

Package leaflet: Information for the patient

CARDURA® 1mg Tablets

CARDURA® 2mg Tablets

Doxazosin mesilate

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.
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- Cardura is a treatment for high blood pressure, or the symptoms caused by enlargement of the prostate gland in men.
 - 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.
 - You should take Cardura regularly to get the maximum benefit, even if you are feeling well.
 - Most people do not have serious problems when taking Cardura but side effects can occur. If you experience swelling of the face, tongue or windpipe, see your doctor immediately. 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.
 - Taking other medicines may sometimes cause problems. Check with your doctor or pharmacist before taking this or any other medicines.
 - If you are, or are trying to become, pregnant, do not take Cardura and tell your doctor or pharmacist.

What is in this leaflet

1. What Cardura is and what it is used for
2. What you need to know before you take Cardura
3. How to take 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

Cardura is one of a group of medicines called alpha-blockers. It is used to treat high blood pressure, or the symptoms caused by enlargement of the prostate gland in men.

Cardura is 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 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. Cardura works by relaxing muscle around the bladder exit and prostate gland so urine is passed more easily.

2. What you need to know before you take Cardura

Do not take Cardura:

- If you are allergic to doxazosin, other types of quinazolines (such as prazosin or terazosin), or any of the other ingredients of this medicine (listed in section 6). This may have been itching, reddening of the skin or difficulty in breathing.

- If you are under 18 years of age.
- If you have low blood pressure.
- 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 light-headed 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 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 Cardura if:

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

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.

Before starting treatment with Cardura your doctor may perform tests to rule out other conditions such as prostate cancer that may cause the same symptoms as benign prostatic hyperplasia.

When you start to take Cardura 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.

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 erectile dysfunction (impotence) with alpha-blockers e.g. sildenafil, tadalafil, vardenafil (please see Section “Warnings and precautions”). 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.

☒ Cardura with food and drink:

Please refer to section 3.

☒ Pregnancy and breast-feeding:

Pregnancy

The safety of using Cardura during pregnancy has not been established. If you are pregnant or trying to become pregnant speak to your doctor, who will decide if Cardura is suitable for you.

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. It may cause drowsiness, make you feel weak or dizzy. If you are affected, do not drive or operate machinery and contact your doctor immediately.

☒ Cardura contains lactose

Cardura 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.

☒ Cardura contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take 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 usual dose of Cardura is one tablet taken once a day.
- If you are taking Cardura for the first time the normal dose is 1mg daily. Your doctor may increase this after a couple of weeks to the usual dose of 2mg or 4mg daily. In some circumstances this may be increased to a maximum of 8mg daily if you are being treated for prostate enlargement, or to a maximum of 16mg if you are being treated for high blood pressure.
- Cardura may be taken in the morning or the evening.
- Cardura can be taken with or without food.
- It is best to take your tablets at about the same time each day with a drink of water.
- Take your tablet as your doctor told you - It is important to keep taking your tablets. They help to control your blood pressure.
- Don't change the dose or stop taking the tablets without first checking with your doctor.
- Don't 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.

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

- Heart attack
- Increased, decreased or irregular heartbeat
- Weakness of arms, legs or problems speaking which may be symptoms of a stroke
- Allergic reactions (hypersensitivity). Symptoms include sudden wheeziness, tightness in chest, difficulty in breathing, swelling of the face, tongue or throat, rash or itching (especially affecting the whole body)

Tell your doctor **immediately** if you experience any of the following symptoms after taking Cardura:

- Chest pain (angina), wheezing, shortness of breath, difficulty breathing
- Feeling your heartbeat (palpitations)
- Fainting
- Yellowing of the skin or the eyes (jaundice)
- Low numbers of white blood cells or blood platelets, which may result in bruising or easy bleeding

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.

Common side effects may affect up to 1 in 10 people

- Dizziness, feeling of spinning or rotation of surroundings (vertigo), headache
- Low blood pressure
- Swelling of feet, ankles or fingers
- Bronchitis, coughing, respiratory tract (nose, throat, lungs) infection
- Nasal stuffiness, sneezing and/or runny nose caused by inflammation of the lining of the nose (rhinitis)
- Stomach/abdominal pains, feeling/being sick
- Urinary tract infection, urinary incontinence (inability to control passing urine), inflammation of the bladder (cystitis)
- Sleepiness, general weakness
- Indigestion, dry mouth
- Itching
- Back pain, painful muscles
- Flu-like symptoms

Uncommon side effects may affect up to 1 in 100 people

- Constipation, wind, inflammation of the stomach and intestines (gastroenteritis) which can cause diarrhoea and vomiting
- Pain or discomfort on passing urine, increased frequency in passing urine, blood in urine
- Inflammation of the joints (gout), painful joints, general pain
- Sleeplessness, agitation, anxiety, depression or nervousness
- Reduced or altered sense of touch or sensation of the hands and feet
- Increased appetite or loss of appetite, weight gain
- Nose bleeds
- Skin rash
- Ringing or noise in the ears, tremor
- Failure / inability to achieve penile erection

- Swollen face
- Liver enzyme increases which may have an effect on some medical tests
- Stroke

Rare side effects may affect up to 1 in 1,000 people

- Increased number of times of passing urine
- Muscle cramps, muscle weakness

Very Rare side effects may affect up to 1 in 10,000 people

- Faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position
- Hepatitis (liver inflammation) or bile disorder
- Hives, hair loss, red or purple patches on the skin, bleeding under the skin
- Tingling or numbness of the hands and feet
- Tiredness, generally feeling unwell
- Blurred vision
- Hot flushes
- Disorder in passing urine, needing to pass urine at night, increased volume of urine passed
- Discomfort or enlargement of the breasts in men
- Persistent painful erection of the penis. Seek urgent medical advice

Not known: frequency cannot be estimated from the available data

- Little or no semen ejaculated at sexual climax, cloudy urine following sexual climax
- Eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye). See section “Warnings and precautions”.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance,

Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adportal

5. How to store Cardura

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

Do not use Cardura after the expiry date which is stated on the carton and tablet blister after Exp. The expiry date refers to the last day of that month. Do not store above 30°C.

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 (as mesilate).
- The other ingredients in each tablet are: magnesium stearate, microcrystalline cellulose, sodium laurilsulfate, sodium starch glycolate (type A) (see section 2 “**Cardura contains sodium**”) and lactose monohydrate (see section 2 “**Cardura contains lactose**”).

Cardura tablets come in two strengths, 1mg and 2mg.

Each tablet contains either 1.213mg doxazosin mesilate (equivalent to 1mg doxazosin) or 2.43mg doxazosin mesilate (equivalent to 2mg doxazosin).

What Cardura looks like and the contents of the pack

The 1mg tablets are white, round and marked with CN1 on one side, with the Pfizer logo on the other.

The 2mg tablets are white, oblong and marked with CN2 and scored on one side, with the Pfizer logo on the other.

Cardura tablets are available in packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Ireland

Viartis Healthcare Limited
Damastown Industrial Park
Mulhuddart
Dublin
Ireland

Malta

Viartis Hellas Ltd
253-255, Mesogion Avenue,
154 51 Neo Psychiko,
Athens, Greece.

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
79090 Freiburg
Germany

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