

KARVIL TABLETS

Carvedilol Tablets USP (6.25mg, 25mg)

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What Karvil is used for?

Karvil contains a medicine called carvedilol. This belongs to a group of medicines called 'beta-blockers'. Karvil is used to treat the following:

- Chronic heart failure.
- High blood pressure (hypertension).
- Angina (chest pain or discomfort that happens when your heart isn't getting enough oxygen).

How Karvil works

- This helps to lower your blood pressure.
- If you have chronic 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.

Before you use Karvil

When you must not use it

- You are allergic (hypersensitive) to carvedilol or any of the other ingredients of Karvil.
- You have ever had wheezing due to asthma or other lung diseases.
- You have severe fluid retention (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 heart beat). Karvil is not suitable for some people with certain types of heart problem.
- You have very low blood pressure.
- You have a problem with the acid levels in your blood ('metabolic acidosis').
- You have a growth on one of your adrenal glands ('phaeochromocytoma').

If you are not sure, talk to your doctor or pharmacist before taking Karvil.

- Before you start use Karvil

Check with your doctor or pharmacist before taking Karvil if:

- 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'.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Karvil.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Karvil can affect the way some medicines work. Also some other medicines can affect the way Karvil 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), and digoxin.
- Catecholamine-depleting agents (for example reserpine and Monoamine oxidase inhibitors (MAOIs), such as isocarboxide and phenelzine (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).
- Cimetidine (used to treat indigestion, heartburn and stomach ulcers).

- Cyclosporin (used after an organ transplant).

How to use Karvil

- How much to use

Always take Karvil exactly as your doctor has told you. You should check with your doctor if you are not sure. Karvil is not suitable for children under the age of 18 years. Swallow each tablet with a drink.

Chronic heart failure:

When used for heart failure, treatment with Karvil should be started by a specialist doctor.

- You should take your tablets at the same time as eating some food.
- The usual starting dose is one 3.125 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 Karvil 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 Karvil').

High blood pressure:

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

Angina:

Adults

- The usual starting dose is 12.5 mg twice a day for two days.
- After two days the dose is usually 25 mg, twice a day.

Elderly

- Your doctor will decide both your starting dose and the best dose for you to take in the longer term.
- The usual maximum dose is 50 mg each day, taken in smaller amounts (divided doses).

- When to use it

Use as directed by your doctor or pharmacist.

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- How long to use Karvil

- Your doctor will tell you how long to take Karvil.

- If you forget to use Karvil

- 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 use too much (overdose)

- If you take more Karvil than you should or someone else takes your Karvil, 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 heart beat, feeling dizzy or light headed, becoming breathless, wheezy or extremely tired.

While you are using Karvil

- Things you must do

Always take Karvil exactly as your doctor has told you.

- Things you must not do

- Do not take Karvil if you are pregnant, trying to get pregnant or breast-feeding, unless your doctor has told you to.
- Do not stop taking this medicine without talking to your doctor. They may want you to stop taking Karvil slowly over one to two weeks.

- Things to be careful of

Operations

- If you are going to have an operation, tell the doctor that you are taking Karvil. This is because some anaesthetics can lower your blood pressure, and it may become too low.

Pregnancy and breast-feeding

- Do not take Karvil if you are pregnant, trying to get pregnant or breast-feeding, unless your doctor has told you to.

Driving and using machines

- You may feel dizzy while taking Karvil. 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 Karvil.

Side effects

The frequency of adverse experiences is not dose dependent, with the exception of dizziness, abnormal vision and decrease in heart beats.

Undesirable effects in chronic heart failure

Adverse experiences most frequently observed in the carvedilol group in clinical trials in congestive heart failure patients and not seen at an equivalent incidence among placebo treated patients are described below;

Central nervous System

Very common: dizziness, headaches are usually mild and occur particularly at the start of treatment. Loss of strength, weakness, or lack of energy - (including fatigue) also occurs very commonly.

Cardiovascular system

Common: decrease in heart beats, low blood pressure when suddenly standing up, edema (including generalized, peripheral, dependent and genital swelling, swelling of the legs, loss of body water and fluid overload).

Uncommon: short loss of consciousness, and cardiac failure.

Gastro-intestinal system

Commonly nausea, diarrhea and vomiting.

Hematology

Rare: thrombocytopenia

Leucopenia (reduction of white blood cell) has been reported in isolated cases

Metabolic:

Commonly: Weight increase and hypercholesterolemia (high amounts of cholesterol in the blood).

Hyperglycemia (high blood sugar), hypoglycemia (low blood sugar) and worsening control of blood glucose are also common in patients with pre-existing diabetes mellitus.

Others

Commonly: vision abnormalities

Rarely: renal failure and renal function abnormalities in patients with diffuse vascular disease and/or impaired renal function

Undesirable effects in hypertension and the long term management of coronary heart disease

The profile of adverse events associated with the use of carvedilol in the treatment of increase in blood pressure and the long term management of coronary heart disease is consistent with that observed in chronic heart failure. The incidence of adverse events in these patient populations is lower, however. Adverse experiences reported in clinical trials in patients with increase in blood pressure and coronary heart disease are;

Central nervous system

Common: dizziness, headaches and fatigue, which are usually mild and occur particularly at the beginning of treatment.

Uncommon: depressed mood, sleep disturbance, numbness.

Cardiovascular system

Common: decrease in heart beats, postural hypotension and short loss of consciousness, especially at the beginning of treatment.

Uncommon: disturbance of peripheral circulation (cold extremities, PVD, exacerbation of cramping pains in the buttock or leg muscles and small blood vessels of the fingers become narrow), AV-block, angina pectoris (including chest pain), symptoms of heart failure and peripheral edema (accumulation of fluid in cell tissue causing swelling).

Respiratory system

Common: Asthma and shortness of breath.

Rare: Stuffy nose.

Gastro-intestinal system

Common: gastro-intestinal upset (with symptoms such as nausea, abdominal pain, diarrhea).

Uncommon: constipation and vomiting.

Skin and appendages

Uncommon: skin reactions (eg. Viral rashes, skin inflammation, urticaria and pruritis).

Blood chemistry and hematology

Isolated cases of increases in ALAT and gamma GT, low platelets count and decrease in white blood cells have been reported.

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Others

Common: pain in extremities.

Common: reduced secretion of tears and eye irritation.

Uncommon: cases of sexual impotence and disturbed vision.

Rare: dryness of mouth and disturbances of urination.

Isolated cases of allergic reactions have been reported.

If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

- MAL number:

Karvil 6.25mg : MAL*****

Karvil 25mg : MAL*****

Manufacturer

Torrent Pharmaceuticals LTD.

Indrad 382 721, District: Mehsana
INDIA.

Product Registration Holder

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Date of revision

18/11/2015

Storage and Disposal of Karvil

- Storage

Store below 30°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

KARVIL TABLETS 6.25 MG

White to off-white, round, flat uncoated tablets with break line on one side and plain on other side.

KARVIL TABLETS 25 MG

White to off-white, round, flat uncoated tablets with break line on one side and plain on other side.

Ingredients

- Active ingredient(s)

Carvedilol

- Inactive ingredients

Lactose Monohydrate

Sucrose(Pharma grade)

Polyvinyl Pyrrolidone(K-30)

Crospovidone XL-10

Magnesium Stearate

Colloidal silicon dioxide

Purified water