

VACODIL TABLETS

Carvedilol (6.25mg, 25mg)

What is in this leaflet

1. What Vacodil is used for
2. How Vacodil works
3. Before you use Vacodil
4. How to use Vacodil
5. While you are using it
6. Side effects
7. Storage and Disposal of Vacodil
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Vacodil is used for

Vacodil is primarily used for management of essential hypertension. It can be used alone or in combination with other antihypertensive agents.

Vacodil is also used for the treatment of chest pain and chronic heart failure.

How Vacodil works

The active ingredient Carvedilol dilates blood vessels and reduce fluid retention. It also acts as an antioxidant and reduces the heart oxygen demand.

Before you use Vacodil

- When you must not use it

Do not use Vacodil:

- if you have hypersensitivity to carvedilol or any component of the product
- if you have heart failure
- if you have liver dysfunction

Vacodil must not be used in patients with other beta-blockers:

- Heart block
- Severe condition of slow heart rate
- Heart rhythm disorder
- Severe low blood pressure
- Cardiogenic shock (heart suddenly can't pump enough blood to meet your body's needs)
- History of asthma

Pregnancy and lactation

Do not take Vacodil if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Vacodil if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor before you start taking Vacodil. Tell your doctor if you have any of the following:

- severe heart failure with low blood pressure
- chronic inflammatory lung disease
- diabetes mellitus
- blood circulation disorder
- history of serious hypersensitivity reactions
- history of skin condition associated with beta-blocker therapy (medications that reduce blood pressure)
- pheochromocytoma (Tumor that forms in the center of the adrenal gland (gland located above the kidney))
- wear contact lenses, as there is a possible reduced flow of tears
- heart disease

Caution should be exercised in patients undergoing general surgery, because of the synergistic negative inotropic effects of Vacodil and anesthetic drugs.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

- Digoxin (medicine to treat various heart conditions)
- Insulin or oral hypoglycemic (medicine to treat type 1 and type 2 diabetes)
- Inducers and inhibitors of hepatic metabolism
- Catecholamine-depleting agents, a drug that can deplete catecholamines, which plays a role in body's physiological response to stress

- Cyclosporine, medicine to prevent organ rejection in people who have received a liver, kidney, or heart transplant
- Verapamil, diltiazem, or other antiarrhythmics, to treat hypertension, chest pain, and certain heart rhythm disorders.
- Clonidine, medicine to treat high blood pressure
- Calcium channel blockers, medicine to treat a variety of conditions, such as high blood pressure, chest pain and Raynaud's disease
- Certain sedatives and drugs, medicines for treating depression

How to use Vacodil

- How much to use

Duration of treatment

Treatment with carvedilol is a long-term therapy. Treatment should not be stopped abruptly but rather gradually reduced at weekly intervals.

Essential hypertension

The recommended dose for initiation of therapy is 12.5 mg daily. May be increased if necessary up to a maximum of 50mg daily.

Chest pain

The recommended dose for initiation of therapy is 12.5 mg twice a day. May be increased if necessary up to a maximum of 100mg daily.

Symptomatic, stable, chronic heart failure

Dosage tailored to suit the individual. The recommended dose initially is 3.125 mg twice daily and may thereafter be increased. Doses should be increased to the highest level tolerated by the patient.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Vacodil for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdosage include low blood pressure, abnormally slow heart action, heart failure, and cardiogenic shock (heart suddenly can't pump enough blood to meet body's needs). There may also be respiratory problems, bronchospasm (sudden constriction of the muscles in the walls of the bronchioles), vomiting, disturbed consciousness and generalized seizures.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Vacodil.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Vacodil to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Vacodil can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe. For chronic heart failure,

- Central nervous system: mild dizziness, headaches and fatigue
- Cardiovascular system: slow heart rate, postural hypotension (blood pressure falls when standing or sitting), low blood pressure, swelling caused by fluid retention, heart block and cardiac failure
- Gastro-intestinal system: nausea, diarrhea and vomiting
- Hematology: low blood platelet, low white blood cells has been reported in isolated cases
- Metabolic: weight increase and high cholesterol. High blood sugar, low blood sugar and worsening control of blood glucose are also common in patients with pre-existing diabetes mellitus
- Others: vision abnormalities, renal failure and renal function abnormalities

For hypertension and the long-term management of coronary heart disease,

- Central nervous system: mild dizziness, headaches and fatigue, depressed mood, sleep disturbances, paresthesia
- Cardiovascular system: slow heart rate, postural hypotension (blood pressure falls when standing or sitting) and uncommonly fainting, heart block, chest pain, symptoms of

heart failure and swelling of lower legs or hands.

- Respiratory system: asthma and shortness of breath and stuffy nose
- Gastro-intestinal system: gastro-intestinal upset (with symptoms such as nausea, abdominal pain, diarrhea). Uncommonly, constipation and vomiting.
- Skin and appendages: skin reactions
- Blood chemistry and hematology: increase in blood components.
- Others: pain in the extremities, reduced lacrimation and eye irritation, sexual impotence and disturbed vision, dryness of the mouth and disturbances in urination and allergic reactions.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Vacodil

- Storage

Store below 30°C. Store in the original container (sensitive to light).

- 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

VACODIL 6.25MG TABLETS:

White to off-white, oval shaped, film-coated tablets debossed with 'F 57' on one side and deep break line on the other side.

VACODIL 25MG TABLETS:

White to off-white, oval shaped, film-coated tablets debossed with 'F 59' on one side and deep break line on the other side.

- **Ingredients**

- Active ingredient(s)
Carvedilol Ph. Eur 6.25mg/25mg

- Inactive ingredients
Polysorbate 80, Polyethylene Glycol 400, Crospovidone type A&B, Colloidal Anhydrous Silica, Lactose Monohydrate, Titanium Dioxide, Povidone, Magnesium Stearate, Sucrose, Hypermellose and Purified water.

- **MAL number(s):**

VACODIL 6.25MG TABLET:

MAL09100262AZ

VACODIL 25MG TABLET:

MAL09100261AZ

Manufacturer

Aurobindo Pharma Limited,
Unit III, Survey No. 313-314,
Bachupally Village, Bachupally
Mandal, Medchal-Malkajgiri District
Hyderabad, Telangana, 500090, India

Product Registration Holder

UNIMED SDN BHD
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Bandar Sri Damansara,
52200, Kuala Lumpur, Malaysia.

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