

## Package leaflet: information for the patient

### Dilatrend 6.25 mg tablets (*Carvedilol*)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Dilatrend is and what it is used for
2. What you need to know before you take Dilatrend
3. How to take Dilatrend
4. Possible side effects
5. How to store Dilatrend
6. Contents of the pack and other information

#### **1. What Dilatrend is and what it is used for**

The name of this medicine is Dilatrend. Dilatrend contains the active substance carvedilol, which belongs to a group of medicines called alfa and beta-blockers that work by relaxing and widening the blood vessels. It is used to treat angina (chest pain) and mild, moderate or severe heart failure. Dilatrend is also used to treat high blood pressure (hypertension).

#### **2. What you need to know before you take Dilatrend**

##### **Do not take Dilatrend:**

- if you are allergic to carvedilol or any of the other ingredients of this medicine (listed in section 6);
- if you have been told you have very severe heart failure and you have fluid retention (swelling) which is being treated with injections of medicines into your veins (intravenously);
- if you have liver disease;
- if you have impaired conduction of the heart (or heart block);
- if you have been told that you have a very slow heartbeat (heartbeat < 50 beats/min);
- if you have very low blood pressure (< 85 mm Hg);
- if you have a history of wheezing due to asthma or other lung diseases;

If any of these apply to you, please talk to your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **Warnings and precautions**

If any of the following conditions apply to you, do not take this medicines before talk to your doctor:

- if you have a very slow heartbeat (bradycardia);
- if you have been told you have a condition called Prinzmetal's angina;
- if you have a lung disease called Chronic Obstructive Pulmonary Disease (COPD);
- if you suffer from any other heart prob;
- if you have or have ever had any problems with your liver, kidneys or thyroid; - if you have diabetes;
- if you have phaeochromocytoma (a tumour of the adrenal gland causing high blood pressure);

- if you have a skin condition known as psoriasis;
- if you have poor circulation affecting hands, feet or lower legs, or Raynaud's phenomenon;
- if you have or have ever had a serious allergic reaction or you are undergoing allergic desensitisation therapy for any type of severe allergy;
- if you wear contact lenses because;
- if you are pregnant. Consult a doctor immediately if you become pregnant during treatment with this medicine. - if you are breast-feeding.

### **Other medicines and Dilatrend**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Take particular care and tell your doctor or pharmacist, if you are taking any of the following medicines:

- if you are taking any other medicines to treat heart or high blood pressure, including diuretics (water tablets), calcium antagonists (e.g. diltiazem or verapamil), amiodarone or digoxin;
- if you are taking fluoxetine or paroxetine (used to treat depression);
- if you are taking rifampicin (in tuberculosis);
- if you are taking cimetidine (used to treat stomach ulcers);
- if you are taking catecholamine-depleting medicines (e.g. reserpine and monoamine oxidase inhibitors (MAOIs) used to treat depression);
- if you are taking non-dihydropyridine calcium channel blockers, amiodarone or other antiarrhythmic drugs (for arrhythmia) ;
- if you are taking clonidine (medicines used to reduce blood pressure or to treat migraine);
- medicines to reduce blood sugar such as oral antidiabetic medicines or insulin;
- ciclosporin or tacrolimus (medicines used to prevent your body rejecting organs after transplant operations);
- non-steroidal antiinflammatory medicines (NSAIDs);
- beta-agonist bronchodilators (used to treat chest tightness and wheezing in asthma or other breast conditions).

### **Operations**

If you need to have an anaesthetic for an operation, tell your hospital doctor you are taking Dilatrend. This is necessary because some anesthetics can lower your blood pressure and it can become too low.

### **Dilatrend with food, drinks and alcohol**

Co-administration of Dilatrend with grapefruit or grapefruit juice should be avoided until discontinuation of Dilatrend. Grapefruit and grapefruit juice can lead to increased blood levels of the active substance carvedilol and unpredictable side effects.

Excessive and regular alcohol intake during treatment with Dilatrend should be avoided as alcohol affects the effect of carvedilol.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant or breast-feeding, do not take this medicine until you have talked to your doctor. Consult your doctor immediately if you become pregnant while taking this medicine.

### **Driving and using machines**

You may experience dizziness or tiredness whilst taking Dilatrend. This is more likely to occur when you first begin treatment, or when the dose is increased. If this occurs, you should not drive or operate machinery. You should avoid drinking alcohol, as it may make these symptoms worse. If you are concerned or want more information, you should talk to your doctor.

### **Dilatrend contains lactose and sucrose (types of sugar)**

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

### 3. How to take Dilatrend

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablet with a small amount of liquid (eg a glass of water). The tablet should not be chewed. Do not take the tablet with grapefruit juice. If possible, take your daily dose at the same time each day.

#### **Chronic heart failure**

For the treatment of heart failure, it is recommended that your treatment with Dilatrend is started and carefully monitored by a hospital specialist.

- It is recommended to take Dilatrend together with food at the same time. You should take your tablets even if you have no appetite. Unless otherwise prescribed, it should usually be taken in the morning or morning and evening.
- The starting dose is 3.125 mg twice a day for two weeks.
- Your doctor will then gradually increase the dose over several weeks until it reaches 25 mg twice a day.
- If you weigh more than 85 kg, your doctor may increase your dose to 50 mg twice a day.
- If you have stopped taking Dilatrend for more than two weeks, you should consult your doctor to explain how to resume treatment (see section “If you stop taking Dilatrend”).

Sometimes, your heart failure may worsen while taking Dilatrend, particularly at the start of your treatment. This may result in increased symptoms (e.g. tiredness, shortness of breath) and signs of fluid retention (e.g. weight gain and swelling of the legs).

If your symptoms or condition worsen whilst taking Dilatrend you should tell your doctor, as he or she may need to change the dose of your other medications or of Dilatrend.

Tell the hospital that you are being treated with Dilatrend if you need to have anesthesia for surgery.

While taking Dilatrend, make sure that you continue with your other treatments for heart failure as advised by your doctor.

#### **High blood pressure (hypertension)**

- The usual starting dose is 12.5 mg once a day for the first two days.
- After this, the dose is increased to 25 mg once a day.
- If necessary, your doctor may increase your dose slowly, over several weeks, up to a maximum of 50 mg once a day or in divided doses.
- If you are an elderly patient, the recommended starting dose is 12.5 mg daily. If necessary, the dose may be increased to a maximum of 50 mg once daily or in divided doses.

#### **Angina**

- The usual starting dose is 12.5 mg twice a day for the first two days.
- After this, the dose is increased to 25 mg twice a day.
- If necessary, your doctor may increase the daily dose after 2 weeks of treatment at the earliest. The maximum daily dose is 50 mg twice a day.
- If you are an elderly patient, your doctor will determine which is the best starting dose for you. The recommended maximum daily dose for elderly patients is 50 mg in divided doses.

#### **Patients with liver problems**

Dilatrend is contraindicated in patients with impaired hepatic function.

#### **Patients with kidney problems**

No dose adjustment is expected, in patients with moderate to severe renal impairment.

#### **Use in children and adolescents**

Dilatrend is not suitable for children under 18 years of age.

**If you take more Dilatrend than you should**

If you accidentally take too many tablets, contact your doctor immediately or go to the nearest hospital casualty department. In case of overdose, severe hypotension, bradycardia, heart failure, cardiogenic shock, sinus arrest and cardiac arrest can be expected. There may also be respiratory problems, bronchospasm, vomiting, impaired consciousness and generalized seizures.

**If you forget to take Dilatrend**

If you forget to take a dose, do not worry. Take another as soon as you remember, provided it is not nearly time for your next dose. Take your next tablet at the normal time, but do not take a double dose to make up for a forgotten tablet.

**Discontinuation of treatment****If you stop taking Dilatrend**

Do not suddenly stop taking Dilatrend before you have spoken to your doctor about it. You may have side effects if you suddenly stop the tablets. Your doctor will tell you how to reduce the dosage gradually and then stop this medicine.

If you are also taking a medicine called clonidine, never stop either treatment unless told to by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Dilatrend can cause side effects, although not everybody gets them.

The frequency of possible side effects is shown in the table below:

Common (occur in less than 1 in 10);

Very common (occur in more than 1 in 10 users);

Uncommon (occur in less than 1 in 100 users);

Rare (occur in less than 1 in 1 000);

Very rare (occur in less than 1 in 10 000 users).

Table 1 below summarizes the adverse reactions reported with respect to the use of carvedilol in important clinical trials:

**Table 1 Adverse reactions from clinical trials**

<b>System-organ class</b>	<b>Adverse reaction</b>	<b>Frequency</b>
Blood and the lymphatic system disorders	Anaemia	Common
	Lowered blood platelet count (thrombocytopenia), which increases the risk of bleeding or bruising.	Rare
	Leukopenia - a condition in which the number of white blood cells (leukocytes) in the blood decreases, which increases the likelihood of infection.	Very rare
Cardiac disorders	Manifestation of heart disease, which can cause fatigue, shortness of breath, swelling of ankles and others. (heart failure)	Very common
	Sometimes there is a strong slow heartbeat (bradycardia)	Common
	Increase in the total volume of blood in the body, in particular in the blood plasma (hypervolemia)	Common

	Increase in total blood volume (Plethora)	Common
	Atrioventricular block	Uncommon
	Angina (including chest pain) - Angina pectoris	Uncommon
Eye disorders	Visual disturbance	Common
	Reduced lacrimation	Common
	Eye irritation	Common
Gastrointestinal disorders	Nausea	Common
	Diarrhoea	Common
	Vomiting	Common
	Indigestion	Common
	Abdominal pain	Common
	Constipation	Uncommon
	Mouth dryness	Rare
<b>System-organ class</b>	<b>Adverse reaction</b>	<b>Frequency</b>
General disorders and administration site conditions	Tiredness	Very common
	Oedema	Common
	Pain	Common
Hepato-biliary disorders	Increased alanine aminotransferase (ALT), aspartate aminotransferase (AST) and gamma-glutamyltransferase (GGT), indicating changes in liver function.	Very rare
Immune system disorders	Hypersensitivity (Allergic reactions)	Very rare
Infections and parasitosis	Pneumonia	Common
	Bronchitis	Common
	Upper respiratory tract infection	Common
	Infections of the urinary tract	Common
Metabolism and nutrition disorders	Increase in weight	Common
	Elevated cholesterol levels (Hypercholesterolemia)	Common
	Impaired blood sugar control (increased hyperglycaemia, decreased -hypoglycaemia of blood glucose (sugar)) in patients with pre-existing diabetes	Common
Musculoskeletal, connective tissue and bone disorders	Pains (e.g. in the arms and legs)	Common
Nervous system disorders	Dizziness	Very common
	Headache	Very common
	In some cases, dizziness or lightheadedness without loss of consciousness (presyncope), short-term loss of consciousness (syncope) may occur.)	Common
	Numbness and tingling sensation on the skin (Paresthesia)	Uncommon
Psychiatric disorders	Depression, depressed mood	Common
	Sleep disturbance	Uncommon
Renal and urinary disorders	Renal failure and abnormal renal function in patients with diffuse vascular disease and/or concomitant renal failure	Common
	Difficulty in passing urine	Rare
Reproductive system and breast disorders	Cases of sexual impotence (erectile dysfunction) have been reported in men	Uncommon
Respiratory, thoracic and mediastinal	Difficulty breathing	Common

disorders	Fluid accumulation in the lungs	Common
	Asthma in predisposed patients	Common
	Stuffy nose	Rare
Skin and subcutaneous tissue disorders	Certain skin reactions (e.g. allergic dermatitis, hives, itching and skin inflammation, increased sweating, psoriatic or lichen planus like skin lesions)	Uncommon
Vascular disorders	Hypotension	Very common
	Dizziness when standing up quickly	Common
	Peripheral circulatory disorders (cold limbs, peripheral vascular disease, exacerbation of intermittent claudication and Raynaud's phenomenon)	Common
	Hypertension	Common

*Description of selected adverse reactions* The frequency of side effects does not depend on the dose, except for dizziness, impaired vision and slow heart rate (bradycardia). Dizziness, short-term loss of consciousness (syncope), headache and fatigue (asthenia) are usually mild and are more likely to occur at the beginning of treatment.

In patients with congestive heart failure, worsening of heart failure and fluid retention may occur during an increase in carvedilol dose.

Cases of heart failure have been reported in patients treated with carvedilol.

Reversible deterioration in renal function has been observed during treatment with carvedilol in patients with chronic heart failure with low blood pressure, ischemic heart disease and diffuse vascular disease and / or impaired renal function..

### **Post marketing side effects**

The following adverse reactions were identified during post-marketing use of carvedilol. Because these events have been reported by an indeterminate population, it is not always possible to reliably estimate their frequency and / or to establish a causal relationship with the effect of the drug.

#### *Heart disorders*

Sinus arrest in predisposed patients (eg elderly patients or patients with pre-existing bradycardia, sinus node dysfunction or atrioventricular block).

#### *Metabolism and nutrition disorders*

Dilatrend can also cause symptoms of diabetes in people with a very mild form of diabetes called 'latent diabetes'; in the presence of pre-existing diabetes, his condition may worsen, so if such signs occur, tell your doctor immediately.

#### *Mental disorders*

Hallucinations

#### *Skin and subcutaneous tissue disorders*

- Hair loss;
- Severe skin side effects (toxic epidermal necrolysis (severe skin blistering), Stevens-Johnson syndrome (severe blistering of the skin, mouth, eyes and genitals).
- Hyperhidrosis.

#### *Renal and urinary disorders*

Isolated cases of urinary incontinence have been reported in women that resolve upon discontinuation of treatment.

If you notice any of these symptoms or others that are bothering you, tell your doctor.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes all possible side effects not listed in this leaflet. You can also report side effects directly via:

Bulgarian Drug Agency  
8 Damyan Gruev Str,  
1303 Sofia, Bulgaria Tel .: +359 2 8903417  
website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Dilatrend**

- Keep this medicine out of the sight and reach of children.
- Keep the blisters in the outer carton in order to protect from light and moisture.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not use this medicine if the tablets show signs of poor quality, but seek the advice of a pharmacist who will tell you what to do.
- If your doctor decides to stop treatment, return the remaining tablets to your pharmacist. Keep them only if your doctor tells you to.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information What Dilatrend contains**

- The active substance is carvedilol. Each tablet contains 6.25 mg carvedilol.
- The other ingredients are: lactose monohydrate, sucrose, povidone K25, crospovidone type A, silica colloidal anhydrous, magnesium stearate and yellow iron oxide (E172).

### **What Dilatrend looks like and contents of the pack**

Dilatrend 6.25 mg tablets are round, yellow, with a dividing line on both sides, with the inscription VM on one side and F1 on the other side.

Dilatrend 6.25 mg tablets is available in Al/Al blisters containing 28 tablets.

### **Marketing Authorisation Holder and Manufacturer:**

Tchaikapharma High Quality Medicines Inc.  
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria  
tel.: 02 / 962 54 54  
fax: 02/ 960 37 03  
e-mail: info@tchaikapharma.com

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