Pharmacode

CARVEDILOL 3.125 mg, 6.25 mg, 12.5 mg & 25 mg TABLETS

PACKAGE LEAFLET: Information for the user

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 your 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 Tablets are and what they are used for
2. What you need to know before you take Carvedilol Tablets
3. How to take Carvedilol Tablets
4. Possible side effects
5. How to store Carvedilol Tablets
6. Contents of the pack and other information

1. WHAT CARVEDILOL TABLETS ARE AND WHAT THEY ARE USED FOR

Carvedilol is a type of medicine called a beta blocker and vasodilator. Carvedilol Tablets are used for the treatment of angina (pains in the chest caused by blockages in the arteries leading to the heart) and mild to moderate heart failure (when the heart cannot pump blood properly to the rest of the body). Carvedilol is also used to treat hypertension (high blood pressure).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CARVEDILOL TABLETS

Do not take Carvedilol Tablets:
- if you are allergic to Carvedilol, or any of the other ingredients of this medicine (listed in section 6)
- if you have fluid retention and require intravenous support with drugs that affect the contraction of heart muscle
- if you have a history of asthma or other lung diseases unless you have consulted your doctor or pharmacist first
- if you have severe hardening of the arteries affecting the circulation in your legs or feet
- if you are receiving verapamil or diltiazem by injection or as an infusion (with a drip)
- if you have an unusually slow heart beat or very low blood pressure sometimes causing dizziness, faintness or light-headedness on standing
- if you have heart block (a heart conduction problem unless a permanent pacemaker is in place) or cardiogenic shock (a weak heart)
- if you have sick-sinus syndrome (sino-atrial block - a heart conduction problem)
- if you have been told you have unstable heart failure
- if you have Prinzmetal's angina (chest pain)
- if you have liver problems
- if you have a phaeochromocytoma (an adrenal gland tumour) unless adequately controlled by medication
- if you have metabolic acidosis (acidification of the blood)
- if you have problems with sugars such as glucose or galactose.

Warnings and precautions
Talk to your doctor or pharmacist before taking Carvedilol Tablets:
- if you have diabetes, as your low blood sugar (hypo) warning signs may be less obvious than usual
- if you have kidney problems. Your doctor may wish to reduce or discontinue your treatment
- if you have severe hardening of the arteries affecting the circulation in your legs or feet or arms
- if you have low blood pressure or are elderly
- if you have first degree heart block or other heart problems
- if you have severe heart failure, low salt and blood levels
- if you have Raynaud's syndrome (usually affecting the fingers) or peripheral vascular disease causing cold hands and feet or pins-and-needles
- if you have thyroid problems
- if you have a phaeochromocytoma (an adrenal gland tumour resulting in high blood pressure, flushing, diarrhoea)
- if you have previously suffered from serious allergic reactions or you are undergoing desensitisation therapy to prevent allergy e.g. to wasp or bee stings
- if you have psoriasis (condition characterized by dry, scaling patches of skin with lesions). Skin symptoms may be increased
- if you suffer from Prinzmetal's angina (chest pain)
- if you wear contact lenses, as Carvedilol may cause dry eyes
- if you have had problems taking debrisoquine (used to treat high blood pressure)
- if you have lung disease associated with breathing problems
- if you are suffering from pain (in feet), weakness, numbness or cramping of muscle due to decreased blood flow
- if you are undergoing surgery.

Other medicines and Carvedilol Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or herbal medicines.

Carvedilol Tablets may interact with other medicines used at the same time such as:
- insulin or tablets to treat diabetes
- monoamine oxidase inhibitors (used to treat depression) e.g. moclobemide, reserpine
- other medicines for your heart or high blood pressure particularly;
  - clonidine
  - alpha blockers e.g. doxazosin, terazosin
  - antiarrhythmics e.g. amiodarone
  - calcium channel blockers e.g. diltiazem, verapamil, nifedipine
  - digitalis drugs e.g. digoxin
  - diuretics (water tablets) e.g. chlorthalidone, cyclopenthiazide
  - nitrates e.g. glyceryl trinitrate
  - guanethidine, guanfacine, clonidine, reserpine, methyldopa
- muscle relaxants used in anaesthesia or anaesthetic drugs (you should tell your doctor before surgery)
- corticosteroids (used to treat different types of diseases, e.g. asthma, skin dermatitis etc.)
- antidepressants e.g. amitriptyline, fluoxetine (used to treat depression)
- cimetidine (used to treat ulcers)
- haloperidol (used in mental illness)
- erythromycin (an antibiotic used for bacterial infections)
- sympathomimetics (used for the nervous system) e.g. ephedrine
- ergotamine (used to treat migraine)
- neuromuscular blocking agents (muscle relaxants used in anaesthesia) e.g. atracurium besilate
- ketoconazole (used to treat fungal infections)
- barbiturates e.g. amylobarbitone (sleeping drug)
- phenothiazines e.g. prochlorperazine (to help stop vomiting and nausea)
- ciclosporin (used following an organ transplant)
- non-Steroidal Anti-Inflammatory Drugs (NSAIDs) e.g. ibuprofen (used for pain, stiffness and inflammation of painful bones, joints and muscles)
- the contraceptive pill or HRT
- rifampicin (used to treat tuberculosis).

Tell your hospital or dentist you are taking Carvedilol Tablets if you are going to have an operation needing an anaesthetic.

Carvedilol Tablets with food, drink and alcohol
Do not drink alcohol while you are taking Carvedilol Tablets.

Pregnancy, breast-feeding and fertility
Use of Carvedilol Tablets is not recommended during pregnancy or during breast-feeding.
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.

Driving and using machines
Carvedilol Tablets may make you feel tired or dizzy or make you feel less alert particularly when you first start using them or when the dose is changed or you are also drinking alcohol at the same time.
Do not drive or use any tools or machines if you notice any of these effects whilst taking Carvedilol Tablets.

Carvedilol Tablet contains Lactose
Patients who are intolerant to **lactose** should note that Carvedilol Tablets contain a small amount of lactose.
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 CARVEDILOL TABLETS

Always take Carvedilol Tablets exactly as your doctor has told you.
Check with your doctor or pharmacist if you are not sure.

Method of Administration
Carvedilol Tablets should be swallowed whole with a drink of water. Do not crush, chew or suck them.

Dosage
Your doctor will decide on the right starting dose for you and on any increase in the dose depending on your condition and whether you are taking any other medicines. Do not change your dose unless your doctor tells you to do so.

The recommended dose is on the label on the carton which will tell you how many tablets you should take and when.

The usual doses for Carvedilol Tablets are as follows:
Heart Failure
If you have been given Carvedilol Tablets for the treatment of heart failure, it is likely that a hospital specialist will have started your treatment.
The usual starting dose is 3.125 mg tablets twice a day (every 12 hours).
You should try to take the tablets with food. However, you should still take your tablets even if you do not have much appetite. Your doctor may gradually increase the strength of your tablets until you find a dose that suits you best.
Carvedilol may worsen your symptoms of heart failure. Please tell your doctor if you notice any such change. While taking Carvedilol Tablets, make sure that you continue with any other treatments you may already be taking for heart failure as advised by your doctor.

High Blood Pressure
The usual starting dose is 12.5 mg once a day. Your doctor will gradually increase the strength of tablets you take until you receive the dose that suits you best. The normal dosage is one 25 mg tablet once a day.

Angina
The usual starting dose is 12.5 mg twice a day for the first two days of your treatment. From then on the usual dose is one 25 mg tablet twice a day.

Use in children and adolescents
Carvedilol Tablets are not suitable for children and adolescents under 18 years of age.

If you take more Carvedilol Tablets than you should:
If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose can cause low blood pressure (leading to feeling faint, shaky and weak), wheezing, vomiting, fits, very slow heartbeat, heart failure/attack, breathing problems and loss of consciousness.

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400 mm

240 mm

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If you forget to take Carvedilol Tablets
If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Carvedilol Tablets
Do not suddenly stop taking your tablets as side effects may occur.
If treatment is to be stopped, your doctor will gradually reduce your dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Carvedilol Tablets can cause side effects although not everybody gets them.
If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:
- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).
- Severe cutaneous adverse reactions (Inflammatory skin eruption, serious illness with blistering of the skin, mouth, eyes and genitals).

This are very serious but rare side effects. You may need urgent medical attention or hospitalisation. Side effects are less likely if you are being treated for angina or hypertension than if you are being treated for heart failure.

Possible side effects in patients being treated for heart failure:

Very common (may affect more than 1 in 10 people):
- dizziness
- headache usually mild at the start of the treatment
- lack of muscle strength and weakness
- heart failure
- low blood pressure.

Common (may affect up to 1 in 10 people):
- lungs disease, bronchitis
- decreased red blood cell, symptoms you may feel are like pale skin, feeling breathless after little exercise, feeling tired
- weight gain
- increased cholesterol (fat) in blood
- changes in blood sugar levels and a worsening of blood sugar control
- depression and depressed mood
- problems with your vision
- slow heart beat
- rapid drop of blood pressure when standing up
- abnormal accumulation of fluid in body causing swelling of ankles, feet or fingers, swelling of penis, swollen legs
- decreased volume of circulating blood
- accumulation of excessive fluid in body
- fluid accumulation in lungs
- generalised pain
- loose stools
- stomach acidity
- indigestion
- feeling unwell
- being sick
- kidney problems
- urinary tract infection.

Uncommon (may affect up to 1 in 100 people):
- heart disease
- feeling faint
- dry, flaky, itchy skin
- rash on skin
- lesion on skin
- increased sweating
- loss of hair.

Rare (may affect up to 1 in 1,000 people):
- decreased platelet counts in blood (this can be detected from a blood test).

Very rare (may affect up to 1 in 10,000 people):
- abnormal lowering of the white blood cell count (this can be identified from a blood test)
- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- raised liver function test
- inability to control the flow of urine in women.

Possible side effects in patients being treated for angina or hypertension:

Very common (may affect more than 1 in 10 people):
- heart failure
- low blood pressure.

Common (may affect up to 1 in 10 people):
- lung disease, bronchitis
- anaemia symptoms you may feel are like pale skin, feeling breathless after little exercise, feeling tired
- depression and depressed mood
- dizziness
- tiredness
- mild headache at the start of the treatment
- dry eye
- vision disturbance
- eye irritation
- slow heart beat
- rapid drop of blood pressure when standing up
- cold hands and feet
- breathing problems
- fluid accumulation in lungs
- asthma
- stomach pain
- pain in tummy
- indigestion
- loose stools
- feeling unwell
- pain in hands and feet
- problems in passing urine
- urinary tract infection
- generalised pain.

Uncommon (may affect up to 1 in 100 people):
- general tiredness
- abnormal sensation in skin
- disturbance in sleep
- disturbed vision
- chest pain
- heart block
- symptoms of heart failure
- swelling of ankles, feet or fingers
- faint
- constipation
- being sick
- skin rash
- skin lesions
- hair loss
- increased sweating
- impotency (difficulty getting or maintaining an erection)
- erectile dysfunction.

Rare (may affect up to 1 in 1,000 people):
- stuffy nose
- fever, muscle aches, chills, headaches, and fatigue
- breathing with a whistling sound
- dryness of mouth.

Very rare (may affect up to 1 in 10,000 people):
- abnormal blood test results
- abnormal liver function test
- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- inability to control the flow of urine in women
- severe cutaneous adverse reactions (Erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis).

Other very rare side effects include chest pain, heart block and worsening of cold extremities in patients who have Raynaud's disease or circulation problems.
Changes in blood sugar levels and a worsening of blood sugar control in patients with diabetes can occur.
Skin problems such as itching, itchy or red rashes or pale skin can occur in rare cases. If you have psoriasis you may experience a worsening of the symptoms.
Breathlessness is common in patients who have a history of breathing problems.
You should report to your doctor if your symptoms or condition worsen, as the dose of your other medications or Carvedilol Tablets may need to be changed.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CARVEDILOL TABLETS

Store in the original package. 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 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Carvedilol Tablets contain:
The active substance is Carvedilol. Each tablet contains either: 3.125, 6.25, 12.5 or 25 mg of Carvedilol. The other ingredients are lactose monohydrate, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, maize starch, yellow iron oxide (E172), colloidal anhydrous silica, talc and magnesium stearate.

What Carvedilol Tablets look like and the contents of the pack:
Carvedilol 3.125 mg Tablets are cream coloured, circular, biconvex tablets marked '3' on one face and plain on reverse face.
Carvedilol 6.25 mg Tablets are cream coloured, circular, biconvex tablets marked '6' on one face and plain on reverse face.
Carvedilol 12.5 mg Tablets are cream coloured, circular, biconvex tablets marked '12' on one face and plain on reverse face.
Carvedilol 25 mg Tablets are cream coloured, circular, biconvex tablets marked '25' on one face and plain on reverse face.

Your medicine is available in packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer:
Relonchem Limited,
Cheshire House, Gorsey Lane,
Widnes, Cheshire, WA8 0RP, UK.

Carvedilol 3.125 mg Tablets - PL 20395/0333
Carvedilol 6.25 mg Tablets - PL 20395/0334
Carvedilol 12.5 mg Tablets - PL 20395/0335
Carvedilol 25 mg Tablets - PL 20395/0336

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This leaflet was last revised in August 2026.

Version A

Pharmacode