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.

1 What is Carvedilol and what is it 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 heart failure 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 digi
- If you have an unusually slow heart beat or very low blood pressure sometimes causing dizziness, faintness or light-headedness on standing up
- If you have heart block or a heart conduction problem unless a permanent pacemaker is in place or cardiological shock (a weak heart
- If you have sick sinus syndrome (sinus-atral 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 metastasis (secondary cancer)
- If you have problems with sugars such as glucose or galactose.

3 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 narrowing 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 Raynaud’s phenomenon)
- If you have thyroid problems
- If you have a phaeochromocytoma (an adrenal gland tumour resulting in high blood pressure, flushing, sweating or palpitations)
- If you have previously suffered from serious allergic reactions or you are undergoing desensitisation the way to prevent allergy e.g. to wasp or bee stings
- If you have poriasis (condition characterised 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 diuretics (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 cramming 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, phenelzine
- other medicines for your heart or high blood pressure particularly;
- corticosteroids
- alpha blockers e.g. doxazosin, terazosin
- antidepressants e.g. amiodarone
- calcium channel blockers e.g. diltiazem, verapamil, nifedipine
- digitalis drugs e.g. digoxin
- diuretics (water tablets) e.g. chlorthalidone, cyclosporin
- nitrites e.g. glyceryl trinitrate
- quinidine, procainamide, clopidogrel, aspirin
- other medicines 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 ulcer)
- haloperidol (used in mental illness)
- sertindole (an antipsychotic used for bacterial infections)
- sympathomimetics (used for the nervous system) e.g. epinephrine
- omeprazole (used to treat acid reflux)
- neuromuscular blocking agents (muscle relaxants used in anaesthesia) e.g. atracurium besylate
- ketamine (used for tranquilisation of children)
- 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 if you are taking Carvedilol tablets if you are going to have an operation requiring 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 contain Lactose

Patients who are lactose intolerant 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.

4 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 whole 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:

- 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 twice a day. If necessary your doctor may gradually increase your dose. The maximum dose taken at one time is 35 mg and the maximum dose taken in one day is 70 mg.
- 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, fast, very slow heartbeat, heart failure, 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.

WARNING: This leaflet is accompanied by a patient information leaflet.

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.
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 is a very serious but rare side effect. 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
• low blood pressure.
Common (may affect up to 1 in 10 people):
• long term diastolic hypertension
• decreased red blood cell, symptoms you may feel are like pale skin, feeling breathlessness 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 decreased 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 peris, swollen legs
• decreased volume of circulating blood
• accumulation of excess fluid in body
• fluid accumulation in lungs
• generalised pain
• swollen face
• 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, itchy, scaly 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).

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
• increased uric acid in blood
• increased cholesterol (fat in blood)
• changes in blood sugar levels and a worsening of blood sugar control
• depression and decreased 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 peris, swollen legs
• decreased volume of circulating blood
• accumulation of excess fluid in body
• fluid accumulation in lungs
• generalised pain
• swollen face
• stomach acidity
• indigestion
• feeling unwell
• being sick
• kidney problems
• urinary tract infection.
Uncommon (may affect up to 1 in 100 people):
• general tiredness
• abnormal sensation in skin
• disturbance in sleep.
Teva Pharmaceuticals Europe B.V

1.3.2
mockup-pil-uk-pl-00289-0546-0547-0548-0549-carvedilol-3.125mg-6.25mg-12.5mg-25mg-tablets

APPROVALS

<table>
<thead>
<tr>
<th>Signed by</th>
<th>Meaning of Signature</th>
<th>Server Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sukanya Dasani</td>
<td>Regulatory Affairs Approval</td>
<td>23-Feb-2017 02:39:23 PM</td>
</tr>
</tbody>
</table>