



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **KARDOZIN 4 mg Tablets**

**Taken by mouth.**

**Active substance:** Each tablet contains 4.85 mg doxazosin mesylate equivalent to 4 mg doxazosin.

**Excipients:** Microcrystalline cellulose, lactose monohydrate (from bovine milk), sodium starch glycolate, sodium lauryl sulfate, magnesium stearate.

**Read all of this PACKAGE 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. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you.*

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### **1. WHAT KARDOZIN IS AND WHAT IT IS USED FOR**

KARDOZIN is available in blister packs containing 20 tablets.

KARDOZIN belongs to a group of blood pressure medicines called alpha-blockers. It is used to treat high blood pressure or the symptoms caused by an enlarged prostate gland in men.

KARDOZIN can be used to treat high blood pressure (hypertension) by widening the blood vessels and making it easier for blood to flow through them. This helps to lower blood pressure. In patients whose blood pressure cannot be adequately controlled with a single medicine that lowers blood pressure, KARDOZIN can be used together with other blood pressure medicines.

In patients with enlarged prostate gland, KARDOZIN is used to treat difficulty in urination and/or frequent urination. This is common in patients with an enlarged prostate gland. KARDOZIN provides easy urination by relaxing the muscle around the bladder outlet and prostate gland.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KARDOZIN**

#### **Do not take KARDOZIN**

- If you have ever experienced an allergic reaction to KARDOZIN, the active substance doxazosin, other types of quinazolines (such as prazosin or terazosin), or any of the ingredients listed in the section of excipients. Allergic reactions may be itching, reddening of the skin or

difficulty breathing.

- If you are breastfeeding.
- If you are younger than 16 years old.
- If you have an enlarged prostate and low blood pressure.
- If you have ever suffered from “orthostatic hypotension”, a type of decrease in blood pressure that causes dizziness or light-headedness when standing up from a lying or sitting position.
- If you have an enlarged prostate with a blockage in your urinary tract, a chronic infection in your urinary tract, or a bladder stone.
- If you have overflow incontinence (you do not feel the urge to urinate) or unable to pass urine ([anuria] which means your body cannot produce urine) with or without kidney problems.

### **Take special care with KARDOZIN**

- If you are pregnant or trying to become pregnant
- If you have liver diseases
- If you are using any other medicines at the same time as this medicine
- If you have heart diseases
- If postural hypotension develops, manifested by dizziness and weakness or rarely fainting (syncope), especially at the beginning of treatment. Your doctor will inform you about how to prevent the symptoms that may arise from postural hypotension and what measures to take if these are seen. During the initial period of doxazosin treatment, if dizziness or weakness occurs, your doctor will warn you to avoid situations that could result in injury.

If you are undergoing have eye surgery because of cataract (clouding of the lens of the eye), please inform your eye specialist before the operation that you are using or have previously used KARDOZIN. This is because KARDOZIN may cause complications during the surgery that can be managed if your specialist is prepared in advance.

When you first start using KARDOZIN, you may feel faint or dizzy when standing up from a lying or sitting position because it lowers blood pressure. If you feel faint or dizzy, you should sit or lie down until you feel better and avoid situations that could cause you to fall or injure yourself. To reduce the possibility of these effects occurring, your doctor may want to measure your blood pressure regularly at the beginning of treatment.

*If any of these warnings apply to you, even if for any time in the past, please consult your doctor.*

### **Using KARDOZIN with food and drink**

KARDOZIN can be taken with or without food.

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine.*

The safety of KARDOZIN use during pregnancy has not been determined. If you are pregnant or trying to become pregnant, you should talk to your doctor for advice, and your doctor will decide whether KARDOZIN is suitable for you.

*If you realize you are pregnant during your treatment, immediately consult your doctor or pharmacist.*

### **Breast-feeding**

*Consult your doctor or pharmacist before taking this medicine.*

Do not use KARDOZIN if you are breast-feeding.

### **Driving and using machines**

Be careful if you will be driving or using machinery. The tablets you are taking may affect your ability to drive or use machines safely and may make you feel weak or dizzy, especially when you first start taking the tablets.

### **Important information about some of the ingredients of KARDOZIN**

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

### **Taking with other medicines**

Some drugs that may interact with KARDOZIN include:

- Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with alpha-blockers. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start drugs for erectile dysfunction.
- Your doctor will be cautious when giving you doxazosin at the same time as phosphodiesterase-5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil) that are used to treat erectile dysfunction in men, since both of these drugs can cause widening of the vessels and symptomatic low blood pressure in some patients.
- If you are using another medicine to treat your high blood pressure, KARDOZIN can lower your blood pressure even more.

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

## **3. HOW TO TAKE KARDOZIN**

### **Instructions for proper use and dose/administration frequency**

If you are taking KARDOZIN for the first time, the usual dose is 1 mg per day. After a few weeks, your doctor may increase this dose to 2 mg or 4 mg per day. In some cases, the dose may be increased to a maximum of 8 mg per day if you are being treated for an enlarged prostate, or to a maximum of 16 mg if you are being treated for high blood pressure.

You should always take your tablets as your doctor has told you. If you are not sure, ask your doctor or pharmacist.

### **Route and method of administration**

KARDOZIN should be taken by mouth.

The tablets can be taken in the morning or the evening.

It is recommended to take your tablets with water and at the same time each day.

### **Different age groups**

#### Use in children

The efficacy and safety of KARDOZIN in children have not been established.

#### Use in the elderly

Dosing should be the same as in adults.



## **Special conditions**

### Kidney failure

If you have kidney failure, your doctor may prescribe you the usual doses, because the amount of medicine in the body does not change and there is no evidence that your medicine worsens existing kidney damage. Doxazosin is not dialyzable.

### Liver failure

As with all medicines that are completely metabolized in the liver, KARDOZIN should be administered with caution to you if there is an evidence of impaired liver function.

*If you think that the effect of KARDOZIN is too strong or too weak, talk to your doctor or pharmacist.*

### **If you take more KARDOZIN than you should**

Taking too many tablets at once can make you feel bad or it may be dangerous. Talk to your doctor right away or go to the nearest hospital emergency department.

*If you have taken more KARDOZIN than you were told to, contact your doctor or pharmacist.*

### **If you forget to take KARDOZIN**

Do not worry. If you forget to take your tablet, skip that dose. Then continue taking it as usual.

*Do not take a double dose to make up for a forgotten dose.*

### **Possible effects when you stop taking KARDOZIN**

It is important that you take your tablets regularly. This helps control your blood pressure. Do not change the dose or stop taking the tablets without first consulting your doctor.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, KARDOZIN can cause side effects in people who are allergic to its ingredients.

**STOP taking KARDOZIN and call an ambulance immediately** if any of the following occur:

- Heart attack
- Weakness in the arms and legs, or speech problems, which may be symptoms of stroke
- Swelling of the face, tongue, or throat, which may occur as a result of an allergic reaction to the medicine

Tell your doctor immediately if any of the following symptoms occur:

- Chest pain
- Shortness of breath, difficulty in breathing
- Fast, slow, or irregular heartbeat
- Feeling your heart beat (palpitations)
- Fainting
- Yellowing of the skin or eyes (jaundice)
- A decrease in white blood cells or platelets, which may result in bruising or easy bleeding

The following events have been reported in patients treated with doxazosin. If any of these side effects get serious or if you feel a side effect not mentioned in this leaflet, please tell your doctor.

Other adverse events are classified as shown in the following categories:

- Very common : may occur in at least 1 in 10 patients.  
Common : may occur in less than 1 in 10 patients, but more than 1 in 100 patients.  
Uncommon : may occur in less than 1 in 100 patients, but more than 1 in 1,000 patients.  
Rare : may occur in less than 1 in 1,000 patients.  
Very rare : may occur in less than 1 in 10,000 patients.  
Not known : cannot be estimated from the available data.

### **Common**

- Dizziness
- Spinning sensation (vertigo)
- Headache
- Low blood pressure
- Low blood pressure when standing up from a sitting or lying position
- Palpitations
- Acceleration of the heartbeat
- Swelling of the feet, ankles or fingers
- Bronchitis
- Cough
- Respiratory tract (nose, throat, lung) infection
- Nasal congestion, sneezing and/or runny nose caused by the flu
- Shortness of breath, difficulty in breathing
- Stomach/abdominal pain
- Feeling unwell
- Urinary tract infection
- Urinary incontinence (inability to control passing urine)
- Sleepiness
- General weakness
- Indigestion
- Heartburn
- Dry mouth
- Itching
- Back pain
- Pain in the muscles
- Flu-like symptoms
- Asthenia (weakness)
- Edema in the arms and legs

### **Uncommon**

- Allergic drug reaction
- Constipation
- Gas (in the stomach and intestines)
- Inflammation of the stomach and intestines that may cause diarrhea or vomiting (gastroenteritis)
- Vomiting
- Pain or discomfort when passing urine
- The need to urinate more than usual
- Passing blood in the urine

- Inflammation in the joints (gout)
- Painful joint
- General pain
- Difficulty in sleeping
- Anxiety
- Restlessness
- Depression
- Irritability
- Fainting
- Decreased or altered feeling or sensitivity of the hands and feet
- Chest pain caused by narrowing/occlusion of the vessels feeding the heart
- Heart attack
- Increase or loss of appetite
- Weight gain
- Nose bleeding
- Redness on the skin
- Ringing in the ears
- Tremor
- Impotence
- Pain
- Facial swelling
- Abnormal liver function tests

**Rare**

- Increase in the number of urination times
- Muscle cramps
- Muscle weakness

**Very rare**

- Decrease in the number of white blood cells
- Decrease in thrombocyte-platelet count
- Slowing of the heartbeat
- Irregular heartbeat
- Narrowing of the bronchi
- Liver inflammation (hepatitis) or gallbladder disease
- Hives
- Hair loss
- Red or purple rashes on the skin
- Subcutaneous bleeding
- Tingling or numbness in hands and feet
- Agitation
- Nervousness
- Fatigue
- General feeling of discomfort
- Increase in wheezing
- Blurred vision
- Flushing



- Hot flashes
- Disturbance in urination
- The need to urinate at night
- Increase in the volume of urine output
- Discomfort or enlargement of the breasts in men
- Painful permanent erection on the penis

#### **Not known**

- Very little or no semen, cloudy urine after ejaculation
- Eye problems may occur during eye surgery for clouding of the lens of the eye (cataract).  
See section “Take special care with KARDOZIN” in the following conditions.

#### Reporting of side effects

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

*If you experience any side effects not included in this leaflet, inform your doctor or pharmacist.*

## **5. HOW TO STORE KARDOZIN**

*Keep KARDOZIN out of reach and sight of children and in its original package.*  
Store at room temperature below 25°C.

#### **Use this medicine in accordance with the expiry date.**

*Do not use KARDOZIN after the expiry date, which is stated on the 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.

#### ***Marketing Authorization Holder***

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#### ***Manufacturer***

DEVA Holding A.Ş.  
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*This package leaflet was approved on 21.11.2017.*