. What are the possible adverse effects?**

Like other drugs, patients who are sensitive to the substance that is in the DĪVATOR'S content may be adverse effects.

**If any of the followings happens, stop using DĪVATOR and IMMEDIATELY report to your doctor or refer to your nearest hospital emergency department:**

- Angioneurotic oedema (Tubercle in face, tongue and trachea that can be obstruct breathing). This serious adverse effect is seen very rare. If any of these existing in you, report it to your doctor immediately.
- In skin, mouth, eyes, around the sexual organ; desquamation, swelling, bubbling and serious illness characterized by fever.
- Skin rash characterized by pink-red blots that may blister on sole and palms.
- Rarely, muscle weakness or inflammation has been seen at patients and very rarely it can be turn into serious, life threatening situation (rhabdomyolysis). In the event of being exhaustion and muscle weakness with fever, sensitiveness or pain, stop using DĪVATOR and report to your doctor immediately.

If your muscle problem continues after your doctor suggested that you do not use DĪVATOR, report to your doctor immediately. In this situation your doctor can make further tests to find out the reasons of your muscle problems.

**Very rare situations** effects less than 1 in 10.000 patients (And this means that it does not be expected these adverse effects to be seen 9.999 in 10.000 patients that use DĪVATOR).

- If you have unexpected or extraordinary bleeding or bruise, this can be liver complaint. Your doctor should make blood tests to control your liver if you have liver

problem symptoms when you take Divator or before taking Divator. If you have symptoms listed below that show liver problem, report to your doctor in the earliest time:

- Exhaustion or weakness feeling
- Loss of appetite
- Epigastralgia
- Urine with dark amber color
- Yellowing the white are of your eyes or skin
- Stevens-Johnson syndrome (serious blister at skin, mouth, eye and sexual organ), erythema multiforme (skin eruption with spotted and red), visual defect, blurred vision, loss of hearing, tendon injuries, liver failure, change in taste, gynaecomastia.

All of these are serious adverse effects.

If you have any of them, emergency medical intervention or hospitalization may require.

These serious adverse effects are seen very rare.

### **Other possible side effects:**

**Common situations** effect 100 patient's 1 to 10 that use DĪVATOR.

- Inflammation at nose pathways, sore throat, nose bleeding
- Allergic reactions
- Raise in blood glucose level (if you have diabetes, continue to follow up your blood glucose levels), raise in blood creatine kinase
- Headache
- Nausea, intestinal obstruction, gas, indigestion, diarrhea
- Arthralgias, muscle pain and back pain
- Blood test results pointing that your liver functions are abnormal

**Uncommon situations** effect 1000 patient's 1 to 10 that use DĪVATOR.

- Loss of appetite, weight gain, decline in blood glucose level (if you have diabetes, continue to follow up your blood glucose levels)
- Have a nightmare, insomnia
- Drowsiness, felting or tingling at hand and foot fingers, decrease in sensibility against pain or touch, change in taste, memory loss
- Blurred vision
- Clanging in ears and/or head
- Throwing up, belching, lower and upper stomach pain, pancreatitis (pancreas inflammation that cause stomach ache)
- Hepatitis (liver inflammation)
- Skin rash and scratching, urtikaria, alopecia
- Neck pain, muscle weakness
- Exhaustion, not feeling good, weakness, chest pain, swelling (oedema) especially in ankle, increased temperature
- Detection of white blood corpuscle at urinary test

**Rare situations** effect 10.000 patient's 1 to 10 that use DĪVATOR.

- Eye disorder
- Unexpected bleeding or bruising
- Yellowness (yellowing the skin and sclera)

- Tendon impairment

**Very rare situations** effect 100.000 patient's 1 to 10 that use DİVATOR.

- One allergic reaction-symptoms; sudden wheezing and chest pain or tightness, swelling at eyelids, face, lips, mouth, tongue and throat, difficulty in breathing, collapse
- Hearing loss
- Gynaecomastia (gynaecomastion at woman and man)

Other side effects that reported with statins (with the same types of drugs with DİVATOR):

- Insomnia and sleep disorders containing have a nightmare, memory loss, confusion
- Sex difficulties
- Depression
- Continuous cough and/or difficulty in breathing or respiratory problems containing fever
- Diabetes. If you have high sugar or levels in your blood, if you are overweight and have high blood pressure; seeing diabetes is more likely. Your doctor will monitor you when you use this drug.

*If you come up with any side effect that does not mentioned in this leaflet, please inform your doctor or pharmacist.*

## **5. Preserving the DİVATOR**

*Preserve DİVATOR in its package and where the children cannot be see or reach.*

Store at room temperature below 25°C.

**Use compatibly with its expiry date.**

*Do not use DİVATOR after the expiry date mentioned on the package.*

If you notice deformities at product and/or its package, do not use DİVATOR.

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Balgat – ANKARA

**The place of Production:** Drogan İlaçları San. Ve Tic. A.Ş. Çubuk – ANKARA

This leaflet has been approved under the date of 06/08/2013.