

CARDURA® TABLET

Doxazosin mesylate (2 mg)

What is in this leaflet

1. What CARDURA is used for
2. How CARDURA works
3. Before you use CARDURA
4. How to use CARDURA
5. While you are using it
6. Side effects
7. Storage and Disposal of CARDURA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What CARDURA is used for

Hypertension

Doxazosin is indicated for the treatment of hypertension and can be used as the initial agent to control blood pressure in the majority of patients. In patients not adequately controlled on a single antihypertensive agent, doxazosin 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.

Benign Prostatic Hyperplasia

CARDURA is also indicated for the treatment of the blockage in urinary flow and symptoms associated with (enlargement of prostate gland in men) benign prostatic hyperplasia (BPH).

CARDURA may be used in BPH patients who are either hypertensive (high blood pressure) or normotensive (normal blood pressure). While the blood pressure changes in normal blood pressure patients with BPH are clinically insignificant, patients with high blood pressure and BPH have had both conditions effectively treated with doxazosin monotherapy.

How CARDURA works

CARDURA is one of a group of medicines called alpha-blockers. 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 patients with an enlarged prostate

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

Before you use CARDURA

- *When you must not use it*

Do not take CARDURA:

- If you have had an allergic reaction in the past to CARDURA, the active ingredient doxazosin, other types of quinazolines or any of the other ingredients listed under "Ingredients"
- If you are breast-feeding
- If you are under 16 years of age.
- If you have an enlarged prostate gland (benign prostatic hyperplasia) and 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.

Pregnancy and lactation

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.

Doxazosin should be used only in the opinion of the physician; the potential benefit outweighs the potential risk. Do not take CARDURA if you are breast-feeding. Ask your doctor or

pharmacist for advice before taking any medicine.

- *Before you start to use it*

Talk to your doctor if you are having the following:

- 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. Your doctor will advise you to avoid situations where injury could result.
- If you have liver disease
- If you are undergoing eye surgery because of cataract (cloudiness of the lens) as it may cause complications called 'intraoperative floppy iris syndrome' (IFIS) during the surgery. Please inform your eye specialist before the operation that you are using or have previously used CARDURA.

Persistent erections lasting longer than 4 hours may occur rarely. You will be advised to contact your doctor immediately if this happens., when getting up from sitting or lying down.

- *Taking other medicines*

There are some medicines that may interact with CARDURA:

- Concomitant administration of CARDURA with a phosphodiesterase type-5 (PDE-5) inhibitor should be used with caution as it may lead to symptomatic hypotension in some patients.
- Caution should be exercised when concomitantly administering doxazosin with a strong CYP 3A4 inhibitor, such as clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole.

CARDURA® TABLET

Doxazosin mesylate (2 mg)

- 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 such as terazosin and prazosin.

How to use CARDURA

- How much to use it

Hypertension

Dosage range of CARDURA is 1 mg to 16 mg daily. It is recommended that therapy be initiated at 1 mg once daily for 1 or 2 weeks to minimize the potential for postural hypotension and/or syncope.

The dosage may then be increased to 2 mg once daily for an additional 1 or 2 weeks.

Daily dosage should then be increased gradually at similar intervals to 4 mg, 8 mg, and 16 mg.

The usual dose is 2 mg to 4 mg once daily.

Benign Prostatic Hyperplasia
Recommended initial dosage of CARDURA is 1 mg.

Depending on the patient's bladder condition and BPH, dosage may then be increased to 2 mg and thereafter to 4 mg and up to the maximum recommended dose of 8 mg.

The usual recommended dose is 2 to 4 mg once daily.

- When to use it

Doxazosin may be administered either in the morning or in the evening.

- How long to use it

Continue taking CARDURA for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may lead to low blood pressure (hypotension). Patient should be made to lie flat on the back looking upwards (head-down position).

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking CARDURA.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give CARDURA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machinery

The ability to engage in activities, such as operating machinery or operating a motor vehicle may be impaired particularly when initiating CARDURA therapy.

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 affected, do not drive or operate machinery and contact your doctor immediately.

Side effects

Like all medicines, CARDURA can cause side effects although not everybody gets them.

Hypertension:

- Feeling of spinning or rotation of surroundings (vertigo)
- Nausea
- Swelling, general body weakness, fatigue, restlessness
- Dizziness, headache, unconsciousness (syncope), drowsiness
- Sneezing and/or runny nose caused by inflammation of the lining of the nose (rhinitis).

CARDURA® TABLET

Doxazosin mesylate (2 mg)

Benign Prostatic Hyperplasia:

- Low white blood cells, low blood platelet count
- Ringing in the ear
- Blurred vision (IFIS see section: "Before you start to use it")
- Abdominal pain, constipation, diarrhoea, indigestion, accumulation of gas, dry mouth, vomiting
- Pain
- Abnormal flow of bile, yellowing of skin (jaundice), liver infection
- Allergy
- Abnormal liver function test, increase in weight
- Eating disorder
- Joint pain, back pain, muscle cramps and weakness, muscle pain
- Loss of sensitivity, tickling of skin, involuntary muscle movement
- Agitation, anxiety, depression, sleeplessness, nervousness
- Painful urination, blood in urine, urinary incontinence (inability to control passing urine), urination during night, excessive urination
- Swelling of male breast, inability to sustain erection, prolonged erection of penis, entry of semen into the urinary bladder instead of urethra during ejaculation.
- Tightening of lung muscles, cough, shortness of breath, bleeding of nose
- Baldness, skin rash, itchy skin, red skin spots, hives
- Hot flushes, low blood pressure, hypotension postural (a form of low blood pressure that happens when suddenly standing up from a lying or sitting position).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my

[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of CARDURA**- Storage**

Keep your tablets out of the reach and sight of children.

Do not use CARDURA after the expiry date which is stated on carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

A white capsule shaped tablet with 'VLE' on one side and 'CN/2' on the other.

- Ingredients

- Active ingredient
Doxazosin

- Inactive ingredients
Sodium starch glycolate, microcrystalline cellulose, lactose, magnesium stearate and sodium lauryl sulfate.

- MAL number:

Product Name	Registration Number
CARDURA 2 mg Tablet	MAL19990562ACRZ

Manufacturer

Pfizer Manufacturing Deutschland GmbH,
Freiburg Im Breisgau,
Germany

Product Registration Holder

Viatrix Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

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