

CARVEDILOL 3.125 mg, 6.25 mg, 12.5 mg and 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 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 drugs called beta-blockers. Beta-blockers slow the heart rate, thus causing the heart to beat more calmly and lower blood pressure.

Carvedilol is used to:

- treat angina and heart failure
- control high blood pressure.

2 What you need to know before you take Carvedilol

Do not take Carvedilol

- if you are allergic to Carvedilol or any of the other ingredients of this medicine
- 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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, methyl dopa
- 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.

Pregnancy, Breast-feeding and Fertility

Use of Carvedilol 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 tablets 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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The tablets should be swallowed preferably with a glass of water.

Your doctor may monitor you at the start of treatment or if your dose is increased. This may involve urine and blood tests.

The usual dose is:

High blood pressure

- **Adults:** The usual starting dose is 12.5 mg once a day for the first two days after which the recommended dose is 25 mg once a day. If necessary your doctor may gradually increase your dose. The maximum dose taken at one time is 25 mg and the maximum dose taken in one day is 50 mg.
- **Elderly:** The usual starting dose is 12.5 mg once a day. If necessary your doctor may increase your dose.

Angina

- **Adults:** The usual starting dose is 12.5 mg twice a day for two days after which the recommended dose is 25 mg twice a day. If necessary your doctor may gradually increase your dose. The maximum daily dose is 50 mg twice a day.
- **Elderly:** The usual starting dose is 12.5 mg twice a day for two days after which the recommended dose is 25 mg twice a day, which is the maximum daily dose.

Heart failure

The tablets should be taken with food to reduce the risk of a fall in blood pressure when standing up, which causes dizziness, light-headedness or fainting.

- **Adults:** The usual starting dose is 3.125 mg twice a day for 2 weeks. Your doctor may gradually increase your dose to 25 mg twice a day. The maximum dose is 25 mg twice a day for patients with a body weight of less than 85 kg. For patients with a body weight above 85 kg, a maximum dose of 50 mg twice a day can be taken.

Liver or Kidney problems

If you have either liver or kidney problems your doctor may prescribe a lower dose.

Elderly

Your doctor may want to monitor you more closely if you are elderly.

Children and adolescents (under 18 years old)

Carvedilol is not recommended for use in children and adolescents under 18 years old.

If you take more Carvedilol 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.

If you forget to take Carvedilol

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

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 product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine 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):

- lack of muscle strength and weakness
- dizziness
- headache usually mild at the start of the treatment
- 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 (Erythma 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 may need to be changed.

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 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

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Do not transfer to another container. Do not use Carvedilol after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. Do not throw away 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 Tablets contain:

- The active ingredient is carvedilol.
- The other ingredients are lactose monohydrate, povidone, crospovidone, colloidal silica anhydrous and magnesium stearate. The tablets contain the following colourings:
 - 3.125 mg tablets: yellow and red iron oxide (E172)
 - 6.25 mg tablets: yellow iron oxide (E172)
 - 12.5 mg tablets: red iron oxide (E172).

What Carvedilol Tablets look like and contents of the pack:

- The 3.125 mg tablets are light peach, round, flat tablets, scored on one side and debossed on the other side with "CVL" at the top and "T1" at the bottom. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
 - The 6.25 mg tablets are light yellow to yellow, round flat tablets, scored on one side and debossed on the other side with "CVL" at the top and "T2" at the bottom. The tablet can be divided into equal halves.
 - The 12.5 mg tablets are mottled light brick red, round flat tablets, scored on one side and debossed on the other side with "CVL" at the top and "T3" at the bottom. The tablet can be divided into equal halves.
 - The 25 mg tablets are white to off-white, round flat tablets, scored on one side and debossed on the other side with "CVL" at the top and "T4" at the bottom. The tablet can be divided into equal halves.
 - The 3.125 mg tablets are available in pack sizes* of 28, 30, 50 and 100 tablets
 - The 6.25 mg, 12.5 mg and 25 mg tablets are available in pack sizes* of 14, 28, 30, 50, 56 and 100 tablets.
- *Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Company Responsible for Manufacture:

Teva Pharmaceutical Works Private Limited Company, Pallagi Street 13, H-4042, Debrecen, Hungary.

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