

Patient Information Leaflet
Cardura® 2mg Tablets
(doxazosin (as mesilate))

Important things that you SHOULD know about your medicine:

- 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. Do not pass it on to others. It may harm them even if their symptoms 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 – see Section 4 for details. If you experience swelling of the face, tongue or windpipe, see your doctor immediately. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- 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.

Please read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important to you. If you have any further questions, ask your doctor or pharmacist.

In this leaflet:

1. What Cardura is and what it is used for
2. Before you take Cardura
3. How to take Cardura
4. Possible side effects
5. How to store Cardura
6. Further information

The name of your medicine is Cardura 2mg Tablets, but will be referred to as Cardura throughout this leaflet.

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. Before you take Cardura



Do not take Cardura:

- If you have had an allergic reaction in the past to Cardura, the active ingredient doxazosin, other types of quinazolines (such as prazosin or terazosin) or any of the other ingredients listed in section 6. This may have been itching, reddening of the skin or difficulty in breathing.
- If you are breast-feeding.
- If you are under 12 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.



Take special care with Cardura:

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

- If you are pregnant or trying to become pregnant
- If you have liver disease
- If you have heart disease
- If 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.

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.

Taking other medicines:

There are some medicines that may interact with Cardura

- **Medicines for erectile dysfunction (impotence) such as sildenafil, tadalafil or vardenafil**
- 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.
- Cardura may lower your blood pressure even more if you are already taking other medicines to treat high blood pressure.

You should always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed, because they might interact with Cardura.



Taking Cardura with food and drink:

Cardura can be taken with or without food.



Pregnancy and Breast-feeding:

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. Do not take Cardura if you are breast-feeding.



Driving and using machinery:

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.



Important information on some ingredients of Cardura

Cardura tablets also contain lactose (a type of sugar). If you have been told you have an intolerance to sugars, consult your doctor before you take your medicine.

3. How to take Cardura

- 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.
- 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 are still not sure how to take your tablets, ask your doctor or pharmacist.

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 miss a dose of Cardura: Do not worry. If you forget to take a tablet, leave that dose out completely. Then go on as before.

4. Possible side effects

Like all medicines, Cardura 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

These can affect between 1 in 10 and 1 in 100 patients:

- 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 infections, urinary incontinence (inability to control passing urine)
- sleepiness, general weakness
- indigestion, dry mouth
- itching
- back pain, painful muscles
- flu like symptoms

Uncommon side effects:

These can affect between 1 in 100 and 1 in 1,000 patients:

- 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

Rare side effects

These can affect between 1 in 1,000 and 1 in 10,000 patients

- increased number of times of passing urine
- muscle cramps, muscle weakness

Very rare side effects

These can affect less than 1 in 10,000 patients:

- 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
- painful persistent erection of the penis

Other side effects

The frequency of these side effects is unknown:

- 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 "Take special care with Cardura".

Reporting 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cardura

- Do not store above 30°C
- Keep out of the reach and sight of children.
- Do not take this medicine after the date printed on the carton and blister.

6. Further information

What Cardura contains

Each tablet contains 2mg doxazosin as doxazosin mesilate as the active ingredient.

The active ingredient in this medicine is doxazosin **mesilate**. This is the new name for doxazosin **mesylate**. The ingredient itself has not changed.

Other Ingredients: magnesium stearate, microcrystalline cellulose, sodium laurilsulfate, sodium starch glycolate and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The tablets are white oblong biconvex tablets: marked "CN 2" and scored on one side and marked with the Pfizer logo on the other.

The product is available in packs of 30 tablets (3 strips of 10 tablets).

Manufactured by: R-Pharm Germany GmbH, Heinrich-Mack-Strasse 35, 89257 Illertissen, Germany.

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

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