PACKAGE LEAFLET:
Information for the patient

DILTIAZEM

Tablets - 60 mg

(Diltiazem hydrochloride)

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT DILTIAZEM IS AND WHAT IT IS USED FOR

Diltiazem tablets contain 60 mg of Diltiazem hydrochloride. Diltiazem is a benzothiazepine calcium – channel blocker. It exerts its effect due to its vasodilator effect in the peripheral and coronary arteries, and limited negative inotropic properties (weakens the contraction of heart muscle). Diltiazem tablets are used in the treatment of angina pectoris and hypertension.

2. BEFORE YOU TAKE DILTIAZEM

Do not take Diltiazem:
- if you are hypersensitive (allergic) to diltiazem hydrochloride or to any of the other ingredients of Diltiazem tablets;
- if you have severe bradycardia (less than 50 beats per minute);
- if you have left ventricular failure with pulmonary stasis;
- if you are pregnant, planning to become pregnant, or are breastfeeding;
- if you suffer from "sick sinus" syndrome, second and third degree AV block in patients without a functioning pacemaker;
- if you are using dantrolene infusion (which is a muscle relaxant with a direct effect on skeletal muscle);
- if you suffer from porphyria.

Take special care with Diltiazem

Ask your doctor before taking Diltiazem:
- if you suffer from congestive heart failure;
- if you suffer from cardiac conduction problems;
- if you suffer from hypotension; decrease in blood pressure associated with diltiazem therapy may occasionally result in symptomatic hypotension;
- if you suffer from acute hepatic injury;
- if you suffer from impaired kidney function.

Taking other medicines

Other concomitant drug treatment may affect or be affected by Diltiazem. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Remember to tell your doctor about the treatment with Diltiazem if you are prescribed another drug during treatment.
It is especially important that your doctor be aware if you are already being treated with:
- beta - blockers (e.g. propranolol);
- cimetidine (medicine to treat stomach ulcers, heartburn and acid reflux);
- digitalics (medicines used in the treatment of heart conditions);
- anesthetics (drugs used in anaesthesia);
- benzodiazepines (e.g. midazolam, triazolam);
- cyclosporin (medicine to suppress the immune system, to prevent ejective reactions after organ transplantation, also used for e.g., certain rheumatic or dermatological problems);
- carbamazepine, phenytoin (anticonvulsant drugs used primarily in the treatment of epilepsy);
- lovastatin, simvastatin (drugs to lower blood cholesterol level);
- rifampin (antibiotic);
- lithium (used to treat mania that is part of bipolar disorder, manic-depressive illness);
- amiodarone, dronedarone (antiarrhythmic drugs);
- erythromycin, clarithromycin, telithromycin (antibiotics);
- alpha-blockers;
- atazanavir, ritonavir (antiretrovirals);
- colchicine (used to prevent or treat gout attacks);
- ivabradine (used for symptomatic management of angina pectoris);
- sirolimus, tacrolimus (immunosuppressive drugs);
- theophylline (used in breathing problems);
- avanafil (for erectile dysfunction).

Taking Diltiazem with food or drinks

Avoid drinking alcohol while taking diltiazem.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.
There are no well-controlled studies in pregnant women, therefore, diltiazem should be avoided in pregnancy.

Breast-feeding

Diltiazem is excreted in human milk. If use of diltiazem is deemed essential, an alternative method of infant feeding should be instituted.

Driving and using machines

It should be taken into account that occasionally asthenia, fatigue and dizziness may occur. If you experience these effects, you should not drive or operate machinery.

Important information about some of the ingredients of Diltiazem

Diltiazem tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE DILTIAZEM

Take this medication exactly as it was prescribed for you. Do not take the medication in higher doses, or take it for longer than recommended by your doctor. Take Diltiazem tablet with a full glass of water, do not crush, chew or break, swallow the pill whole. Do not stop taking this medication without first talking to your doctor. If you stop taking diltiazem suddenly, your condition may become worse. If you are being treated for high blood pressure, keep using this medication even if you feel fine. High blood pressure often has no symptoms.

The usual doses are prescribed below:
Adults: the usual dose **in angina pectoris** is one tablet (60 mg) three times daily. However, patient responses may vary and dosage requirements can differ significantly between individual patients. If necessary, the divided dose may be increased to 360 mg/day.
In **hypertension** the initial dose is 60 to 120 mg twice daily, increased as required to a maximum of 360 mg daily.

Elderly and patients with impaired hepatic or renal function: the recommended starting dose is one tablet (60 mg) twice daily. The heart rate should be measured regularly in these groups of patients and the dose should not be increased if the heart rate falls below 50 beats per minute.
Children: not recommended for use in children.

If you take more Diltiazem than you should

If you take more Diltiazem than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the actions to be taken.
Symptoms of overdose may include: dizziness, low blood pressure, very slow heartbeat including complete heart block and asystole.

If you forget to take Diltiazem

If you forget a dose (or more doses), take the next dose when it is the normal time to take it.
Do not take a double (or higher) dose to make up for the forgotten dose(s).

If you stop taking Diltiazem

Do not stop taking diltiazem suddenly, because your condition may become worse.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

In therapeutic dosage, diltiazem usually is well tolerated. Serious adverse reactions requiring discontinuance of diltiazem therapy or dosage adjustment are rare; however, gastrointestinal tract disturbances, skin eruptions, and bradycardia may result in discontinuance of the drug in about 1% of patients.

Cardiovascular effects

Adverse cardiovascular effects of diltiazem include: hypotension or postural hypotension (hypotension occurs secondarily to the vasodilating action of diltiazem on vascular smooth muscles), angina, arrhythmia, worsening of congestive heart failure, syncope, hot flushes, vasculitis, sino-atrial and atrioventricular block, palpitations. Swelling and/or edema (in particular oedema of the lower limbs) have been reported in patients receiving this drug orally.

Gastrointestinal effects

Nausea, anorexia, vomiting, diarrhea, abdominal pain, dyspepsia, dysgeusia, GI hemorrhage, gastric ulcers, constipation, dry mouth, thirst, weight gain and gingival hyperplasia.

Nervous system effects

Adverse nervous system effects of diltiazem include: headache, somnolence, dizziness and asthenia. Extrapyramidal reactions have been reported rarely in patients receiving diltiazem.

Hepatic effects

Mild to marked elevations in liver function test results (e.g., LDH, creatine kinase, creatine phosphokinase, alkaline phosphatase, bilirubin) and hepatocellular injury have been reported rarely in patients receiving oral diltiazem, usually early in therapy (e.g., 1-8 weeks after initiation); although a causal relationship to the drug is uncertain in most cases, it is likely in some cases.
Adverse hepatic effects of oral diltiazem have been reversible following discontinuance of the drug.

Local and dermatological effects

Rash has been reported in about 1% of patients receiving diltiazem. Photosensitivity reactions, urticaria, skin hypertrophy and pruritus have been reported in less than 1% of patients.
Simple erythema or occasionally desquamative erythema (with or without fever), erythema multiforme, exfoliative dermatitis and acute generalised exanthematous pustular dermatitis have also been reported.

Other side effects

Other side effects of diltiazem include: dyspnea, malaise, gynaecomastia, rhinitis, cough increase, nasal congestion, neck pain, back pain, ocular irritation, blurred vision, hemolytic anemia, increased bleeding time.

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

5. HOW TO STORE DILTIAZEM

Keep out of the reach and sight of children.
Do not use Diltiazem after the expiry date which is stated on the package.
Do not store above 25°C.
Store in the original package in order to protect from light and humidity.

6. FURTHER INFORMATION

What Diltiazem tablets contain:

The active substance is Diltiazem hydrochloride.
Each tablet contains 60 mg of diltiazem hydrochloride.
The other ingredients are: lactose, PEG 6000, hydrogenated vegetable oil, hydroxypropylmethylcellulose, magnesium stearate.

Contents of the pack

Box with 30 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 April 2016.

SPECIFICATION

CROPING AREA 12 x 19 cm

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