

Package leaflet: Information for the patient

CARDURA[®]

(Doxazosin Mesylate)

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Cardura is and what it is used for

What Cardura is

Cardura is one of a group of medicines called alpha-blockers.

How Cardura works

Cardura can be used to treat high blood pressure (hypertension), by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure. In patient with enlarged prostate gland, Cardura works by relaxing muscle around the bladder exit and prostate gland so urine is passed more easily.

What Cardura is used for

Cardura is used to treat high blood pressure, or the symptoms caused by enlargement of the prostate gland in men. Cardura may be used in combination with another agent such as a thiazide diuretic, a beta-blocker, a calcium antagonist or an angiotensin-converting enzyme inhibitor. In patients with an enlarged prostate gland, Cardura is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate gland.

2. What you need to know before you take Cardura

Do not use Cardura

- If you are allergic to doxazosin, other types of quinazolines, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cardura, if you have any of the following:

- you are pregnant or trying to become pregnant
- you have impaired liver function
- you are also taking other medicines
- you have coronary 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 Cardura. This is because Cardura may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Persistent painful erections may occur very rarely. If this happens you should contact a doctor immediately.

When you start to take Cardura you may experience faintness or dizziness and weakness, or rarely loss of consciousness. 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.

Children and adolescents

Cardura is not recommended for use in children or adolescents below 18 years as safety and efficacy have not yet been established. Benign prostate hyperplasia is not relevant in children.

Other medicines and Cardura

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

There are some medicines that may interact with Cardura. Ask your doctor or pharmacist before use if you are taking any of these medicines as they may change the effect of Cardura:

- 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 medicines called PDE 5 inhibitors for the treatment of 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.

- Cardura may lower your blood pressure even more if you are already taking other medicines to treat high blood pressure.
- Medicines to treat bacterial or fungal infections, e.g. clarithromycin, itraconazole, ketoconazole, telithromycin, voriconazole.
- Medicines used in the treatment of HIV e.g. indinavir, nelfinavir, ritonavir, saquinavir.
- Nefazodone, a medicine used to treat depression.

Pregnancy and breast-feeding

Pregnancy

The safety of using Cardura during pregnancy has not been established. If you are pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breast-feeding

Small amounts of doxazosin, the active substance of Cardura, can get into your breast milk. You should not use Cardura during breast-feeding unless your doctor advises you to do so.

Driving and using machines

Take care if you drive or operate machinery. Your tablets may affect your ability to drive or operate machinery safely, particularly when you first start to take them. They may make you feel weak or dizzy. If you are affected, do not drive or operate machinery and contact your doctor immediately.

3. How to use Cardura

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

- The recommended dose of Cardura is one tablet taken once a day either in the morning or in the evening.
- If you are taking Cardura for the first time the normal dose is 1 mg daily. Your doctor may increase this after a couple of weeks to the usual dose of 2 mg or 4 mg daily. In some circumstances this may be increased to a maximum of 8 mg daily if you are being treated for prostate enlargement, or to a maximum of 16 mg if you are being treated for high blood pressure.
- Do not change the dose or stop taking the tablets without first checking with your doctor.
- Do not wait until your tablets are finished before seeing your doctor.

If you take more Cardura than you should

Too many tablets at once may make you unwell. If several tablets are taken it may be dangerous. Tell your doctor immediately or go to your nearest hospital casualty department.

If you forget to take Cardura

Do not worry. If you forget to take a tablet, leave that dose out completely. Then go on as before. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of these effects may be serious.

STOP taking Cardura and call an ambulance immediately if you experience any of the following:

- Weakness of arms, legs or problems speaking which may be symptoms of a stroke
- Swelling of the face, tongue or throat which may be the result of an allergic reaction to this medicine

The following events have been reported in patients being treated with Cardura. If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

- vertigo (external spinning sensation)
- nausea
- asthenia, edema, fatigue and malaise (feeling overtired)
- dizziness, headache, postural dizziness, somnolence (sleepiness), syncope (fainting)
- rhinitis

Benign Prostatic Hyperplasia

- leukopenia, thrombocytopenia
- tinnitus
- blurred vision, IFIS (Intraoperative Floppy Iris Syndrome)
- abdominal pain, constipation, diarrhea, dyspepsia (abdominal discomfort), flatulence (passing wind), mouth dry, vomiting
- pain
- cholestasis (decrease in bile flow), hepatitis, jaundice
- allergic reaction
- abnormal liver function tests, weight increase
- anorexia (loss of appetite)
- arthralgia, back pain, muscle cramps, muscle weakness, myalgia
- hypoesthesia (loss of sensation), paresthesia (sensation of the skin), tremor
- agitation, anxiety, depression, insomnia, nervousness
- dysuria (painful urination), hematuria (blood in the urine), micturition disorder, micturition frequency, nocturia, polyuria, urinary incontinence
- gynecomastia (swollen male breast tissue), impotence, priapism (painful erection of the penis), retrograde ejaculation
- bronchospasm aggravated, coughing, dyspnea (shortness of breath), epistaxis (nosebleeds)
- alopecia (hair loss), pruritus (itchy skin), purpura (blood spots), skin rash, urticaria
- hot flushes, hypotension, hypotension postural

5. How to store Cardura

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Avoid exposure to heat and sunlight and moisture

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 Cardura contains

The active substance is doxazosin. Cardura tablets include the following inert ingredients: sodium starch glycolate, microcrystalline cellulose, lactose, magnesium stearate and sodium lauryl sulfate.

What Cardura looks like and contents of the pack

Cardura (doxazosin) is available with the following presentations

- 2 mg tablets: 2x10's blister pack
- 4 mg tablets: 2x10's blister pack

Cardura/PIL/PK-01

According to Cardura/LPD/PK-04/ CDS V 09 dated: July 14, 2016

Marketed by:

Karachi, Pakistan.