

Package leaflet: Information for the patient

Eucardic 12.5 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 Eucardic is and what it is used for
2. What you need to know before you take Eucardic
3. How to take Eucardic
4. Possible side effects
5. How to store Eucardic
6. Contents of the pack and other information

1. What Eucardic is and what it is used for

Eucardic contains the active substance carvedilol. It belongs to a group of medicines called ‘beta-blockers’.

Eucardic 12.5 mg Tablets are used to treat the following:

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

Eucardic works by making your blood vessels relax and widen.

- This helps to lower your blood pressure.
- If you have congestive 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 Eucardic to help treat your condition.

2. What you need to know before you take Eucardic

Do not take Eucardic if:

- You are allergic (hypersensitive) to carvedilol or any of the other ingredients of this medicine (listed in Section 6).
- You have ever had wheezing or asthma.
- You have severe heart failure (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 heartbeat). Eucardic is not suitable for some people with certain types of heart problems.
- You have very low blood pressure.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Eucardic if:

- You have problems with your lungs.
- 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 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'.
- You have a growth on one of your adrenal glands ('phaeochromocytoma').

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

Children and adolescents

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

Other medicines and Eucardic

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Eucardic can affect the way some medicines work. Also some other medicines can affect the way Eucardic 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, including water tablets (diuretics), 'calcium channel blockers' (for example diltiazem or verapamil) or medicines to control an irregular heartbeat (for example digoxin and amiodarone).
- Catecholamine-depleting agents (for example reserpine and Monoamine oxidase inhibitors (MAOIs), such as isocarboxazid and phenelzine (used to treat depression)).
- Fluoxetine or paroxetine (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).
- Ciclosporin or tacrolimus (used after an organ transplantation).
- Non-steroidal anti-inflammatory drugs (NSAIDs, for example aspirin, indomethacin and ibuprofen).
- Beta-agonist bronchodilators (used to treat chest tightness and wheezing due to asthma or other chest conditions (for example salbutamol and terbutaline sulphate)).
- Adrenaline/epinephrine (used to treat severe allergic reactions).

Eucardic with food, drink and alcohol

Taking Eucardic simultaneously or promptly with grapefruit or grapefruit juice should be avoided. Grapefruit or grapefruit juice can lead to an increase in the active ingredient carvedilol in the blood and cause unpredictable adverse effects.

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

Operations

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

Pregnancy and breast-feeding

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

Taking Eucardic when you are pregnant could harm your baby. Do not take Eucardic if you are pregnant, or might be pregnant, unless your doctor tells you to. Your doctor will discuss with you whether you should take Eucardic during your pregnancy.

You should not breast-feed during treatment with Eucardic.

Driving and using machines

You may feel dizzy while taking Eucardic. This is more likely when you start treatment or if your treatment is 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 Eucardic.

Eucardic contains lactose and sucrose

This medicine contains lactose and sucrose, which are 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 medicinal product.

3. How to take Eucardic

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

Congestive heart failure:

- 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 (187 lb) the dose may be increased up to 50 mg twice a day.
- If you have stopped taking Eucardic 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 Eucardic').

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.
- If your angina is not under control, your doctor may increase your dose slowly, over several weeks up to 50 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).

Use in children and adolescents

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

How you should take Eucardic

- Swallow each tablet with a drink of water.
- The tablet can be divided into equal doses.

If you take more Eucardic than you should

- If you take more Eucardic than you should, or someone else takes your Eucardic tablets, 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 heartbeat, sinus arrest (your heartbeat becomes very slow or stops), feeling dizzy or light-headed, becoming breathless, wheezy or extremely tired.

If you forget to take Eucardic

- 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 Eucardic

Do not stop taking this medicine without talking to your doctor. They may want you to stop taking Eucardic slowly over 1 to 2 weeks.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. However, it is possible that you could get any of the side effects listed below.

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 - Very rarely, 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).

Other side effects:

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.
- 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.
- 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.
- Hair loss.
- 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). This normally will get better when treatment is stopped.

- 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):

- Eucardic 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 Eucardic.
- You may sweat excessively (hyperhidrosis).

Reporting of side effects

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

Website: www.hpra.ie

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

5. How to store Eucardic

- Eucardic tablets should be kept in their original packaging to protect them from moisture and light.
- Eucardic tablets do not require any special temperature storage conditions.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister foils after Exp. The expiry date refers to the last day of that month.
- 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 protect the environment.

6. Contents of the pack and other information

What Eucardic contains

- The active substance is carvedilol. Each Eucardic 12.5 mg Tablet contains 12.5 mg (milligrams) of carvedilol.
- The other ingredients are: lactose monohydrate, sucrose, povidone (E 1201), crospovidone (E 1202), colloidal anhydrous silica (E 551), magnesium stearate (E 572), red iron oxide (E 172) and yellow iron oxide (E 172).

What Eucardic looks like and contents of the pack

Eucardic 12.5 mg Tablets are round and light brown in colour and have a score line on both sides. The tablets are marked BM on one side and H3 on the other.

Eucardic 12.5 mg Tablets are supplied in blister packs containing either 14, 28, 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

CHEPLAPHARM Arzneimittel GmbH
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For information about this medicine, contact the medical information department on +44 800 145 5034 or email: cheplapharm@redlinepv.co.uk.

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