

Carvedilol HEXAL® 6.25/ 12.5/25mg Tablet

Carvedilol (6.25/12.5/25mg)

What is in this leaflet

1. What **Carvedilol HEXAL** is used for
2. How **Carvedilol HEXAL** works
3. Before you take **Carvedilol HEXAL**
4. How to take **Carvedilol HEXAL**
5. While you are using **Carvedilol HEXAL**
6. Possible side effects
7. After using **Carvedilol HEXAL**
8. Product description
9. Marketing authorization holder and manufacturer

What Carvedilol HEXAL is used for

Carvedilol HEXAL is used to treat

- High blood pressure (hypertension)
- Chest pain (angina pectoris)
- Chronic heart failure

How Carvedilol HEXAL works

Carvedilol HEXAL contains the active ingredient carvedilol. It belongs to the group of medicines called 'beta blockers'. These medicines work by relaxing the blood vessels and slowing down the heart rate. Carvedilol also possesses antioxidant effect.

Before you use Carvedilol HEXAL

- When you must not use it

Do not take **Carvedilol HEXAL** if you:

- Have ever had allergic reaction to carvedilol, the active ingredient, or to any other ingredients in **Carvedilol HEXAL**
- Have severe heart failure
- Have asthma or other conditions that causes breathing difficulties
- Have liver problems, including liver failure

- Have a slow heart beat or serious problems with the heart rhythm (second or third degree heart block)
- Suffering from cardiogenic shock (second or third degree heart block)
- Suffering from cardiogenic shock (a state where heart is damaged and unable to supply sufficient blood to organs in body)
- Have very low blood pressure
- Have metabolic acidosis (excessive acidity in the body fluid)
- Have Prinzmetal's angina, a type of chest pain
- Untreated pheochromocytoma (a rare tumor in adrenal gland)
- Have poor circulation to your fingers and/or toes (peripheral vascular disease)
- Taking injectable medicine of verapamil or diltiazem.

If you are not sure whether you should start taking this medicine, consult your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Are pregnant, think you are pregnant or planning to become pregnant.
- Are breast feeding or plan to breast feed
- Have kidney problems
- Have any breathing difficulties including asthma
- Suffering from diabetes
- Have thyroid disorders
- Low blood pressure
- High blood pressure
- Wearing contact lenses

- Undergoing desensitization therapy for any allergy reactions
- Have poor circulation to your fingers and/or toes (peripheral vascular disease)
- Suffers from Raynaud's syndrome (a condition causing numbness, tingling and colour change in fingers and toes when exposed to the cold)
- Suffers from first degree heart block
- Plan to undergo surgery
- Have lactose intolerance, as this medicine contains lactose
- Have a history of swelling of the face, lips, tongue, throat, hands or feet.

- Taking other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines including medicines obtained without a prescription.

There may be interference between Carvedilol and some other medicines including:

- Medicines to treat irregular heartbeat such as, amiodarone, calcium channel-blockers of verapamil and diltiazem type
- Calcium channel-blockers of dihydropyridine group such as nifedipine, amlodipine and felodipine for treating high blood pressure
- Nitrates such as glyceryl trinitrate (GTN) for chest pain.
- Digoxin, a medicine used for heart failure
- Cyclosporin, an immunosuppressant
- Diabetic medicines including insulin
- Clonidine, a medicine used to treat high blood pressure, migraine or menopause symptoms
- Anesthetics

Carvedilol HEXAL® 6.25/ 12.5/25mg Tablet

Carvedilol (6.25/12.5/25mg)

- Phenytoin and phenobarbital, medicines for epilepsy
- Phenothiazine and haloperidol, medicines used in treatment of mental illness such as psychoses
- Tricyclic antidepressants such as imipramine and amitriptyline for depression
- Fluoxetine, a medicine used to treat depression
- Monoamine-oxidase inhibitors (MAOIs) such as phenelzine and tranylcypromine, medicines used to treat depression
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen for pain relief
- Vasodilator medicines (widening blood vessels) to treat high blood pressure
- Estrogen hormone for contraception
- Steroid medicines from corticosteroid group, such as hydrocortisone
- Cimetidine, a medicine for heart burn or peptic ulcer
- Antifungal such as ketoconazole
- Antibiotic such as rifampicin and erythromycin
- Sympathomimetic medicines such as salbutamol and isoproterenol
- Ergotamine, a medicine used for migraine
- Muscle relaxants
- Other medicines for lowering blood pressure including reserpine, guanethidine, methyl dopa and guanfacine
- Alcohol

These medicines may be affected by Carvedilol or may affect how well it works. You may need different amounts of your medicines or take

different medicines. Your doctor or pharmacist will have more information on the medicines to be careful with or to avoid while taking Carvedilol.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you are pregnant or planning to become pregnant. Carvedilol may be harmful to your unborn baby during pregnancy. Your doctor will discuss the risks and benefits of taking Carvedilol during pregnancy.

Carvedilol passed into breast milk. Your doctor will discuss the risks and benefits of taking Carvedilol during breast feeding.

How to use Carvedilol HEXAL

Always take **Carvedilol HEXAL** according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist. The directions given by your doctor may differ from this leaflet.

- How much to use

High Blood Pressure

The recommended dose for initiation of therapy is 12.5 mg once a day for the first two days. Thereafter, the recommended dosage is 25 mg once a day. If necessary, the dosage may be increased every two weeks up to the recommended maximum daily dose of 50 mg given once a day or in divided doses (twice daily).

Coronary Artery Disease (Angina Pectoris)

The recommended dose for initiation of therapy is 12.5 mg twice daily for

the first two days. Thereafter, the recommended dosage is 25 mg twice daily. If necessary, the dosage may be increased every two weeks up to the recommended maximum daily dose of 100 mg given in divided doses (twice daily).

Chronic heart Failure

The usual starting dose in heart failure is 3.125 mg twice daily. If well tolerated, the dose is usually increased every two weeks, first to 6.25 mg twice daily, then 12.5 mg twice daily and followed by 25 mg twice daily.

In treatment of heart failure, Carvedilol is usually given as an addition to basic therapy medicines.

- When to use it

Take Carvedilol during or immediately after a meal, at the same time every day for the best effect and to minimize risk of some of the side effects.

- How long to use it

Continue to take your medicines as long as your doctor tells you. The medicine helps to control your condition but not to cure it. It is important that you continue to take the medicine even if you feel healthy.

Do not stop taking Carvedilol suddenly. If you are to stop taking Carvedilol, your doctor will advise you to reduce the dose slowly over approximately two weeks.

- If you forget to use it

Take the dose as soon as you remember and continue taking as normal. If it is almost time for your

Carvedilol HEXAL® 6.25/ 12.5/25mg Tablet

Carvedilol (6.25/12.5/25mg)

next dose, skip the dose you missed and take your next dose at the normal time it is due. Do not take a double dose to make up for the dose you missed or taking more than one dose at a time. This may cause unwanted side effects.

- If you use too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of overdose may include severe low blood pressure (dizziness, fainting), breathing difficulties, vomiting, reduced consciousness, convulsions, heart failure and cardiac arrest.

While you are using it

- Things you must do

- Always follow your doctor's instruction carefully.
- Tell your doctor immediately if you notice any unusual symptoms or discomfort.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Carvedilol.
- If you become pregnant, or plan on becoming pregnant while taking Carvedilol, tell your doctor immediately.
- Inform any other doctors, dentists and pharmacists who treat you that you are taking Carvedilol.
- If you plan to have surgery that needs general anesthetic, tell your doctor or dentist that you are taking Carvedilol.

- Visit your doctor regularly so that they can check on your progress. Your doctor may examine your eyes and test your blood glucose and kidney function from time to time.

- Things you must not do

- Do not stop taking Carvedilol or change the dose without first checking with your doctor.
- Do not take Carvedilol to treat any other complaint unless your doctor tells you to.
- Do not give Carvedilol to anyone else, even if they have the same condition as you.

- Things to be careful of

- Be careful while driving or operating machinery until you know how Carvedilol affects you.
- Carvedilol may reduce your alertness which may affect your ability to drive a car or operate machinery particularly when you started or when the dose is increased. Do not drink alcohol while taking **Carvedilol**. Alcohol may further reduce your alertness.
- If you wear contact lenses, you may also have a reduction in the amount of tear fluid in your eyes.

Side effects

All medicines can have side effects. Carvedilol may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects and they worry you:

- *Headache and dizziness
- *Orthostatic hypotension (feeling of lightheaded, dizzy or faint when getting out of bed or standing up)
- Abnormal or blurry vision, dry eyes

- *Slow heart rate
- Gastrointestinal disturbances (nausea, vomiting, diarrhoea)
- Loss of control of blood sugar in diabetics
- Weight increase
- Fluid retention. Signs include overall swelling of parts of your body (hands, legs, feet, ankle)
- *Fatigue
- Pain in limbs or extremities
- Increase in cholesterol level. (* mild and usually happens at the start of your treatment.)

Tell your doctor immediately or go to nearest hospital if you notice any of the following:

- Sleep disorders
- Depression
- Dry mouth
- Paresthesia (feeling of numbness or tingling sensation)
- Impotence
- Skin reactions (itchiness, redness, psoriasis)
- Visual disturbances, eye irritation.
- Bruising or bleeding more easily than normal
- Sign of infection such as fever, chills, sore throat or mouth ulcers.
- Difficulties in breathing, chest pain
- Fainting
- Worsening of heart failure
- Sudden or worsening of kidney failure
- Increase in liver enzymes
- Uneven heart beating

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→

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Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Carvedilol

- Storage

Store in a cool dry place, not above 30°C. Keep in original package to protect from light.

Do not store **Carvedilol HEXAL** or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach and sight of children.

- Disposal

Do not use **Carvedilol HEXAL** after the expiry date which is stated on the carton and blister. If your doctors tell you to stop taking **Carvedilol HEXAL** or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

Product Description

- What it looks like

Carvedilol HEXAL® 6.25mg

Tablet:

Yellow, round, convex, bisected tablet with a pressure-sensitive scoring notch, encoded C2.

Carvedilol HEXAL® 12.5mg

Tablet:

Red/brown, round, convex, bisected tablet with a pressure-sensitive scoring notch, encoded C3.

Carvedilol HEXAL® 25mg Tablet:

White, round, convex, bisected tablet with a pressure-sensitive scoring notch, encoded C4.

- Ingredients

Carvedilol HEXAL® 6.25mg

Tablet:

Contains 6.25mg carvedilol.

Carvedilol HEXAL® 12.5mg

Tablet:

Contains 12.5mg carvedilol.

Carvedilol HEXAL® 25mg Tablet:

Contains 25mg carvedilol.

- Inactive ingredients

Lactose monohydrate,
Microcrystalline cellulose,
crospovidone, povidone, silica
colloidal anhydrous, magnesium
stearate.

Colouring agent:

Carvedilol HEXAL® 6.25mg: Ferric
oxide yellow

Carvedilol HEXAL® 12.5mg: ferric
oxide yellow, ferric oxide red.

- MAL number:

i) **Carvedilol HEXAL® 6.25mg**

Tablet:

MAL10110001AZ

ii) **Carvedilol HEXAL® 12.5mg**

Tablet:

MAL10110002AZ

iii) **Carvedilol HEXAL® 25mg**

Tablet:

MAL10110003AZ

Manufacturer

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By:

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