

Package leaflet: Information for the patient

Carvsanna 6.25 mg, 12.5 mg and 25 mg tablets

carvedilol

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.

What is in this leaflet

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

1. What Carvsanna is and what it is used for

Carvsanna belongs to the group of drugs, alpha- and beta blockers. Carvsanna is used in the treatment of high blood pressure and the treatment of angina pectoris. Carvsanna is also used as a supplementary treatment in heart failure.

2. What you need to know before you take Carvsanna

Do not take Carvsanna

- if you are allergic to carvedilol or to any of the other ingredients of this medicine (listed in section 6).
- if you have **untreated or unstable heart failure** or certain types of **disturbances in the conduction system of the heart** (so-called AV-block of type II and III unless you have a pacemaker, or so-called sick sinus node).
- if you are suffering from a severe **liver disease**.
- if you have a very **low pulse (less than 50 beats per minute)** or very **low blood pressure**.
- if you are suffering from severely **compromised cardiac function** (cardiogenic shock).
- if you are suffering from **serious disturbance in the body's acid-base balance** (metabolic acidosis, acidaemia).
- if you have **asthma** or other **respiratory diseases** with a tendency to tightness in the throat caused by cramping (e.g., chronic obstructive pulmonary disease).
- if you are suffering from severe breathing problems (acute **pulmonary embolism**)
- if you are suffering from an unusual form of angina pectoris (**Prinzmetal angina**)
- if you are suffering from heart failure following a respiratory disease (cor pulmonale)
- if you are suffering from an over function of the adrenal gland (**pheochromocytoma**) and this is not being treated with medication
- if you are taking **MAO inhibitors** (e.g. moclobemide) (except for MAO-B inhibitors)

- if you receive intravenous treatment with **verapamil, diltiazem** or another medicine used to treat heart rhythm disorders (antiarrhythmics)
- if you are **breast-feeding**

Warnings and precautions

Talk to your doctor or pharmacist before taking Carvsanna.

Your doctor will prescribe Carvsanna with special caution in the following situations:

- if you have **heart failure** accompanied by
 - low blood pressure,
 - **compromised blood and oxygen supply to the heart** (ischaemic heart disease) and **hardening of the arteries** (atherosclerosis),
 - and/or **kidney problems**.
 Your renal function should be monitored then. It may be necessary to reduce your dose.
- if you have had a **heart attack**. This condition must be treated sufficiently before taking Carvsanna.
- if you have a certain type of **disturbances in the conduction system of the heart** (so-called AV-block of type I).
- if you have hypertension due to organic reasons.
- if you have **diabetes**. Treatment with Carvsanna may mask the signs of low blood sugar. Your blood sugar should therefore be monitored regularly.
- if you have severely **poor blood circulation in the hand and feet**.
- simultaneous treatment with medicines used to treat heart failure (digitalis glycosides) or heart rhythm disorders (e.g. verapamil, diltiazem)
- low blood pressure (orthostatic hypotension)
- acute inflammatory heart disease
- a tightening of the heart valves or the outflow tract
- end-stage peripheral artery disease
- labile or secondary hypertension
- simultaneous treatment with some other blood pressure-lowering medicines (alpha1-receptor antagonists or alpha2-receptor agonists)
- if you have **Raynaud's phenomenon** (fingers or toes turn first bluish, then whitish and then reddish together with pain). Carvsanna may worsen the symptoms.
- if you have **over function of thyroid gland**, with elevated production of thyroid hormone, Carvsanna may mask the symptoms.
- if you are using Carvsanna and are to undergo an **operation** involving an anaesthetic. You should discuss this with the doctor responsible for the anaesthesia well in advance.
- if you have a very **low pulse (less than 55 beats per minute)**.
- if you have had a serious **allergic reaction** (e.g. to an insect bite or food) or if you are undergoing or are due to undergo **allergic desensitisation therapy**. Carvsanna may increase your sensitivity to allergens and your risk of having serious anaphylactic reactions. Also, while taking Carvsanna, medicines used to treat allergic (anaphylactic) reactions such as adrenalin (epinephrine), may be less effective.
- if you have **psoriasis**.
- severe skin reactions (e.g. toxic epidermal necrolysis [TEN] or Stevens-Johnson syndrome [SJS])
- if you use **contact lenses**. Carvsanna may reduce tear production.

Withdrawal syndrome

Treatment with Carvsanna should not be stopped suddenly. This applies in particular to patients with a heart disease caused by reduced blood flow in the coronary heart vessels. Instead, the dose should be reduced gradually over a period of 2 weeks.

Children and adolescents

The safety of Carvsanna in children and adolescents below 18 years of age has not been established. Carvsanna is therefore not recommended for use in children and adolescents below 18 years of age.

Elderly

Elderly patients can be more sensitive to carvedilol and must be monitored more carefully.

Other medicines and Carvsanna

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Other concomitant drug treatment may affect or be affected by Carvsanna.

It is **especially important** that your doctor be aware if you are already being treated with:

- **Digoxin** or **digitoxin** (to treat heart failure).
- **Insulin** or **oral anti-diabetic medicines** (blood sugar reducing agents) as their blood sugar reducing effect can be increased and the symptoms of low blood sugar covered up.
- **Rifampicin** (antibiotic used in treating tuberculosis).
- **Carbamazepine** (medicine to treat epilepsy).
- **Fluconazole** (medicine to treat mycosis).
- **Paroxetine, fluoxetine, bupropion** (medicine to treat depression).
- Drugs containing **reserpine, guanetidine, methyldopa, guanfacine** and **monoaminooxidase inhibitors** (MAOIs) (medicines to treat depression and Parkinson's disease), as these may give rise to further reduction in the heart rate.
- **Ciclosporin or tacrolimus** (medicine to suppress the immune system, to prevent ejective reactions after organ transplantation also used for e.g., certain rheumatic or dermatological problems).
- Medicines to treat irregular heartbeat (**e.g. verapamil, diltiazem, quinidine, amiodarone**).
- **Clonidine** (medicine to reduce blood pressure).
- **Sympathomimetics** (drugs which increase the function of the sympathetic nervous system).
- Medicines used to treat breathing problems (e.g. **salbutamol, formoterol**).
- **Dihydropyridines** (medicine to treat high blood pressure and heart diseases).
- **Other blood pressure reducing drugs**. Carvsanna can enhance the effects of other blood pressure reducing drugs given concurrently (e.g. **alpha₁-receptor antagonists, nitrates**) and drugs where reduction in blood pressure transpires as a side effect, e.g. **barbiturates** (in the treatment of epilepsy), **phenothiazines** (to treat psychoses), tricyclic **antidepressants** (in the treatment of depression) **vasodilating drugs** (drugs for widening the blood vessels).
- **Neuromuscular blocking preparations** (drugs which reduce muscle tension).
- **Ergotamine** (migraine medicine).
- **Anaesthetics** (drugs used in anaesthesia).
- **Certain painkilling tablets** (NSAID), **oestrogens** (hormones) and **corticosteroids** (adrenal hormone), as these can in some instances reduce the blood pressure reducing effect of Carvsanna.
- **Cinacalcet** (medicine used to treat problems with parathyroid glands).

Carvsanna with food, drink and alcohol

Taking Carvsanna at the same time as or close to grapefruit or grapefruit juice should be avoided while the treatment is being introduced. Grapefruit and grapefruit juice can lead to an increase in the amount of the active substance carvedilol in the blood and possibly to unpredictable side effects. Consuming alcohol during therapy with Carvsanna should be limited, as alcohol can affect how Carvsanna works.

Pregnancy and 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.

There is a risk of harm to the unborn child. Carvsanna should only be used during pregnancy if your doctor deems it necessary. Always, therefore, consult your doctor before using Carvsanna during pregnancy.

It is not known whether Carvedilol passes over in human breast milk and should therefore not be used during breastfeeding.

Driving and using machines

Dizziness and tiredness may occur at the beginning of treatment, after dose increase, on changing products or in combination with alcohol. At correct dose levels it is not known whether Carvedilol impairs the ability to drive or use machines. If you feel dizzy or weak when taking the tablets, you should avoid driving or work involving sharp attention.

Carvsanna 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 Carvsanna

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you feel that the effects of Carvsanna are too strong or too weak, talk to your doctor or pharmacist.

You should swallow the tablets with at least half a glass of water. You can take the tablets with or without food. Patients with heart failure should however take the tablets with food in order to reduce the risk of dizziness on sudden standing.

The tablets can be divided into equal doses.

Carvsanna tablets are available in the following strengths: 6.25 mg, 12.5 mg and 25 mg

High blood pressure

Adults

The normal dose is 1 tablet Carvsanna 12.5 mg (corresponding to 12.5 mg carvedilol) for the first two days and 2 tablets Carvsanna 12.5 mg (corresponding to 25 mg carvedilol) once daily thereafter. For this dosage, other strengths of Carvedilol are available.

If necessary the dose may be further increased gradually at intervals of at least two weeks. The recommended maximum daily dose is 50 mg.

Elderly

The recommended dose is 1 tablet Carvsanna 12.5 mg (corresponding to 12.5 mg carvedilol) once daily.

If necessary, the dose may be further increased gradually at intervals of at least two weeks to the maximum daily dose of 50 mg.

Angina pectoris

Adults

The normal dose is 1 tablet Carvsanna 12.5 mg (corresponding to 12.5 mg carvedilol) twice daily for two days and 2 tablets Carvsanna 12.5 mg (corresponding to 25 mg carvedilol) twice daily thereafter. For this dosage, other strengths of Carvsanna are available.

If necessary the dose may be further increased gradually at intervals of at least two weeks. The recommended maximum daily dose is 100 mg.

Elderly

The normal dose is 1 tablet Carvsanna 12.5 mg (corresponding to 12.5 mg carvedilol) twice daily for two days and 2 tablets Carvsanna 12.5 mg (corresponding to 25 mg carvedilol) twice daily thereafter. The recommended maximum daily dose is 50 mg.

Heart failure

The normal starting dose is 3.125 mg carvedilol twice daily for two weeks. The dose may be increased incrementally, usually at two week intervals.

The dose may however need to be increased or reduced. Your doctor will advise you accordingly. The recommended maximum daily dose is 25 mg given twice daily in patients weighing less than 85 kg and 50 mg twice daily in patients weighing more than 85 kg, provided that heart failure is not severe. A dose increase to 50 mg twice daily should be performed carefully under close medical supervision.

If you take more Carvsanna than you should

If you have taken more Carvsanna than you should, or if children have been taking medicine by accident, please contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on action to be taken.

Symptoms of overdose can include feelings of faintness due to excessively low blood pressure, slow heart rate and in serious instances occasional missed heartbeats. Breathing difficulties, constricted airways, malaise, lowered level of consciousness and seizures may occur.

If you forget to take Carvsanna

If you forget a dose (or more doses), take the next dose when it is the normal time to take it. Do not take a double (or a larger) dose to make up with the forgotten dose(s).

If you stop taking Carvsanna

Do not suddenly stop your treatment or change the dose unless instructed by your doctor. Your treatment should be phased out gradually over a period of two weeks. Any sudden discontinuation can make your symptoms worse.

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 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
- Heart failure
- Low blood pressure
- Weakness

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
- Fainting
- 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, nausea, 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, hallucinations
- Nightmares
- 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)
- Constipation
- Impotence

Rare (may affect up to 1 in 1,000 people)

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

Very rare (may affect up to 1 in 10,000 people, including isolated cases)

- Low numbers of white blood cells
- Psychosis
- Allergic reactions
- Severe skin reactions, including blistering, red or purple marks or peeling of the skin. It can also affect the mouth, eyes and other mucous membranes. (Stevens-Johnson syndrome, toxic epidermal necrolysis or Erythema multiforme)
- Changes in the liver function test
- Involuntary leakage of urine in women (urinary incontinence).

Not known (frequency cannot be estimated from the available data)

- Hair loss

The drug class of beta-receptor blockers can trigger hidden diabetes.

Excessive sweating can occur (hyperhidrosis).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in **Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Carvsanna

Keep this medicine out of the sight and reach of children.

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

Blister (PVC/PVdC-Aluminium)

6.25 mg:

Do not store above 30°C.

Store in the original package in order to protect from light.

12.5 mg and 25 mg:

Store in the original package in order to protect from light.

This medicinal product does not require any special temperature storage conditions.

Blister (OPA/Aluminium/PVC-Aluminium)

Store in the original package in order to protect from light.

This medicinal product does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Carvsanna contains

- The active substance is carvedilol.
Each tablet contains 6.25/12.5/25 mg of carvedilol.
- The other ingredients are cellulose microcrystalline, lactose monohydrate, crospovidone, povidone, silica, colloidal anhydrous, magnesium stearate.

What Carvsanna looks like and contents of the pack

6.25 mg tablets: white, biconvex, capsule shaped tablets debossed "C" with breakline and "2" on one side and plain on the other.

12.5 mg tablets: white, biconvex, capsule shaped tablets debossed "C" with breakline and "3" on one side and plain on the other.

25 mg tablets: white, biconvex, capsule shaped tablets debossed "C" with breakline and "4" on one side and plain on the other

Pack sizes: 10, 14, 28, 30, 50, 56, 60, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden:

Carvsanna 6,25/12,5/25 mg tablett

Germany:

Carvedilol AbZ 12,5/25 mg Tabletten

This leaflet was last revised in 11 December 2025.

[To be completed nationally]

QR code and URL [To be completed nationally]

<Other sources of information>

<Latest approved information on this medicine (<Summary of product characteristics> <and> Package Leaflet) is available by scanning the <QR code> included in the <PL> <outer carton> with a smartphone/device. The same information is also available on the following URL: {URL} to be included <and the {NCA} website>>