

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 more 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.

VEDICOR 6.25 mg tablets
VEDICOR 12.5 mg tablets
VEDICOR 25 mg tablets
carvedilol

What is in this leaflet:

1. What **VEDICOR** is and what it is used for
2. What you need to know before you take **VEDICOR**
3. How to take **VEDICOR**
4. Possible side effects
5. How to store **VEDICOR**
6. Contents of the pack and other information

1. What **VEDICOR** is and what it is used for

VEDICOR belongs to a group of medicines called beta-blockers that work by relaxing and widening the blood vessels. This makes it easier for your heart to pump blood around the body and reduces blood pressure and strain on your heart.

VEDICOR is used:

- for the treatment of high blood pressure (hypertension),
- for the treatment of chest pain that occurs when the arteries that supply your heart with blood carrying oxygen are narrowed which results in less oxygen reaching your heart muscles (angina),
- for the treatment of weakening of the heart muscle (heart failure), in combination with other medicines.

2. What you need to know before you take **VEDICOR**

DO NOT TAKE **VEDICOR**:

- if you are allergic to **VEDICOR** or any of the other ingredients of this medicine (listed in section 6).
 - if you have a history of wheezing due to asthma or other lung diseases,
 - if you have been told you have very severe heart failure and you have fluid retention (swelling) which is being treated with injections of medicines into your veins (intravenously),
 - if you have liver disease,
 - if you have been told that you have a very slow heartbeat,
 - if you have very low blood pressure,
 - if you have been told you have a condition called Prinzmetal's angina,
 - if you have phaeochromocytoma (a tumour of the adrenal gland causing high blood pressure) which is not being treated,
 - if you are suffering from serious disturbances in the body's acid-base balance (metabolic acidosis),
 - if you have very poor blood circulation in the hands and feet resulting in coldness and pain in them,
 - if you have a particular conduction defect of the heart (called an AV heart block Grade II or III (unless a pacemaker is fitted) or a SA block),
 - if you are currently being treated with injections of verapamil or diltiazem (used in the treatment of high blood pressure or heart problems),
- If any of these apply to you, do not take **VEDICOR**.

Warnings and precautions

Talk to your doctor or pharmacist before taking **VEDICOR**:

- have been told you suffer from any other heart problems,
- have or have ever had any problems with your liver kidneys or thyroid, have diabetes. **VEDICOR** may hide your usual symptoms of low blood sugar, have a skin condition known as psoriasis,
- have poor circulation affecting hands, feet or lower legs, or Raynaud's phenomenon,
- have or have ever had a serious allergic reaction or you are undergoing allergic desensitisation therapy for any type of severe allergy, wear contact lenses because

VEDICOR may cause the eyes to be drier than normal.

Other medicines and **VEDICOR**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The administration of **VEDICOR**:

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

Take particular care and tell your doctor or pharmacist, if you are taking any of the following medicines:

- medicines used to treat an irregular heartbeat (e.g. diltiazem, verapamil or amiodarone), nitrate medicines for angina (e.g. isosorbide mononitrate or glyceryl trinitrate),
- medicines used to treat heart failure (e.g. Digoxin), any other medicine used to treat high blood pressure (e.g. doxazosin, reserpine, amlodipine or indoramin),
- medicines used to treat depression or other mental health conditions (e.g. fluoxetine, tricyclic antidepressants, barbiturates, phenothiazines, haloperidol or monoamine oxidase inhibitors (MAOIs),
- medicines used to prevent your body rejecting organs after transplant operations (e.g. ciclosporin),
- medicines to reduce blood sugar such as oral antidiabetic medicines or insulin,
- medicines used to reduce blood pressure or to treat migraine (e.g. clonidine or ergotamine), certain painkilling agents such as non-steroidal anti-inflammatory medicines (NSAIDs) (e.g. ibuprofen or diclofenac), medicines used for hormone replacement therapy (e.g. estrogens), corticosteroids used to suppress inflammatory or allergic reactions (e.g. prednisolone),

- medicines used to treat bacterial infections (e.g. rifampicin or erythromycin),
 - medicines used to treat stomach ulcers, heartburn and acid reflux (e.g. cimetidine),
 - medicines used to treat fungal infections (e.g., ketoconazole),
 - medicines sometimes used in decongestant cough and cold remedies (e.g. ephedrine or pseudoephedrine),
- If you need to have an anaesthetic for an operation, tell your hospital doctor you are taking **VEDICOR**.

VEDICOR with food, drink and alcohol

You should take **VEDICOR** with water. If you are taking **VEDICOR** to treat heart failure, you should take this medicine with water at your mealtime (see section 3. How to take **VEDICOR**). Do not drink alcohol whilst taking **VEDICOR** as it might worsen the effects of alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, do not take this medicine until you have talked to your doctor. Consult your doctor immediately if you become pregnant while taking this medicine.

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

You may experience dizziness or tiredness whilst taking **VEDICOR**. This is more likely to occur when you first begin treatment, or when the dose is increased. If this occurs, you should not drive or operate machinery. You should avoid drinking alcohol, as it may make these symptoms worse. If you are concerned or want more information, you should talk to your doctor.

VEDICOR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take **VEDICOR**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. **VEDICOR** should be swallowed with a drink of water.

High blood pressure

Adults: The usual starting dose is 12.5 mg once a day for the first two days. After this, the dose is increased to 25 mg once a day. If necessary, your doctor may gradually increase the dose further at intervals of two weeks or more.

The maximum recommended daily dose is 50 mg (the maximum recommended single dose is 25 mg).

Elderly: Your doctor will usually start you on 12.5 mg once a day and continue with this dose for the length of your treatment. If necessary, your doctor may increase your dose gradually at intervals of two weeks or more.

Angina

Adults: The usual starting dose is 12.5 mg twice a day for the first two days. After this, the dose is increased to 25 mg twice a day. If necessary, your doctor may gradually increase the dose further at intervals of two weeks or more to a maximum of 100 mg a day in two doses.

Elderly: The recommended starting dose is 12.5 mg twice a day for two days. After this, the dose may be increased to 25 mg twice a day, which is the recommended maximum daily dose.

Heart failure

Adults and elderly: For the treatment of stable heart failure, the tablets should be taken twice a day, in the morning and in the evening, and should be taken with food in order to reduce the risk of side effects.

The starting dose is 3.125 mg twice a day for two weeks. Your doctor will then gradually increase the strength of tablets you take at intervals of two weeks or more until you receive the dose that suits you best.

If you weigh less than 85 kg, the maximum recommended dose of **VEDICOR** is 25 mg twice a day, if you weigh more than 85 kg, your doctor may increase your dose to 50 mg twice a day. For the treatment of heart failure, it is recommended that your treatment with **VEDICOR** is started and carefully monitored by a hospital specialist.

If you have stopped taking **VEDICOR** for more than two weeks, you will need to return to the starting dose and increase the dose gradually again. Sometimes, your heart failure may worsen while taking **VEDICOR**, particularly at the start of your treatment. This may result in increased symptoms (e.g. tiredness, shortness of breath) and signs of fluid retention (e.g. weight gain and swelling of the legs).

If your symptoms or condition worsen whilst taking **VEDICOR** you should tell your doctor, as he or she may need to change the dose of your other medications or of **VEDICOR**.

While taking **VEDICOR**, make sure that you continue with your other treatments for heart failure as advised by your doctor.

Patients with liver problems

Depending on your condition, your doctor may reduce your dose compared to those recommended above.

Children and adolescents (under 18 years old)

VEDICOR are not recommended in this age group.

If you take more **VEDICOR** than you should

If you accidentally take too many tablets, contact your doctor immediately or go to the nearest hospital casualty department. You may feel dizzy, sick, faint, breathless/wheezy, very drowsy, or experience convulsions.

If you forget to take **VEDICOR**

If you forget to take a dose, do not worry. Take another as soon as you remember, provided it is not nearly time for your next dose. Take your next tablet at the normal time, but do not take a double dose to make up for a forgotten tablet.

If you stop taking VEDICOR

Do not suddenly stop taking **VEDICOR** before you have spoken to your doctor about it. You may have side effects if you suddenly stop the tablets. Your doctor will tell you how to reduce the dosage gradually and then stop this medicine. If you are also taking a medicine called clonidine, never stop either treatment unless told to by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The frequency of possible side effects is shown in the table below:

The majority of side effects are dose-related and disappear when the dose is reduced or the treatment discontinued. Some side effects can occur at the beginning of treatment and resolve spontaneously as the treatment continues.

Very common: may affect more than 1 in 10 people

- Dizziness
- Headache
- Tiredness
- Low blood pressure
- Heart failure

Common: may affect up to 1 in 10 people

- Bronchitis, pneumonia, upper respiratory tract infection
- Infections of the urinary tract
- Low numbers of red blood cells
- Increase in weight
- Elevated cholesterol levels
- Loss of control of blood sugar in people with diabetes
- Depression, depressed mood
- Visual disturbance
- Reduced lacrimation, eye irritation
- Slow heart rate
- Oedema (swelling of the body or parts of the body), fluid overload, increased volume of blood in the body
- Dizziness when standing up quickly
- Problems with blood circulation (signs include cold hands and feet), hardening of the arteries (atherosclerosis) worsening of symptoms in patients with Raynaud's disease (fingers or toes turn first bluish, then whitish, and then reddish together with pain) or claudication (pain in the legs which worsens when walking)
- Asthma and breathing problems
- Fluid accumulation in the lungs
- Diarrhoea
- Malaise, vomiting, stomach pains, indigestion
- Pains (e.g. in the arms and legs)
- Acute renal insufficiency and disturbances in renal function in patients with hardening of the arteries and/or impaired renal function
- Difficulty in passing urine

Uncommon: may affect up to 1 in 100

- people
- Sleep disturbance
- Confusion
- Fainting
- Abnormal sensation
- Disturbances in the heart's conduction system, angina pectoris (including chest pain)
- Certain skin reactions (e.g. allergic dermatitis, hives, itching and skin inflammation increased sweating, psoriatic or lichen planus like skin lesions)
- Hair loss
- Impotence

Rare: may affect up to 1 in 1,000 people

- Lowered blood platelet count (thrombocytopenia)
- Mouth dryness (dryness of the mouth)
- Stuffy nose

Very rare: may affect up to 1 in 10,000

- people
- Low numbers of white blood cells
- Allergic reactions
- Changes in the liver function test
- Involuntary leakage of urine in women (urinary incontinence).
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis)

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.

5. How to store VEDICOR

Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month

6. Contents of the pack and other information

What VEDICOR contains

The active substance is **VEDICOR**. Each tablet contains 6.25mg, 12.5 mg or 25 mg **VEDICOR**.

-The other ingredients are: lactose monohydrate, microcrystalline cellulose, copovidone, crospovidone, colloidal silicon dioxide, magnesium stearate, titanium dioxide (E171), quinoline yellow (E104)

What VEDICOR looks like and contents of the pack

Box of 30 tablets, round with brake line on one side, of 6,25 mg carvedilol in blister pack (3 blisters x 10 tablets).

Box of 30 tablets, round with brake line on one side, of 12,5 mg carvedilol in blister pack (3 blisters x 10 tablets).

Box of 30 tablets, round with brake line on one side, of 25 mg carvedilol in blister pack (3 blisters x 10 tablets).

Manufacturer and Marketing Authorization Holder

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75300 Lukavac
Bosnia and Herzegovina

Date and number of marketing authorization

VEDICOR, tablet, 30 x 6,25 mg:

Number: 04-07.3-2-328/15

Date: 10.03.2015.

VEDICOR, tablet, 30 x 12,5 mg:

Number: 04-07.3-2-329/15

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