

Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel



Package leaflet: information for the user
Carvedilol 3.125 mg film-coated tablets
Carvedilol 6.25 mg film-coated tablets
Carvedilol 12.5 mg film-coated tablets
Carvedilol 25 mg film-coated 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 Carvedilol is and what it is used for
2. What you need to know before you take Carvedilol
3. How to take Carvedilol
4. Possible side effects
5. How to store Carvedilol
6. Contents of the pack and other information

1. What Carvedilol is and what it is used for

Carvedilol belongs to a group of medicines called beta-blockers.

Carvedilol is 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)

Carvedilol 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 Carvedilol to help treat your condition.

2. What you need to know before you take Carvedilol

DO NOT TAKE Carvedilol 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). Carvedilol is not suitable for some people with certain types of heart problems.
- You have very low blood pressure.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Carvedilol 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 desensitize 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 carvedilol.

Children and adolescents

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

Other medicines and Carvedilol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription or herbal medicines. This is because carvedilol can affect the way some medicines work. Also some other medicines can affect the way carvedilol 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 used 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).

Carvedilol with food, drink and alcohol

Taking carvedilol simultaneously or promptly with grapefruit or grapefruit juice should be avoided.

Grapefruit or grapefruit juice can lead to an increase of carvedilol in the blood and cause unpredictable adverse effects.

Do not drink alcohol while taking carvedilol. 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 carvedilol. This is because some anaesthetics can lower your blood pressure, and it may become too low.

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.

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

You should not breast-feed during treatment with carvedilol.

Driving and using machines

You may feel dizzy while taking Carvedilol. 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 carvedilol.

Carvedilol 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 medicine.

3. How to take Carvedilol

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist 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 carvedilol 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 carvedilol').

High blood pressure

- The usual starting dose is 12.5 mg once a day for the first 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.

Use in children and adolescents

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

How you should take Carvedilol film-coated tablets

- Swallow each tablet with a drink of water.

If you take more Carvedilol than you should

- If you take more Carvedilol film-coated tablets than you should, or someone else takes your 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 Carvedilol

- 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 Carvedilol

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

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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 pains/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).
- 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):

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Carvedilol

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 label after EXP. The expiry date refers to the last day of that month.

Do not store above 30° C.

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 Carvedilol contains

- The active substance is carvedilol. Each tablet contains 3.125 mg, 6.25 mg, 12.5 mg or 25 mg carvedilol.
- The other ingredients are: lactose monohydrate, silica colloidal anhydrous, crospovidone (Type A), crospovidone (Type B), povidone 30, sucrose, magnesium stearate
Tablet coating: macrogol 400, polysorbate 80, titanium Dioxide (E 171), hypromellose

What Carvedilol looks like and contents of the pack

Film-coated tablet

Carvedilol 3.125 mg film-coated tablets

Film-coated tablets white to off-white, oval, engraved with "E" on one side and "01" on the other.

Carvedilol 6.25 mg film-coated tablets

Film-coated tablets white to off-white, oval, engraved with "F57" on one side and scored on the other side. The tablet can be divided into equal doses.

Carvedilol 12.5 mg film-coated tablets

Film-coated tablets white to off-white, oval, engraved with "F58" on one side and scored on the other side. The tablet can be divided into equal doses.

Carvedilol 25 mg film-coated tablets

Film-coated tablets white to off-white, oval, engraved with "F59" on one side and scored on the other side. The tablet can be divided into equal doses.

Blister:

Package sizes: 5, 7, 10, 14, 15, 20, 28, 30, 40, 50, 56, 60, 90, 98, 100, 120, 150, 200, 250, 300, 400, 500 and 1000 film-coated tablets.

HDPE:

Package sizes: 30, 50, 60, 100, 250, 500 and 1000 film-coated tablets

It is possible that not all presentations are marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA46QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

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