**Package leaflet: Information for the patient**

**Carvedilol Krka 3.125 mg tablets**
**Carvedilol Krka 6.25 mg tablets**
**Carvedilol Krka 12.5 mg tablets**
**Carvedilol Krka 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 Carvedilol Krka is and what it is used for

Carvedilol Krka contains a medicine called carvedilol. This belongs to a group of medicines called 'betablockers'.

Carvedilol Krka 3.125 mg and 6.25 mg tablets are used to treat the following:
- Congestive heart failure.
- High blood pressure (hypertension).

Carvedilol Krka 12.5 mg and 25 mg tablets are used to treat the following:
- Congestive heart failure.
- High blood pressure (hypertension).
- Angina (chest pain or discomfort that happens when your heart isn't getting enough oxygen).

Carvedilol Krka works by making your blood vessels relax and widen.
- This helps to lower your blood pressure.
- If you have congestive 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.

Your doctor may give you other medicines as well as Carvedilol Krka to help treat your condition.

## 2. What you need to know before you take Carvedilol Krka

**Do not take Carvedilol Krka**
- if you are allergic (hypersensitive) to carvedilol or any of the other ingredients of this medicine (listed in section 6).
- if your heart failure has worsened recently (you have severe fluid retention and are breathless, even when sitting) and you are receiving intravenous medication to help your heart work.

- if you have a history of wheezing due to asthma.
- if you have liver disease.
- if you have a conduction defect of the heart (or 'heart block').
- if you have a slow heartbeat (less than 50 beats per minute).
- if you have sick sinus sydrome (irregular heartbeat).
- if you suffer from cardiogenic shock (a state in which a weakened heart is unable to pump enough blood to meet the body's needs).
- if you have very low blood pressure (systolic blood pressure below 85 mm Hg).

If any of the above apply to you, consult your doctor or pharmacist before taking Carvedilol Krka.

**Warnings and precautions**
Check with your doctor or pharmacist before taking Carvedilol Krka if:
- you have a condition called Prinzmetal's angina (cardiac chest pain that occurs at rest)
- you suffer from any other heart problems.
- you have lung disease (this includes asthma and chronic obstructive pulmonary disease). This medicine may cause wheezing or spasm in the lung.
- you have had any problems with your liver, kidneys or thyroid.
- you have diabetes (high blood sugar).
- you have a skin condition known as psoriasis, after taking beta-blocker medicines.
- you have a circulation disorder (usually affecting the fingers) called Raynaud's phenomenon.
- you have an allergy and are having treatment to desensitize you.
- you have ever had a serious allergic reaction (for example, sudden swelling causing difficulty breathing or swallowing, swelling of the hands, feet or ankles, or a severe rash).
- you wear contact lenses (you may notice that your eyes become drier than usual).
- you have problems with your blood vessels (peripheral vascular disease).
- you have phaeochromocytoma (a tumour of the adrenal gland causing high blood pressure). An initial treatment with appropriate medicines (alpha-blockers) should be started before using any beta-blocker.

**Other medicines and Carvedilol Krka**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Be sure to advise if you are taking any of the following medicines:
- calcium channel blockers e.g. verapamil or diltiazem (for irregular heartbeat)
- antiarrhythmics, e.g. amiodarone (for irregular heartbeat)
- any other medicine that may additionally decrease the heart rate, e.g. reserpine
- medicines known as monoamine oxidase inhibitors e.g. isocarboxide and phenelzine (for depression)
- fluoxetine and paroxetine (used to treat depression)
- digoxin (for heart failure)
- medicines for your blood pressure, including diuretics (water tablets) (Carvedilol Krka may intensify the effect of these medicines)
- antidiabetic medicines (metformin) or insulin (Carvedilol Krka may intensify the effects of these medicines)
- clonidine (for migraine, menopausal flushing, high blood pressure or Tourette's syndrome)
- ciclosporin or tacrolimus (for preventing rejection of a transplanted organ)
- rifampicin (used to treat bacterial infections, including tuberculosis)
- non-steroidal anti-inflammatory drugs (NSAIDs)
- beta-agonist bronchodilators (used to treat chest tightness and wheezing due to asthma or other chest conditions).
- adrenaline/epinephrine (used to treat severe allergic reactions).

**Carvedilol Krka with food, drink and alcohol**

Taking Carvedilol Krka simultaneously or promptly with grapefruit or grapefruit juice should be avoided. Grapefruit or grapefruit juice can lead to an increase in the active ingredient carvedilol in the blood and cause unpredictable adverse effects.
Do not drink alcohol while taking Carvedilol Krka. It could cause your blood pressure to fall too low and increases the risk of you getting side effects.

**Operations**
Tell your hospital doctor you are taking carvedilol if you need to have an anaesthetic for surgery. Beta-blockers reduce the risk of arrhythmias during anaesthesia; however, the risk of hypotension (low blood pressure) may be increased.

**Carvedilol Krka with food and drink**
Take the tablets with a drink of water, without chewing or crushing them. Patients with congestive heart failure should take Carvedilol Krka with food.

**Pregnancy, fertility and breast-feeding**
Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, trying to get 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.
You should not breast-feed during treatment with Carvedilol Krka.

**Driving and using machines**
If you feel tired or dizzy while taking your tablets, you should not drive or operate machinery. This is more likely when you start treatment or if your treatment is changed, and when you drink alcohol. Consumption of alcohol should be avoided, as these symptoms may be made worse. 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 Carvedilol Krka.

**Carvedilol Krka contains lactose and sucrose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. How to take Carvedilol Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Carvedilol Krka 3.125 mg, 6.25 mg, 12.5 mg and 25 mg tablets are used to treat High blood pressure and Congestive heart failure:

**High blood pressure:**

In patients with high blood pressure, the recommended maximum single dose is 25 mg and the recommended maximum daily dose is 50 mg.

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

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

**Congestive heart failure:**

*Adults and elderly*
**While taking Carvedilol Krka, make sure that you continue with your other treatments for heart failure as advised by your doctor.**

In heart failure patients, treatment with Carvedilol Krka is recommended to be started and supervised by a hospital specialist.

The tablets should be taken twice a day – in the morning and in the evening.

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.
For patients with a body weight of less than 85 kg, the recommended maximum single dose is 25 mg and the recommended maximum daily dose is 50 mg.

For patients with a body weight above 85 kg, the recommended maximum single dose is 50 mg and the recommended maximum daily dose is 100 mg.

Carvedilol Krka 12.5 mg and 25 mg tablets are used to treat Angina:

**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.
If your angina is not under control, your doctor may increase your dose slowly, over several weeks up to 50 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).

**Patients with kidney problems**
Dose adjustment may be required, depending on your blood pressure. Your doctor will decide which dose is best suited for you.

**Patients with liver disease**
Carvedilol Krka should not be taken by patients with liver problems.

**Patients undergoing surgery**
Tell your hospital doctor you are taking Carvedilol Krka if you need to have an anaesthetic for surgery. This is because some anaesthetics can lower your blood pressure and it may become too low.

**Use in children and adolescents**
Carvedilol Krka tablets are not recommended for use in children under 18 years of age.

**If you take more Carvedilol Krka than you should**
If you accidentally take too many tablets (overdose), you or someone else should contact your nearest hospital casualty department or tell your doctor immediately.

The following effects may happen if you have taken more tablets than you should: being sick, a slow heartbeat or even sudden cessation of heart beating, feeling dizzy or light headed, becoming breathless, convulsions (a person's body shakes rapidly and uncontrollably), feeling wheezy or extremely tired.

In cases of severe overdose, urgent treatment in a hospital Intensive Care Unit is necessary.

Duration of the antidote treatment depends on the seriousness of the overdose; supportive treatment must be continued until the patient stabilises.

**If you forget to take Carvedilol Krka**
Do not take a double dose to make up for a forgotten tablet. Take another as soon as you remember. 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 Carvedilol Krka**
You should always consult with your doctor before stopping Carvedilol Krka treatment. You should not stop Carvedilol Krka treatment abruptly as this can temporarily make your condition worse. Your doctor may want you to stop taking Carvedilol Krka slowly over a period of two weeks.

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 possible side effects and how likely you are to get them will depend on the reason you are being treated with Carvedilol Krka.

**If you experience any of the following, contact your doctor or go to a hospital immediately:**

**Severe allergic reactions.** Signs may include sudden swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.

**Chest pains** accompanied by shortness of breath, sweating and feeling sick.

**Passing water (urinating) less often** with swelling of legs, indicating problems with your kidneys.

**Very low blood sugar (hypoglycaemia)** which might cause seizures or unconsciousness.

Skin reactions  Very rarely, severe skin conditions (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) can occur. Redness, often associated with blisters may appear on the skin or mucous membranes, such as the inside of the mouth, the genital areas or the eyelids. These can appear initially as circular patches often with central blisters, which may progress to widespread peeling of the skin and can be life threatening. These serious skin reactions are often preceded by headache, fever and body aches (flu-like symptoms).

**Very common (affect more than 1 in 10 people):**
- Feeling dizzy.
- Headache.
- Feeling weak and tired.
- Problems with your heart. The signs include chest pains, tiredness, shortness of breath and swelling of your arms and legs.
- Low blood pressure. The signs include feeling dizzy or lightheaded.

Feeling dizzy, having a headache and feeling weak and tired are usually mild and more likely to happen at the beginning of your treatment.

**Common (affect less than 1 in 10 people):**
- Infections of the airway (bronchitis), lung (pneumonia), nose and throat (upper respiratory tract). The signs include wheezing, shortness of breath, chest tightness and sore throat.
- Infections of the urinary tract which can cause problems in passing water.

- Low numbers of red blood cells (anaemia). The signs include feeling tired, pale skin, a fluttering sensation in your heart (palpitations) and being short of breath.
- Increase in weight.
- Increase in cholesterol levels (shown by a blood test).
- Loss of control of blood sugar in people with diabetes.
- Feeling depressed.
- Fainting.
- Problems with your sight, sore or dry eyes due to fewer tears being made.
- A slow heart beat.
- Feeling dizzy or light-headed after standing up.
- Fluid retention. The signs include: overall swelling of your body, swelling of parts of your body, for example your hands, feet, ankles and legs, and an increase in how much blood you have in your body.
- Problems with blood circulation in your arms and legs. The signs include cold hands and feet, whiteness, tingling and pain in your fingers and a pain in your leg which gets worse when you walk.
- Breathing problems or asthma.
- Fluid build-up in the lungs (pulmonary oedema).
- Feeling sick or being sick.
- Diarrhoea.
- Stomach pain/indigestion.
- Pain, possibly in your hands and feet.
- Problems with your kidneys, including changes to how often you pass urine.

**Uncommon (affect less than 1 in 100 people):**
- Disturbed sleep.
- Tingling or numbness of your hands or feet.
- Chest pain (angina pectoris).
- Heart failure.
- Problems with your skin, including skin rashes which may cover a lot of your body, a lumpy rash (hives), feeling itchy and dry skin patches.
- Hair loss.
- Being unable to get an erection (erectile dysfunction).
- Constipation.

**Rare (affect less than 1 in 1,000 people):**
- Low number of platelets in your blood. The signs include bruising easily and nose bleeds.
- A stuffy nose, wheezing and flu-like symptoms.
- A dry mouth.

**Very rare (affect less than 1 in 10,000 people):**
- Low numbers of all types of white blood cells. The signs include infections of the mouth, gums, throat and lungs.
- Allergic (hypersensitivity) reactions. The signs may include difficulty breathing or swallowing caused by sudden swelling of the throat, or face or swelling of your hands, feet and ankles or severe skin reactions.
- Changes in liver function which show up in a blood test.
- Some women may have difficulty with bladder conotrol when they pass water (urinary incontinence). This normally will get better when treatment is stopped.
- Severe skin conditions (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) can occur. Redness, often associated with blisters may appear on the skin or mucous membranes, such as the inside of the mouth, the genital areas or the eyelids. These can appear initially as circular patches often with central blisters, which may progress to widespread peeling of the skin and can be life threatening. These serious skin reactions are often preceded by headache, fever and body aches (flu-like symptoms).

**Not known (frequency cannot be estimated from the available data):**
- Carvedilol Krka can also cause development of the signs of diabetes in people who have a very mild form of diabetes called 'latent diabetes'.
- There have been some reports of hallucinations in patients taking Carvedilol Krka.
- You may sweat excessively (hyperhidrosis).

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Carvedilol Krka

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 package and blister. The expiry date refers to the last day of that month.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. 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 Carvedilol Krka contains**
The active substance is carvedilol. Each tablet contains 3.125 mg, 6.25 mg, 12.5 mg or 25 mg tablet.

The other ingredients are sucrose, lactose monohydrate, povidone K25, colloidal anhydrous silica, crospovidone and magnesium stearate.

**What Carvedilol Krka looks like and contents of the pack**
Carvedilol Krka 3.125 mg tablets are round, slightly biconvex white bevel-edged tablets.
Carvedilol Krka 6.25 mg tablets are oval, slightly biconvex white tablets, marked with S2 on one side and scored on the reverse.
Carvedilol Krka 12.5 mg tablets are oval, slightly biconvex white tablets, marked with S3 on one side and scored on the reverse.
Carvedilol Krka 25 mg tablets are round, slightly biconvex white bevel-edged tablets, scored on one side.

Carvedilol Krka is supplied in blisters containing 14, 28, 30, 50, 56, 60 or 100 tablets or containers containing 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

**This leaflet was last revised in**