

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S3

**DILATREND®** 6,25 mg tablets

**DILATREND®** 12,5 mg tablets

**DILATREND®** tablets

Carvedilol

Contains sugar (lactose and sucrose) – See section 2.

### **Read all of this leaflet carefully before you start taking DILATREND**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- DILATREND has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **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**

DILATREND contains the active substance carvedilol. It belongs to a group of medicines called 'beta-blockers'.

DILATREND is used to treat the following:

- High blood pressure (hypertension).
- Congestive heart failure.
- Heart failure following a recent heart attack.

DILATREND works by making your blood vessels relax and widen.

This helps to lower your blood pressure.

Your doctor may give you other medicines as well as DILATREND to help treat your condition.

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

### **Do not take DILATREND:**

- If you are hypersensitive (allergic) to carvedilol or any of the other ingredients of DILATREND (listed in section 6).
- If you have ever had wheezing due to asthma or other lung diseases.
- If you have severe fluid retention (swelling of your ankles and feet).
- If you have problems with your liver.
- If you have problems with your heart (for example "heart block", slow or uneven heartbeat).
- If you have low blood pressure.
- If you have a problem with acid levels in your blood (metabolic acidosis).
- If you have a growth on one of your adrenal glands (phaeochromocytoma).

Do not take DILATREND if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking DILATREND.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking DILATREND:

- If you have problems with your lungs.
- If you have problems with your kidneys.
- If you have diabetes (high blood sugar).
- If you wear contact lenses.
- If you have problems with your blood vessels (peripheral vascular disease) or with the blood circulation in your fingers and toes (Raynaud's phenomenon).
- If you have ever had problems with your thyroid.
- If you have ever had a serious allergic reaction (for example, sudden swelling causing difficulty breathing or swallowing, swelling of the hands, feet and ankles or a severe rash).
- If you have had an allergy and are having treatment to desensitise you.
- If you have a skin disorder called psoriasis, after taking beta-blocker medicines.
- If you have a heart condition called "Prinzmetal's vasospastic or variant angina".
- If you have a tumour that develops in one of your adrenal glands (phaeochromocytoma).

#### *Children and adolescents*

DILATREND is not suitable for children under the age of 18 years.

#### **Other medicines and DILATREND**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking or have recently taken other medicines. This is because DILATREND can affect the way some medicines work. Also some medicines can affect the way DILATREND works.

Tell your doctor or pharmacist if you are taking any of the following:

- Other medicines for your heart or your blood pressure, including water tablets (diuretics), calcium channel blockers (e.g. diltiazem or verapamil), digoxin, and amiodarone.

- Catecholamine-depleting agents (e.g. reserpine and monoamine oxidase inhibitors (MAOIs)).
- Fluoxetine and paroxetine (used to treat depression).
- Medicines for diabetes, such as insulin or metformin.
- Rifampicin (used to treat infections).
- Guanethidine or bethanidine.
- Phenothiazines (e.g. chlorpromazine).
- Ciclosporin and tacrolimus (used after an organ transplant).
- Medicines used when your heart does not beat smoothly (e.g. disopyramide, quinidine, procainamide, lignocaine, phenytoin).
- Clonidine (used to treat high blood pressure, migraine and flushing in the menopause).
- Isoprenaline (used to treat asthma).
- Cimetidine (used to treat indigestion, heartburn and stomach ulcers).
- Non-steroidal anti-inflammatory drugs (NSAIDs, including aspirin).
- Beta-agonist bronchodilators (used to treat chest tightness and wheezing due to asthma or other chest conditions (e.g. salbutamol and terbutaline sulphate)).

### **DILATREND with food, drink and alcohol**

Swallow the tablets with a glass of water.

You should take your tablets at the same time as eating some food.

Do not drink alcohol while taking DILATREND. It could cause your blood pressure to fall too low and increases the risk of you getting side effects.

Do not take DILATREND with grapefruit juice as it may increase the effects of DILATREND.

### **Operations**

If you are going to have an operation, tell your doctor that you are taking DILATREND. This is because some anaesthetics can lower your blood pressure, and it may become too low.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking DILATREND.

There is no adequate clinical experience with DILATREND in pregnant women. DILATREND should not be used in pregnant women, as foetal harm may occur.

DILATREND and/or its metabolites are excreted in breast milk. Breastfeeding is therefore not recommended while taking DILATREND.

### **Driving and using machines**

You may feel dizzy while taking DILATREND. This is more likely when you start treatment, or if your treatment has changed, and when you drink alcohol. If this happens to you, do not drive or use any tools or machines. Talk to your doctor if you notice any other problems that might affect driving, using tools or machines while you are taking DILATREND.

It is not always possible to predict to what extent DILATREND may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DILATREND affects them.

### **DILATREND contains lactose and sucrose**

DILATREND contain lactose and sucrose, which are types of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking DILATREND.

DILATREND 6,25 mg tablet contains 51,8 mg lactose and 21,25 mg sucrose per dose. Each DILATREND 12,5 mg tablet contains 59,1 mg lactose and 12,5 mg sucrose per dose. Each DILATREND 25 mg tablet contains 10 mg lactose and 25 mg sucrose per dose This should be taken into account in patients with diabetes mellitus.

### **3. How to take DILATREND**

Do not share medicines prescribed for you with any other person.

Always take DILATREND exactly as your doctor has told you. You should check with your doctor if you are not sure. Treatment with DILATREND is long-term therapy and should not be stopped abruptly, but reduced gradually at weekly intervals

#### ***High blood pressure:***

The usual starting dose is 12,5 mg once a day for two days. After two days the dose is usually 25 mg once a day. If necessary, your doctor may gradually increase the dose further at intervals of two weeks or more to a maximum of 50 mg a day in two doses. If you are elderly, you may not need any more than 12,5 mg a day.

#### ***Congestive heart failure:***

*Adults and elderly:* The usual starting dose is 3,125 mg (half a 6,25 mg tablet), twice a day for two weeks. Your doctor will then increase the dose slowly, over several weeks, up to 25 mg twice a day. If you weigh more than 85 kg the dose may be increased to 50 mg twice a day. When used for heart failure, treatment with DILATREND should be started by a specialist doctor. If you have stopped taking DILATREND for more than two weeks you should talk to your doctor. He will need you to go back to the starting dose again.

#### ***Congestive heart failure following a recent heart attack:***

When used for heart failure following a recent heart attack, treatment with DILATREND should be started by a specialist doctor. The usual starting dose is 6,25 mg. If you tolerated the first dose, your doctor will then increase the dose to 6,25 mg twice a day and maintain for it 3 to 10 days. Your doctor may then increase your dose to 12,5 mg twice a day and then to a maximum of 25 mg twice a day. Your doctor will decide which dose is best for you and monitor you carefully each time the dose is increased or changed.

If you have the impression that the effect of DILATREND is too strong or too weak, talk to your doctor or pharmacist.

### **Patients with liver problems**

Patients with liver problems must not take DILATREND.

### **Patients with diabetes**

DILATREND may increase insulin resistance and mask hypoglycaemic symptoms and decrease the body's response to hypoglycaemia.

### **Children and adolescents**

DILATREND is not suitable for children and adolescents under the age of 18 years.

### **If you take more DILATREND than you should**

If you take more DILATREND than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen if you have taken more tablets than you should: a slow or pauses in your heartbeat, feeling dizzy or light-headed, becoming breathless, wheezy or extremely tired.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### **If you forget to take DILATREND**

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking DILATREND**

Do not stop taking DILATREND without talking to your doctor. Your doctor may want you to stop taking DILATREND slowly over one to two weeks.

#### **4. Possible side effects**

DILATREND can have side effects.

The possible side effects and how likely you are to get them will depend on the reason you are being treated with DILATREND.

Not all side effects reported for DILATREND are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking DILATREND, consult your doctor, pharmacist or other healthcare professional for advice.

**If you get any of the following serious side effects contact your doctor immediately or seek urgent medical advice / go to the hospital emergency department:**

- Severe allergic reactions: signs may include sudden swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.
- Chest pains accompanied by shortness of breath, sweating and feeling sick.
- Sinus arrest - signs include your heartbeat becoming very slow or stopping. You may also feel dizzy, unusually tired and short of breath. This may occur especially in people over 65 years old or with other heartbeat problems.
- Passing water (urinating) less often with swelling of legs, indicating problems with your kidneys.
- Very low blood sugar (hypoglycaemia) which might cause seizures or unconsciousness.
- Skin reactions - Infrequently, severe skin conditions (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) can occur. Redness, often associated with blisters may appear on the skin or mucous membranes, such as the inside of the mouth, the genital areas or the eyelids. These can appear initially as circular patches often with central blisters, which may progress to widespread peeling of the skin and can be life threatening. These serious skin reactions are often preceded by headache, fever and body aches (flu-like symptoms).

These are all very serious side effects. If you have them, you may have had a serious reaction to DILATREND. You may need urgent medical attention or hospitalisation.

Very common (may affect more than 1 in 10 people):

- Feeling dizzy.
- Headache.
- Feeling weak and tired.
- Problems with your heart. The signs include chest pains, tiredness, shortness of breath and swelling of your arms and legs.
- Low blood pressure. The signs include feeling dizzy or light-headed.

Feeling dizzy, having a headache and feeling weak and tired are usually mild and more likely to happen at the beginning of your treatment.

Common (may affect up to 1 in 10 people):

- Infections of the airway (bronchitis), lung (pneumonia), nose and throat (upper respiratory tract). The signs include wheezing, shortness of breath, chest tightness and sore throat.
- Infections of the urinary tract which can cause problems in passing water.
- Low numbers of red blood cells (anaemia). The signs include feeling tired, pale skin, a fluttering sensation in your heart (palpitations) and being short of breath.
- Increase in weight.
- Increase in cholesterol levels (shown by a blood test).
- Loss of control of blood sugar in people with diabetes.
- Feeling depressed.
- Problems with your sight, sore or dry eyes due to fewer tears being made.
- A slow heartbeat, or pauses in your heartbeat (especially in elderly patients or patients with pre-existing heart-rhythm problems).
- Feeling dizzy or light-headed after standing up.

- Fluid retention. The signs include: overall swelling of your body, swelling of parts of your body for example your hands, feet, ankles and legs and an increase in how much blood you have in your body.
- Problems with blood circulation in your arms and legs. The signs include cold hands and feet, whiteness, tingling and pain in your fingers and a pain in your leg which gets worse when you walk.
- Breathing problems.
- Feeling sick or being sick.
- Diarrhoea.
- Stomach pain/indigestion.
- Pain, possibly in your hands and feet.
- Problems with your kidneys, including changes to how often you pass urine.

Uncommon (may affect up to 1 in 100 people):

- Disturbed sleep.
- Tingling or numbness of your hands or feet.
- Problems with your skin, including skin rashes which may cover a lot of your body, a lumpy rash (hives), feeling itchy and dry skin patches
- Hair loss (alopecia).
- Being unable to get an erection (erectile dysfunction).
- Constipation.

Rare (may affect up to 1 in 1,000 people):

- Low numbers of platelets in your blood. The signs include bruising easily and nose bleeds.
- A stuffy nose, wheezing and flu-like symptoms.
- A dry mouth.

Very rare (may affect up to 1 in 10,000 people):

- Low numbers of all types of white blood cells. The signs include infections of the mouth, gums, throat and lungs.
- Allergic (hypersensitivity) reactions. The signs may include difficulty breathing or swallowing caused by sudden swelling of the throat, or face or swelling of your hands, feet and ankles.
- Kidney problems which show up in a blood test.
- Some women may have difficulty with bladder control when they pass water (urinary incontinence).
- Severe skin conditions (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) can occur. Redness, often associated with blisters may appear on the skin or mucous membranes, such as the inside of the mouth, the genital areas or the eyelids. These can appear initially as circular patches often with central blisters, which may progress to widespread peeling of the skin and can be life threatening. These serious skin reactions are often preceded by headache, fever and body aches (flu-like symptoms).

Not known (frequency cannot be estimated from the available data):

- DILATREND can also cause development of the signs of diabetes in people who have a very mild form of diabetes called 'latent diabetes'.
- There have been some reports of hallucinations in patients taking DILATREND.
- You may sweat excessively (hyperhidrosis).

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

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DILATREND.

## **5. How to store DILATREND**

Store your tablets at or below 30 °C in the original packaging to protect them from light.

Store all medicines out of reach of children.

Do not use this medicine after the expiry date shown on the label.

If your doctor decides to stop the treatment, return any leftover tablets to the pharmacist. Only keep them if your doctor tells you to.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What DILATREND contains**

The active substance is carvedilol.

Each DILATREND 6,25 mg tablet contains 6,25 mg carvedilol. The other ingredients are lactose monohydrate (51,8 mg), sucrose (21,25 mg), povidone, crospovidone, colloidal anhydrous silica, magnesium stearate, yellow iron oxide (E172).

Each DILATREND 12,5 mg tablet contains 12,5 mg carvedilol. The other ingredients are lactose monohydrate (59,8 mg), sucrose (12,5 mg), povidone, crospovidone, colloidal anhydrous silica, magnesium stearate, yellow iron oxide (E172), red iron oxide (E172).

Each DILATREND tablet contains 25 mg carvedilol. The other ingredients are lactose monohydrate (10 mg), sucrose (25 mg), povidone, colloidal anhydrous silica, crospovidone, magnesium stearate.

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

DILATREND 6,25 mg is a yellow, round tablet with a bilateral score line and coded BM on one side and F1 on the other side available in blister packs.

DILATREND 12,5 mg is a light brown, round tablet with a bilateral score line and coded BM on one side and H3 on the other side available in blister packs.

DILATREND is an off-white to yellowish pale-beige, round biconvex tablet, with a bilateral score line and coded BM on one side and D5 on the other side available in blister packs.

Pack sizes of 10, 30 and 100 tablets.

Not all pack sizes are marketed.

### **Holder of Certificate of Registration**

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent

South Tower, 1st Floor

Sandton 2196

South Africa

Ethical assistance Line: +27 (0)11 784 0077

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