

# Cardusin®

Cardusin 1mg tablet  
Cardusin 2mg tablet  
Cardusin 4mg tablet  
(Doxazosin)

## 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.

### In this leaflet:

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

#### 1. What **Cardusin** is and what it is used for

**Cardusin** belongs to the group known as vasodilators. These substances cause the blood vessel to widen, which reduces the blood pressure.

**Cardusin** can also reduce tension in the muscle tissues of the prostate and the urinary tract.

**Cardusin** is used to treat:

- high blood pressure.
- symptoms of an enlarged prostate.

#### 2. what you need to know before you take **Cardusin**

##### Do not take **Cardusin**:

- if you are allergic to doxazosin, other medicines from the same group (known as quinazolines, such as e.g. prazosin and terazosin) or any of the other ingredients of this medicine (listed in section 6).
- if you have a history of a condition known as 'orthostatic hypotension' which is a form of low blood pressure that causes you to feel dizzy or lightheaded when you stand up from sitting or lying down.
- if you have an enlarged prostate gland with one of the following: any kind of congestion or blockage in your urinary tract, a longstanding infection of the urinary tract or you have bladder stones.
- if you are breast-feeding.
- if you have an enlarged prostate gland (benign prostatic hyperplasia) and have low blood pressure.
- if you have overflow incontinence (you do not feel the urge to urinate), or anuria (your body is not producing any urine) with or without kidney problems.

##### Warnings and precautions:

Talk to your doctor or pharmacist before taking **Cardusin** if you :

- suffer from serious heart problems such as e.g. severely reduced cardiac function or a restrictive and painful sensation in the chest (angina pectoris).
- are on a strict low-salt diet.
- are using diuretics.
- have kidney or liver problems.

If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used **Cardusin**.

This is because **Cardusin** may cause complications during the surgery which can be managed if your specialist is prepared in advance.

##### Important information about **Cardusin**:

The likelihood of your blood pressure dropping too fast is greatest at the start of treatment or when the dosage is increased. You may observe this as dizziness or more rarely fainting when changing position.

To reduce the risk of this happening, your doctor will check your blood

pressure thoroughly at the start of treatment and when the dosage is increased. You should therefore avoid situations at the start of treatment in which dizziness or faintness could cause injury.

**Cardusin** may also affect the results of some blood and urine tests. If you are due to have a blood or urine test make sure that you tell you are taking **Cardusin**.

##### Children and adolescents:

**Cardusin** is not recommended for use in children or adolescents below 18 years as safety and efficacy have not yet been established.

Take special care with **Cardusin**:

The following are reasons why **Cardusin** may not be suitable for you:

- If you are pregnant or trying to become pregnant.
- If you have liver disease.
- If you are also taking other medicines.
- If you have heart disease.

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

If any of these apply to you speak to your doctor before taking this medicine.

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

When you start to take **Cardusin** you may experience faintness or dizziness caused by low blood pressure, when getting up from sitting or lying down. If you feel faint or dizzy, you should sit or lie down until you feel better and avoid situations where you might fall or hurt yourself. Your doctor may want to measure your blood pressure regularly at the start of therapy to reduce the possibility of these effects happening.

##### Other medicines and **Cardusin**:

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

- Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or lightheadedness, 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.

- **Cardusin** may lower your blood pressure even more if you are already taking other medicines to treat high blood pressure such as terazosin and prazosin.

- Nitrates (medicines for heart problems) such as nitroglycerine and isosorbide nitrate: these can exacerbate the hypotensive effect;

- certain painkillers for rheumatism (known as non-steroidal antiinflammatory drugs) such as naproxen, ibuprofen or any other antiinflammatory painkiller: these can reduce the hypotensive effect;
- medications that could also possibly affect the liver metabolism, e.g. cimetidine (a medicine for stomach problems).

##### Pregnancy, breast-feeding and fertility:

Ask your doctor or pharmacist for advice before taking any medicine.

The safety of using cardusin during pregnancy has not been established.

If you are pregnant or think you may be pregnant or are planning to have a baby, Ask your doctor or pharmacist for advice before taking this medicine.

**Cardusin** should only be used during pregnancy if your doctor decides that the benefits for the mother outweigh the possible risk for the foetus.

Do not breast feed while taking **Cardusin**.

##### Driving and using machines:

**Cardusin** can sometimes cause dizziness or fainting. In such an event, you should exercise care during activities that require attentiveness, such as driving, operating machinery and working at heights. If you are unsure whether **Cardusin** is having a negative effect on your ability to drive, discuss this with your doctor.

##### **Cardusin** 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.

##### 3. How to take **Cardusin**

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

The recommended dose is:

##### High Blood Pressure

The initial dose is 1mg daily (= 24 hours) in a single dose. After 1 to 2 weeks, the dose is generally increased to 2mg in a single daily dose (= 24 hours).

This dose is also retained for 1 to 2 weeks. If necessary, the dosage can be further increased to 4,8 or 16mg per day, until the desired reduction in blood pressure is achieved. The maximum daily dose is 16mg. An initial dose should preferably be taken before going to bed; this means that any dizziness you may experience is less of a problem.

##### Enlarged Prostate

The initial dose is 1mg daily (= 24 hours) in a single dose. After this the usual dose is 2mg or 4mg daily. In some circumstances this may be increased to a maximum of 8mg daily.

The tablets should be taken as a single dose each day (= 24 hours).

The tablets must be taken with plenty of water.

- **If you take more **Cardusin** than you should:** If you have taken more than the prescribed dose, you should consult your doctor and/or pharmacist immediately. If you feel extremely dizzy or think you might faint, you should lie down immediately with your head down.

- **If you forget to take **Cardusin**:**

If you have forgotten to take a tablet, then skip it and take the next tablet at the usual time.

You should check with your doctor or pharmacist if you are unsure. Do not take a double dose to make up for a forgotten dose.

- **If you stop taking **Cardusin**:**

If you suddenly stop taking **Cardusin**, the complaints you suffered prior to the start of treatment may recur. It is therefore better not to stop taking this medication suddenly. Your doctor will decrease the dosage gradually. You should always check with your doctor or pharmacist if you are unsure. 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.

Some side effects could be serious:

If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions such as wheezing, shortness of breath, extreme dizziness or collapse, swelling of the face or throat, or a serious skin rash with red spots or blisters (especially affecting the whole body).
- Chest pain (angina pectoris), increased or irregular heartbeat, heart attack or stroke(symptoms may include collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech, and loss of speech).
- Yellowing of the skin or whites of the eyes, caused by liver problems (jaundice).
- Unusual bruising or bleeding caused by low blood platelets.
- Presence of blood in the urine.
- Hepatitis (liver disease with nausea, vomiting, loss of appetite, generally feeling unwell, fever).
- Cholestasis (blocked flow of bile - can cause itchy skin, pale stool, and dark urine).

These side effects are uncommon (affects 1 to 10 users in 1,000) or rare (affects 1 to 10 users in 10,000)

##### Other side effects:

**Common:** (may affect up to 1 in 10 people):

respiratory tract infection(nose, throat, lung), urinary tract infection(symptoms may include:

pain or a burning sensation when you urinate or a frequent need to urinate), urinary incontinence (inability to control passing urine), dizziness, sleepiness , headache, feeling of spinning (vertigo), feeling or sensation of irregular heartbeat (palpitation), increased heart rate, low blood pressure and low blood pressure as a result of getting up from a sitting or lying position (postural hypotension), inflammation of the air passages within the lungs, cough, shortage of breath, nasal stuffiness and/or runny nose, abdominal pain, indigestion, dry mouth, feeling sick (nausea), itching (pruritus), back and muscle pain, inflammation of the bladder, feeling of weakness (asthenia), chest pain, influenza like symptoms, swelling of the ankles, feet or fingers (peripheral oedema).

**Uncommon:** (may affect 1 in 100 people):

gout, increased appetite, loss of appetite, agitation, depression, anxiety, insomnia, nervousness,tremor, stroke, reduced sense of touch or sensation, fainting, ringing or noise in the ears (tinnitus), flushing, nosebleed, constipation, flatulence, vomiting (being sick), inflammation of the gastrointestinal tract, diarrhoea, abnormal liver function test, skin rash, joint pain, painful or difficult urination, difficulty to develop an erection (impotence), pain, swelling of the face, weight increase.

**Very Rare** (may affect up to 1 in 10000 people):

dizziness postural (dizziness as a result of getting up from a sitting or lying position),tingling or numbness of the hands and feet (paraesthesia), reduced

number of white blood cells(symptoms may include frequent infections such as fever, severe chills, sore throat or mouth ulcers), blurred vision, reduced heart rate, hot flushes, bronchial spasm (difficulty in breathing, wheezing or coughing), muscle cramps and weakness, polyuria (passing large volumes of urine), increased blood levels of urea and creatin, urticaria , hair loss (alopecia), rash

caused by bleeding under the skin, disorder in passing urine, needing to pass urine at night, increased volume of urine passed, temporary enlargement of the breasts in men (gynaecomastia), painful persistent erection, feeling tired (fatigue), malaise.

**Not known** (frequency cannot be estimated from available data):

- eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye).

- little or no semen ejaculated at sexual climax, cloudy urine following sexual climax (retrograde ejaculation).

##### 5. How to store **Cardusin**

- 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 blister and pack .

- The expiry date refers to the last day of that month.

- Do not store above 30°C, store in a dry place.

- 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. Further Information

###### What **Cardusin** contains

- The active substance is doxazosin. Each tablet contains 1/2/4 mg doxazosin (as doxazosin mesylate).

- The other ingredients are: microcrystalline cellulose, Sodium lauryl sulphate, sodium starch glycollate, magnesium stearate

###### What **Cardusin** looks like and contents of the pack

**Cardusin** 1mg tablets:

White, circular shaped, biconvex, uncoated tablet.

**Cardusin** 2mg tablets:

White, oblong shaped, biconvex , uncoated tablet.

**Cardusin** 4mg tablets:

White, diamond shaped, uncoated tablet.

**Cardusin** 1/2/4 tablets are available in packs containing 3 blisters.

Each blister contains 10 tablets.

###### Marketing Authorization Holder and Manufacturer:

Azal Pharma

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###### To report any Side effect

National Medicines and Poisons Board (NMPB)

Fax (+249)18532263

E-mail: inf@nmpb.gov.sd

Website: www.nmpb.gov.sd

###### THIS IS A MEDICATION

- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of pharmacist who sold the medication.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consultation your doctor.

- Keep medication out of reach of children.

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