

DILATREND®

Carvedilol (6.25mg, 25mg)

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1. What Dilatrend is used for

Dilatrend contains a medicine called carvedilol. This belongs to a group of medicines called 'beta-blockers'.

Dilatrend is used to treat the following:

- Chronic heart failure.
- High blood pressure (hypertension).
- Angina (chest pain or discomfort that happens when your heart isn't getting enough oxygen).

2. How Dilatrend works

Dilatrend works by making your blood vessels relax and widen.

- This helps to lower your blood pressure.
- If you have chronic heart failure, this makes it easier for your heart to pump blood around your body.
- If you have angina, this will help stop the chest pain.

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

3. Before you take Dilatrend

- When you must not use it

- You are allergic (hypersensitive) to carvedilol or any of the other ingredients of Dilatrend (listed in Section 8: Product Description).
- You have ever had wheezing due to asthma or other lung diseases.
- You have severe fluid retention (swelling of your hands, ankles and feet) which is being treated by medicines given into one of your veins (intravenously).
- You have problems with your liver.
- You have problems with your heart (for example 'heart block' or slow heart beat). Dilatrend is not suitable for some people with certain types of heart problem.
- You have very low blood pressure.
- You have a problem with the acid levels in your blood ('metabolic acidosis').
- You have a growth on one of your adrenal glands ('phaeochromocytoma').

If you are not sure, talk to your doctor or pharmacist before taking Dilatrend.

- Before you start to use it

Check with your doctor or pharmacist before taking Dilatrend if:

- You have problems with your kidneys.
- You have diabetes (high blood sugar).
- You wear contact lenses.
- You have problems with your blood vessels (peripheral vascular disease).

- You have ever had problems with your thyroid.
- 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 have an allergy and are having treatment to desensitise you.
- You have a history of severe anaphylactic reactions (a whole body allergic reaction), as the effect of medicinal product used for treatment might be reduced.
- You have problems with the blood circulation in your fingers and toes ('Raynaud's phenomenon').
- You have had 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.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Dilatrend can affect the way some medicines work. Also some other 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 blood pressure,

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including water tablets (diuretics), 'calcium channel blockers' (for example diltiazem or verapamil), and digoxin.

- Catecholamine-depleting agents (for example reserpine and Monoamine oxidase inhibitors (MAOIs), such as isocarboxide and phenelzine (used to treat depression)).
- Medicines for diabetes, such as insulin or metformin.
- Clonidine (used to treat high blood pressure, migraine and flushing in the menopause).
- Rifampicin (used to treat infections).
- Cimetidine (used to treat indigestion, heartburn and stomach ulcers).
- Ciclosporin (used after an organ transplant).

Important information about some of the ingredients of Dilatrend

This medicine 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 this medicine.

4. How to use Dilatrend

Always take Dilatrend exactly as your doctor has told you. You should check with your doctor if you are not sure. Dilatrend is not suitable for children under the age of 18 years.

Swallow each tablet with a drink.

Chronic 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 one 3.125 mg tablet (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 up to 50 mg twice a day.
- If you have stopped taking Dilatrend for more than two weeks you should talk to your doctor. They will need you to go back to the starting dose again (see section 'If you stop taking Dilatrend').

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 your blood pressure is not under control, your doctor may increase your dose slowly, over several weeks up to 50 mg a day.
- If you are elderly, you may not need any more than 12.5 mg a day to control your blood pressure.

Angina:

Adults

- The usual starting dose is 12.5 mg twice a day for two days.
- After two days the dose is usually 25 mg, twice a day.

Elderly

- Your doctor will decide both your starting dose and the best dose for you to take in the longer term.
- The usual maximum dose is 50 mg each day, taken in smaller amounts (divided doses).

- If you forget to use it

- 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 use take more Dilatrend than you should

- If you take more Dilatrend than you should or someone else takes your Dilatrend, 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.

- If you stop taking Dilatrend

Do not stop taking this medicine without talking to your doctor.

They may want you to stop taking Dilatrend slowly over 1 to 2 weeks.

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

5. While you are using Dilatrend

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Dilatrend.

You should also tell your surgeon and anaesthetist if you are having surgery.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Make sure you drink enough water during exercise and hot weather when you are taking Dilatrend, especially if you sweat a lot.

Tell your doctor if you become pregnant while taking Dilatrend.

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Tell your doctor that you are taking Dilatrend if you are going to have any laboratory tests.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked. Your doctor may examine your eyes and test your blood glucose and kidney function from time to time.

- Things you must not do

Do not stop taking Dilatrend or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Dilatrend should only be stopped by gradually reducing the amount over a two-week period.

Do not give Dilatrend to anyone else even if they have the same condition as you.

Do not use Dilatrend to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

- Things to be careful of

Be careful driving or operating

machinery until you know how Dilatrend affects you.

Dilatrend may affect your ability to drive a car or operate machinery when started or when the dosage is increased.

If you wear contact lenses you may also notice a reduction in the amount of tear fluid in your eyes. When taken with grapefruit juice the amount of Dilatrend absorbed by your body may be increased.

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Talk to your doctor about drinking alcohol before taking Dilatrend. Alcohol can change how the medicine affects your condition. Your doctor may advise you to limit your alcohol intake.

6. Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dilatrend.

Dilatrend helps most people with heart failure but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- headache (this is usually mild and happens at the start of your treatment)
- tiredness, drowsiness
- low blood pressure. The signs include feeling dizzy or lightheaded especially after you stand up
- faintness

- abnormal or blurry vision
- slow heart rate
- diarrhea
- nausea or vomiting
- bronchitis
- loss of control of blood sugar in diabetics
- weight increase
- fluid retention. The signs include overall swelling of parts of your body for example your hands, feet, ankles and legs
- unusual hair loss or thinning
- dry or irritated eyes
- indigestion
- stomach pain or discomfort
- unusual weakness
- general pain or discomfort, pain in extremities
- frequent need to urinate, difficulty or pain when passing urine
- depression
- hallucination
- asthma
- excessive sweating.

These are the more common side effects of Dilatrend. Mostly these are mild and will decrease as you get used to your medicine.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- itching, dark urine, loss of appetite, yellowing of skin or eyes, or feeling "flu-like" with no clear cause.
- shortness of breath or swelling of the mouth or tongue
- uneven heart beating
- swelling of the feet or legs due to fluid build up
- bleeding or bruising more easily than normal

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may

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occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. After using Dilatrend

- Dilatrend tablets should be kept in their original packaging to protect them from moisture and light.
- Dilatrend tablets do not require any special temperature storage conditions.
- Keep out of the reach and sight of children.
- Do not use Dilatrend after the expiry date printed on the pack.
- Do not throw away any left over tablets. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

8. Product Description

- What Dilatrend looks like

6.25 mg tablet – yellow round tablet with raised centre, scored and with BM on one side and F1 on the other. Available in blister packs of 30,100 tablets.

25 mg tablet – white to pale yellow-beige round tablet with raised centre, scored and with BM

on one side and D5 on the other. Available in blister packs of 30,100 tablets.

Not all pack sizes may be marketed.

- Ingredients

Each DILATREND tablet contains 6.25 mg or 25 mg of carvedilol as the active ingredient.

In addition, each tablet contains the following inactive ingredients.

- sucrose
- lactose
- povidone
- crospovidone
- colloidal anhydrous silica
- magnesium stearate
- yellow iron oxide [172] (6.25mg only)

This medicine does not contain gluten

- MAL number:

Dilatrend tablet 6.25mg
(MAL19991009ACZ)

Dilatrend tablet 25mg
(MAL19940581ACZ)

9. Manufacturer

Made for CHEPLAPHARM
Arzneimittel GmbH, Greifswald,
Germany.

By Delpharm Milano S.r.l., Segrate
(MI), Italy.

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent Paradigm, No.1,
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