PACKAGE LEAFLET:
Information for the patient

ATENOLOL

Film-coated tablets – 100 mg
(Atenolol)

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

In this leaflet:

1. WHAT ATENOLOL IS AND WHAT IT IS USED FOR
Atenolol, a selective beta-blocker agent, blocks cardiac beta 1 receptors which affect mainly the cardiovascular system (decrease heart rythm, decrease cardiac contraction and decrease blood pressure); in patients with angina pectoris, it lowers myocardial oxygen requirements, decreases angina crisis frequency, lowers nitrate requirements, and increases the physical work tolerance. Atenolol decreases the systolic and diastolic arterial pressure.
Atenolol is indicated in arterial hypertension (essential or renal, alone or combined with other drugs); angina pectoris caused by coronary arteriosclerosis; ventricular arrythmia; arrythmia or supraventricular tachycardia; acute myocardial infarction.
Your doctor may have given you Atenolol for another purpose. Ask your doctor if you want to know why you were given Atenolol.

2. BEFORE YOU TAKE ATENOLOL
Do not take Atenolol if you:
- are allergic to atenolol or beta-blockers in general;
- are allergic to any of the other ingredients mentioned in the end of this leaflet;
- have second and third degree A - V block;
- have sinusal bradycardia;
- have decompensated congestive heart failure;
- have cardiogenic shock;
- have Prinzmetal's angina;
- have sick sinus syndrome;
- have hypotension;
- have asthma or history of obstructive respiratory diseases;
- have phaeochromocytoma (apart from specific use with alpha-blockers);
- have metabolic acidosis;
- have severe peripheral arterial disease;
- have acute myocardial infarction associated with hypotension (< 100 mm Hg);
- have Raynaud's disease.

Immediate withdrawal of treatment with atenolol in cardiac patients is contraindicated.
If you think that you suffer from one of the above mentioned conditions, do not take the tablets, first talk to your doctor and follow his advices.

Take special care with Atenolol
Tell your doctor if you:
- are allergic to other drugs, especially if they are in the same group with Atenolol;
- are pregnant or are planning to get pregnant during the time you are taking Atenolol;
- are breastfeeding or planning to breastfeed;
- suffer from angina pectoris (Atenolol should not be discontinued abruptly during treatment of angina pectoris; the abrupt discontinuation may cause severe rythm disorders, myocardial infarction and sudden death);
- suffer from coronary failure (it is advisable, as for all other beta-blocking agents, to gradually reduce the dose);
- suffer from bronchial asthma and other lung diseases (bronchitis, emphysema); cardioselective beta-blockers as Atenolol can be given with extreme caution when there is no alternative of treatment because of the risk of acute bronchospasms occurrence, especially when high doses are used;
- have conductivity disorders (first degree A-V block), because it has suppressing effect in cardiac conductivity;
- suffer from portal hypertension (risk of deterioration in liver function);
- suffer from hyperthyroidism or thyrotoxicosis, because Atenolol may mask hyperthyroidism signs and symptoms in patients suspected for thyrotoxicosis;
- suffer from diabetes because Atenolol may mask the symptoms of hypoglycemia and for this reason it should be used with caution;
- suffer from psoriasis, depression or myasthenia gravis;
- suffer from renal or hepatic diseases; the initial dose should be reduced;
- are elderly;
- have any allergy because atenolol can increase sensitivity to allergens causing a severe reaction, and may reduce the response to adrenaline;
- are having a surgery and are taking Atenolol. Beta-blockers should be withdrawn 24 to 48 hours before surgery. It is of the greatest importance that the anaesthetist is aware that beta-blockers are being taken.

Patients on long-term treatment with a beta-blocker should have their medication stopped gradually over a period of 1 to 2 weeks.

Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Concomitant use of atenolol with calcium-channel blockers may increase the risk of AV block and bradycardia when atenolol given with diltiazem; severe hypotension and heart failure when atenolol given with nifedipine; asystole, severe hypotension and heart failure when atenolol given with verapamil. It is necessary that at least 48 hours have passed from the discontinuing of verapamil or diltiazem when starting treatment with atenolol and vice versa.
Sympathomimetics can cause a mutual antagonization and consequently reduce their effect. The hypotensive effect is also antagonised by corticosteroids and estrogens.
Concomitant use of atenolol and clonidine may result in bradycardia and severe cardiac deprimation. If the two drugs are co-administered, atenolol should be withdrawn several days before gradually discontinuing clonidine. If replacing clonidine by atenolol therapy, the administration of atenolol should be delayed for several days after clonidine administration has stopped.
Some non-steroidal antiinflammatory drugs may decrease the antihypertensive effect of atenolol.
Prazosin may increase the risk of orthostatic hypotension.
Ampicillin may decrease the antihypertensive and antianginal effect of atenolol.
Concomitant use of atenolol with insulin can make more difficult the control of diabetes.
Amiodarone may cause bradycardia, AV block and myocardial depression when it is co-administered with beta-blockers.
Caution is required also by the concomitant use of anti-arrhythmics of the first class.
ACE inhibitors, alcohol, alpha-blockers, general anesthetics, angiotensin II receptor antagonists, MAO inhibitors, phenothiazines, anxiolytics and hypnotics, diuretics and nitrates, may enhance the hypotensive effect of atenolol.
Cardiac glycosides increase the risk of AV block and bradycardia if they are administered simultaneously with atenolol.
Concomitant use of atenolol with moxisylyte may cause severe postural hypotension.
Fingolimod may increase the risk of bradycardia when co-administered with atenolol.
These medicines may be affected by Atenolol or may affect the way it acts. For this reason, during their concomitant use, the increase or decrease of atenolol dose is required. Your doctor or pharmacist will advice you.

Taking Atenolol with food and drinks
Alcohol may interact with Atenolol by increasing the hypotensive effect, therefore it should not be consumed during the time of treatment.

Pregnancy
Tell your doctor or pharmacist if you are pregnant, or planning to get pregnant.
The use of Atenolol during pregnancy should be avoided.
The doctor or pharmacist will discuss on the risks and benefits of taking this drug during pregnancy.

Breastfeeding
Tell your doctor or pharmacist if you are breastfeeding.
Atenolol is distributed into breast milk, and it is present in equal or higher concentrations than those in maternal plasma. The use of Atenolol during breastfeeding should be avoided, as it may lead to bradycardia and other side effects in the newborn baby.
The doctor or pharmacist will discuss on the risks and benefits of taking this drug if you are breastfeeding or planning to do so.

Driving and using machines
Be careful while driving or using machines until you see how Atenolol affects you because it may cause visual blurring and may affect the ability to drive or use machines.

3. HOW TO TAKE ATENOLOL
Always take Atenolol only as your doctor has told you. If you feel that the effects of Atenolol are too strong or too weak, talk to your doctor or pharmacist.
You should take the tablets at the same time every day.
Atenolol tablets should be swallowed whole with a glass of water.

Atenolol dosage is as follows:
in arterial hypertension: 50 - 100 mg daily, although 50 mg is generally adequate. The full effect is usually evident within 1 to 2 weeks.
in prophylaxis of angina crisis: 50 - 100 mg daily, given as a single dose or in divided doses.
in cardiac arrhythmias: 50 - 100 mg daily.
in myocardial infarction: treatment should be started within 12 hours of the onset of chest pain. It should be started with intravenous atenolol injection followed by an oral dose of 50 mg - 100 mg daily.

Renal impairment
Reduced doses may be required in patients with impaired renal function.

Ask your doctor for advice if you are not sure how to use the drug.

If you take more Atenolol than you should
If you take more Atenolol than you should, or if the children take it accidentally, please contact your doctor, the hospital, or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to take Atenolol
If you forget to take one dose, take the next dose in its usual time.
Do not take a double dose to make up a forgotten dose.

If you stop taking Atenolol
Patients on long-term treatment with a beta-blocker should have their medication stopped gradually over a period of 1 to 2 weeks. Abrupt withdrawal of beta-blockers may exacerbate angina and may lead to sudden death.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
All medicines can cause side effects. Sometimes they are serious, sometimes not.
Do not panic by this list of possible side effects. You may not get any of them.
Tell your doctor if any of the following side effects concerns you:
- cardiovascular system (bradycardia, severe hypotension, second or third degree A-V block, heart failure, peripheral vasoconstriction, cold extremities, faint; abrupt withdrawal of beta-blockers may exacerbate angina and may lead to sudden death);
- respiratory system (bronchospasms, dyspnea);
- central nervous system (insomnia, confusion and sleep disorders including nightmares, headache, tiredness, dizziness, depression, hallucinations, lethargy, somnolence, slurred speech; more rare effects are paresthesia, peripheral neuropathy);
- digestive system (nausea, vomiting, diarrhea, constipation, abdominal cramps);
- urogenital system (impotence, difficulty urinating or frequent urination);
- hematopoietic system (agranulocytosis, purpura, thrombocytopenia);
- blurred vision, dry eyes;
- noise in the ears;
- skin rash, pruritus, exacerbation of psoriasis, exanthema, alopecia;
- weight change, facial oedema, muscular weakness;
- hyperglycemia, hypoglycemia, hyperlipidemia;
- antinuclear antibodies.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ATENOLOL
Keep out of the sight and reach of children!
Do not use Atenolol after the expiry date which is stated on the package.
Store below 25°C!
Keep in the original package to protect it from light and humidity.

6. FURTHER INFORMATION
What Atenolol – Film-coated tablets 100 mg contain
The active substance is atenolol.
Each film-coated tablet contains 100 mg atenolol.
The other ingredients are: magnesium carbonate, microcrystalline cellulose, starch, sodium laurylsulphate, magnesium stearate, sodium starch glycolate, talc, povidon (K-30), Opadry II orange.

Contents of the pack
Box with 30 film-coated tablets.

Explanatory of the illustration icons on the packaging:

Ask your doctor or pharmacist.

Content.

Warning.

Tablet shape.

Marketing Authorisation Holder and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in June 2012.

SPECIFICATION

CROPING AREA 15 X 25 cm

PAY ATENTION, all the layers are visible. If you have to print this document please check or uncheck the specific layers.