

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DILATREND® 6,25 mg tablet

DILATREND® 12,5 mg tablet

DILATREND® tablet

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 or your pharmacist.
- 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 DILATREND CONTAINS

Each DILATREND 6,25 mg tablet contains 6,25 mg carvedilol.

Inactive ingredients: Lactose, sucrose, povidone, crospovidone, colloidal anhydrous silica, magnesium stearate, yellow iron oxide (E172).

Each DILATREND 12,5 mg tablet contains 12,5 mg carvedilol.

Inactive ingredients: Lactose, sucrose, povidone, crospovidone, colloidal anhydrous silica, magnesium stearate, yellow iron oxide (E172), red iron oxide (E172).

Each DILATREND tablet contains 25 mg carvedilol.

Inactive ingredients: Sucrose, lactose, povidone, colloidal anhydrous silica, crospovidone, magnesium stearate.

Contains: lactose and sucrose.

WHAT DILATREND IS USED FOR

DILATREND works by making your blood vessels relax and widen.

DILATREND is used to treat the following:

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

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

BEFORE YOU TAKE DILATREND

Do not take DILATREND if:

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

DILATREND is not suitable for children.

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

Take special care with DILATREND

Check with your doctor or pharmacist before taking DILATREND if:

- You have diabetes (high blood sugar).
- You have ever had problems with your thyroid.
- You have problems with your kidneys.
- 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).
- You wear contact lenses.
- 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 are going to have an operation tell your doctor that you are taking DILATREND, as some anaesthetics can lower your blood pressure.
- You have had an allergy and are having treatment to desensitise you.
- You have a skin disorder called psoriasis, after taking beta-blocker medicines.
- You have a type of angina called “Prinzmetal’s variant angina”.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take DILATREND.

Pregnancy and Breastfeeding

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.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking DILATREND.

Driving and using machinery

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.

Important information about some of the ingredients of DILATREND

DILATREND contains 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.

Taking other medicines with 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 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.

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

- 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 (used after an organ transplant)
- Medicines for 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)).
- *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.

HOW TO TAKE DILATREND

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.

Swallow the tablets with a glass of water.

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 you are elderly, you may not need any more than 12,5 mg a day.

Heart failure:

- When used for heart failure, treatment with DILATREND should be started by a specialist doctor.
- You should take your tablets at the same time as eating some food.
- 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.
- 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.

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 - 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.

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 heart-beat, 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 center.

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.

Effects when treatment with DILATREND is stopped

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

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.

Contact your doctor immediately if you get any of the following side effects:

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.

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).

Frequent side effects

- Feeling dizzy.
- Headache.
- Feeling weak and tired.
- Problems with your heart. The signs include heart attack, heart failure - symptoms include shortness of breath, frequent coughing, especially when lying down, swollen feet, ankles, and legs, abdominal swelling and pain, fatigue, dizziness or fainting, 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.

- 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 heart-beat.
- 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 shortness of breath.
- Problems with blood flow to 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.
- Disturbed sleep.
- Fainting.
- 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.
- Increased sweating
- Hair loss.
- Being unable to get an erection (erectile dysfunction).
- Constipation.

Less frequent side effects

- 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.

- 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.

Other side effects that can happen while you are on DILATREND therapy:

- Some women may have difficulty with bladder control when they pass water (urinary incontinence).
- Hair loss (alopecia)
- Loss of control of blood sugar in people with diabetes, including aggravation of diabetic symptoms and a mild form of diabetes in which there are no overt symptoms but there are abnormal responses to some test procedures.

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

STORING AND DISPOSING OF 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).

PRESENTATION

DILATREND 6,25 mg: available in blisters containing 10, 30 or 100 tablets.

DILATREND 12,5 mg: available in blisters containing 30 or 100 tablets.

DILATREND (25 mg): available in blisters containing 30 or 100 tablets.

IDENTIFICATION

DILATREND 6,25 mg: Yellow, round tablet with a bilateral score line and coded BM on one side and F1 on the other side.

DILATREND 12,5 mg: Light brown, round tablet with a bilateral score line and coded BM on one side and H3 on the other side.

DILATREND Tablet: 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.

REGISTRATION NUMBERS

DILATREND 6,25 mg: 31/7.1.3/0198

DILATREND 12,5 mg: 31/7.1.3/0199

DILATREND tablet: X/7.1.3/246

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

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