PACKAGE LEAFLET:
Information for the user

DILAPRO

TABLETS - 12.5 mg, 25 mg (Carvedilol)

Read all of this leaflet carefully before you start using 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 DILAPRO IS AND WHAT IT IS USED FOR?

Dilapro contains carvedilol as active substance, which causes unselective blockade of beta-1 and beta-2 receptors and selective blockade of alpha-1 receptors in heart and vascular system.
Dilapro is used in:
- the treatment of essential high blood pressure
- the treatment of chronic stable angina pectoris
- supplementary treatment in chronic stable heart failure.

2. BEFORE YOU TAKE DILAPRO

Do not take Dilapro in:
- hypersensitivity (allergy) to carvedilol or to any of the other ingredients of Dilapro;
- cardiogenic shock;
- decompensated heart failure;
- acute pulmonary embolism;
- prinzmetal's angina;
- severe hypotension (systolic blood pressure < 90 mm Hg);
- very low pulse (patients which are treated with Dilapro in heart failure, should have at least a pulse of 65 beats / minute);
- disturbances in the conduction system of the heart: AV-block of type II and III, sick sinus syndrome, sinoatrial block (pacemaker therapy is excluded);
- cardiac failure because of pulmonary airway diseases (cor pulmonale);
- asthma and chronic obstructive pulmonary disease;
- untreated phaeochromocytoma;
- clinically severe manifest of liver dysfunction;
- metabolic acidosis;
- case of taking at the same time monoaminooxidase inhibitors (MAOIs) (except MAOIs-B);
- concomitant intravenous treatment with verapamil, diltiazem or other antiarrythmic drugs;
- breastfeeding.

Take special care with Dilapro
Ask your doctor before taking Dilapro:
- if you have heart failure accompanied by:
- low blood pressure;
- compromised blood and oxygen supply to the heart (ischaemic heart disease) and narrowing of the arteries (atherosclerosis);
- and/or kidney problems (your renal function should be monitored then. It may be necessary to reduce your dose);
- if you have diabetes. Treatment with Dilapro may mask the signs of low blood sugar. Your blood sugar should therefore be monitored regularly;
- if you have severe breathing problems for which you are not receiving medication. Dilapro may worsen these breathing difficulties;
- if you use contact lenses. Carvedilol may reduce tear production;
- if you have Raynaud's phenomenon (fingers or toes turn first bluish, then whitish and then reddish together with pain). Dilapro may worsen the symptoms;
- if you have overfunction of thyroid gland, with elevated production of thyroid hormone. Dilapro may mask the symptoms;
- if you are using Dilapro and are to undergo an operation involving an anaesthetic. You should discuss this with the doctor responsible for the anaesthesia well in advance;
- if you have a very low pulse (less than 55 beats per minute);
- if you have had a serious allergic reaction (e.g. to an insect bite or food) or if you are undergoing or are due to undergo allergic desensitisation therapy because Dilapro may weaken the efficacy of medicines used to treat such allergic reactions;
- if you have psoriasis;
- in children and adolescents (below 18 years of age) due to insufficient data on the efficacy and harm that it may cause; it is not recommended to use carvedilol in these patients;
- in elderly, because they may be sensitive to carvedilol and should be monitored carefully. As with other beta-blockers, carvedilol must not be discontinued suddenly, but gradually, especially in patients with coronary circulatory disorders.

Effects of misuse as doping agent
Use of Dilapro may cause positive doping results.
Health consequences may not be predicted. Health hazard may not be excluded.

Taking other medicines:
Other concomitant drug treatment may affect or be affected by Dilapro. 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 Dilapro if you are prescribed another drug during the treatment.
It is especially important that your doctor be aware if you are already being treated with:
- digoxin (to treat heart failure);
- rifampicin (antibiotic used in treating tuberculosis);
- cimetidine (medicine to treat stomach ulcers, heartburn and acid reflux);
- ketoconazole (medicine to treat mycosis);
- fluoxetine (medicine to treat depression);
- haloperidol (medicine to treat particular mental/psychic disorders);
- erythromycin (antibiotic);
- cyclosporin (medicine to suppress the immune system, to prevent ejective reactions after organ transplantation also used for e.g., certain rheumatic or dermatological problems);
- clonidine (medicine to reduce blood pressure or to treat migraine);
- verapamil, diltiazem, amiodarone (medicines to treat irregular heartbeat);
- quinidine, disopyramide, mexiletin, propafenone, flecainide (drugs to treat irregular heartbeat);
- other blood pressure reducing drugs. Carvedilol can enhance the effects of other blood pressure reducing drugs given concurrently (e.g. alpha1-receptor antagonists) and drugs where reduction in blood pressure transpires as a side effect, e.g. barbiturates (in the treatment of epilepsy), phenothiazines (to treat psychoses), tricyclic antidepressants (in the treatment of depression) vasodilating drugs (drugs for widening the blood vessels) and alcohol;
- insulin or oral anti-diabetic medicines (blood sugar reducing agents) as their blood sugar reducing effect can be increased and the symptoms of low blood sugar covered up;
- inhaled anaesthetics (drugs used in anaesthesia);
- sympathomimetics (drugs which increase the function of the sympathetic nervous system);
- dihydropyridines (medicines to treat high blood pressure and heart diseases);
- nitrates (medicine to treat heart diseases);
- neuromuscular blocking preparations (drugs which reduce muscle tension);
- ergotamine (migraine medicine);
- certain painkilling tablets (NSAID), oestrogens (hormones) and corticosteroids (adrenal hormone), as these can in some instances reduce the blood pressure reducing effect of carvedilol;
- drugs containing reserpine, guanethidine, methyldopa, guanfacine and monoaminooxidase inhibitors (MAOIs), medicines to treat depression, as these may give rise to further reduction in the heart rate.

Taking Dilapro with food and drinks
Carvedilol may enhance the effects of alcohol.

Pregnancy
Ask your doctor or pharmacist for advice before taking this medicine.
There is a risk of harm to the unborn child. Carvedilol may only be used during pregnancy if your doctor deems it necessary. Always, therefore, consult your doctor before using Dilapro during pregnancy.

Breastfeeding
Carvedilol passes over in human breastmilk and should therefore not be used during breastfeeding.

Driving and using machines
Treatment with this drug requires regular medical examinations.
Dizziness and tiredness may occur at the beginning of treatment or when the treatment is changed or during interaction with alcohol. If you feel dizzy or weak when taking the tablets, you should avoid driving or work involving high attention.

3. HOW TO TAKE DILAPRO

Always take Dilapro exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Dilapro are too strong or too weak, talk to your doctor or pharmacist.
You should swallow the tablets with at least half glass of water.
It is recommended to take Dilapro with food, to allow the absorption of the active substance to be slower and the risk of orthostatic hypotension to be reduced.
Treatment duration is determined by the doctor. Usually, carvedilol treatment lasts and must not be discontinued suddenly.
Carvedilol must be withdrawn gradually (1-2 weeks).

Administration only in adults:
If not otherwise prescribed by the doctor, the usual dose is:

Chronic stable heart failure	**Daily dose**
Initial dose	In the first 14 days: 3.125 mg carvedilol in the morning and 3.125 mg carvedilol in the evening.
Maintenance dose	If this dose is tolerated, it is increased in intervals of at least 2 weeks in: 6.25 mg carvedilol in the morning and 6.25 mg carvedilol in the evening, then 12.5 mg carvedilol in the morning and 12.5 mg carvedilol in the evening, then 25 mg carvedilol in the morning and 25 mg carvedilol in the evening. The maximum tolerated dose will be taken by the patient.
Maximum dose in special cases	25 mg carvedilol in the morning and 25 mg carvedilol in the evening.

High blood pressure	**Daily dose**
Initial dose	In the first 2 days 12.5 mg carvedilol in the morning.
Maintenance dose	25 mg carvedilol once daily in the morning.
Maximum dose in special cases	At least after 14 days: 25 mg carvedilol in the morning and 25 mg carvedilol in the evening.

Note! A unique dose of 25 mg or a daily dose of 50 mg should not be exceeded.

Chronic Stable Angina Pectoris	**Daily dose**
Initial dose	In the first 2 days 12.5 mg carvedilol in the morning and 12.5 mg carvedilol in the evening.
Maintenance dose	25 mg carvedilol in the morning and 25 mg carvedilol in the evening.
Maximum dose in special cases	After at least 14 days: 50 mg carvedilol in the morning and 50 mg carvedilol in the evening.

Administration in the elderly
In essential hypertension

Initial dose	In the first two days: 12.5 mg carvedilol in the morning.
Maintenance dose	If the effect is not sufficient, the dose can be increased further at intervals of at least 14 days from: 12,5 mg carvedilol in the morning and 12,5 mg carvedilol in the evening, up to 25 mg carvedilol in the morning and 25 mg carvedilol in the evening.
Maximum dose	25 mg carvedilol in the morning and 25 mg carvedilol in the evening.

At the beginning of treatment, 12.5 mg carvedilol daily is recommended also for elderly. In some patients, this dose can assure sufficient decrease of blood pressure also in the long-term treatment.

In chronic stable angina pectoris

Maximum dose	In the long-term treatment 25 mg carvedilol in the morning and 25 mg carvedilol in the evening.

In the elderly, the daily dose of 2 x 25 mg carvedilol in divided doses, should not be exceeded.

If you have taken more Dilapro than you should:
If you have taken more Dilapro than you should, or if the children have been taking the 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 can include: feelings of faintness due to excessively low blood pressure, slow heart rate and in serious instances occasional missed heartbeats. Also breathing difficulties, constricted airways, malaise, lowered level of consciousness and seizures may occur.

If you forget to take Dilapro:
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 a higher) dose to make up for a forgotten dose(s).

If you stop the treatment with Dilapro:
The dose of this drug should not be changed without medical advice. Also, the treatment should not be stopped without medical advice. The treatment with Dilapro should not be discontinued suddenly, but should be reduced gradually.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, carvedilol can cause side effects, although not everybody gets them.
The frequency of possible side effects is shown in the table below:

Very common	Occur in more than 1 in 10 users
Common	Occur in less than 1 in 10, but more than 1 in 100 users
Uncommon	Occur in less than 1 in 100 users but more than 1 in 1.000 users
Rare	Occur in less than 1 in 1.000, but more than 1 in 10.000 users
Very rare	Occur in less than 1 in 10.000 users, including isolated cases

The majority of side effects are dose-related and disappear when the dose is reduced or the treatment discontinued. Some side effects can occur at the beginning of treatment and resolve spontaneously as the treatment continues.

Side effects in patients with chronic stable heart failure:
Very common:
Elevated blood glucose in diabetics, fluid overload, generalised oedema (swelling of more than one part of the body) and genital oedema, visual disturbances, slow heart rate, dizziness (e.g. when standing up quickly), malaise, diarrhoea and vomiting.

Common:
Lowered blood platelet count (thrombocytopenia) and dizziness.

Uncommon:
Constipation.

Rare:
Fainting, disturbances in the heart's conduction system, worsening of heart failure at the beginning of treatment and worsening of renal function.
Acute renal insufficiency and disturbances in renal function in patients with hardening of the arteries and/or impaired renal function have occurred in rare instances.

Side effects in patients with raised blood pressure (essential hypertension) or chest pain (chronic stable angina pectoris):
Very common:
Dizziness (e.g. when standing up suddenly), tiredness, headache, slow heart rate in particular at the beginning of treatment.
Dry eyes and pain in the arms and legs.

Common:
Elevated cholesterol levels, malaise, stomach pains and diarrhoea.

Rare:
Altered blood count (leucopoenia and thrombocytopenia), oedema (swelling of more than one part of the body), sleep disturbances, depression, abnormal sensation, cold hands and feet, blocked nose, constipation, vomiting, worsening of renal function and fainting.

Very rare
Visual disturbances, eye irritation, mouth dryness, difficulty in passing urine and impotence.

In very rare instances, disturbances in the heart's conduction system and worsening of symptoms in patients with glaucoma or Raynaud's disease (fingers or toes turn first bluish, then whitish, and then reddish together with pain) may also occur.
Certain skin reactions (e.g. allergic dermatitis, itching and skin inflammation may occur).
Psoriatic skin problems may occur or pre-existing psoriasis may worsen.
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 DILAPRO

Keep out of the reach and sight of children.
Do not use Dilapro 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 Dilapro - Tablets 12.5 mg contain
The active substance is carvedilol.
Each tablet contains 12.5 mg of carvedilol.
The other ingredients are: microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica.

What Dilapro - Tablets 25 mg contain
The active substance is carvedilol.
Each tablet contains 25 mg of carvedilol.
The other ingredients are: microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica.

Contents of the pack
Dilapro 12.5 mg: Box with 30 tablets.
Dilapro 25 mg: Box with 30 tablets.

Explanatory of the illustration icons on the packaging:

Ask your doctor or pharmacist.

Should not be used during pregnancy.

Use in persons aged 18 and over.

Contents.

Warning.

Tablet shape.

Marketing authorisation holder (MAH)

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel./Fax: 00355 4 23 62 800
Tirana - Albania

This leaflet was last revised in November 2013.

SPECIFICATION

CROPING AREA 16 X 42.4 cm

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