

# CARDURA® XL TABLETS

Doxazosin mesylate (4 mg)

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## What CARDURA XL is used for *Hypertension*

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

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

## How CARDURA XL works

CARDURA XL 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. Poor and/or frequent urination is common in patients with enlarged prostate gland. CARDURA XL works by relaxing muscle around the bladder exit and prostate gland so urine is passed more easily.

## Before you use CARDURA XL

### - When you must not use it

Do not take CARDURA XL:

If you have had an allergic reaction in the past to CARDURA XL, the active ingredient doxazosin, other types of quinazolines or any of the other ingredients listed under "Ingredients".

### *Pregnancy and lactation*

The safety of using CARDURA XL 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.

Do not take CARDURA XL if you are breast-feeding.

Clinical studies have shown CARDURA XL passes into the human breast milk.

CARDURA XL should be used only in the opinion of the physician if the potential benefit outweighs the potential risk.

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 have a history of gastrointestinal disorder (intestinal narrowing).
- If you are undergoing eye surgery because of cataract (cloudiness of the lens) as it may cause complications called 'intraoperative floppy iris syndrome' during surgery. Please inform your eye specialist before the operation that you are using or have previously used CARDURA XL.
- Persistent erections lasting longer than 4 hours may occur rarely. You will be advised to contact your doctor immediately if this happens.

### - Taking other medicines:

There are some medicines that may interact with CARDURA XL:

- Concomitant administration of CARDURA XL 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 CARDURA XL with a strong CYP 3A4 inhibitor, such as clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole.

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

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 XL.

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## How to use CARDURA XL

### - How much to use

The usual dose of CARDURA XL is one 4 mg modified release tablet taken as a single daily dose.

Your doctor may wish to increase your dose to 8 mg. This is the maximum dose of CARDURA XL.

In liver impaired patients, the dosage of CARDURA XL should be used with caution.

### - When to use it

Use as directed by your doctor or pharmacist.

The CARDURA XL tablets should be swallowed as a whole with water and not chewed, divided or crushed.

### - How long to use it

Continue taking CARDURA XL 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 take 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.

## 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 product name.

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 XL to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

CARDURA XL is a modified release tablet that is contained within a non-absorbable shell designed to slowly release the medicine into the body on swallowing the tablet. Since the empty tablet is eliminated from the body via bowel movements, you may occasionally observe empty tablet the stool. This is expected and you should not be concerned.

### *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 XL therapy.

## Side effects

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

The following events have been reported in patients being treated with CARDURA XL. 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 (>1%) reported are as follows:

### Hypertension

- irregular heartbeat, rapid heart rate
- feeling of spinning or rotation of surroundings (vertigo)
- abdominal pain, dry mouth, nausea
- lack of energy, chest pain, swelling
- back pain, muscle pain
- low blood pressure while standing up from sitting or lying position (postural hypotension)
- dizziness, headache
- bronchitis, coughing
- itchy skin
- urinary tract infection, urinary incontinence (inability to control passing urine)

### Benign Prostatic Hyperplasia

- feeling of spinning or rotation of surroundings (vertigo)
- lack of energy (asthenia), swelling
- abdominal pain, indigestion, nausea
- respiratory tract infections, urinary tract infection
- back pain, muscle pain
- dizziness, headache, sleepiness
- inflammation of the lining of the lungs (bronchitis), shortness of breath (dyspnea), allergic reaction (rhinitis)
- sleepiness, general weakness (asthenia)
- low blood pressure, low blood pressure while standing up from sitting or lying position (postural hypotension)

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npa.gov.my](http://npa.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## Storage and Disposal of CARDURA XL

### - Storage

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

Store below 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

CARDURA XL 4 mg Tablet  
Round, biconvex shaped, white film coated tablet approximately 9.0 mm in diameter with an orifice on one side imprinted with 'CXL 4'.

### - Ingredients

- Active ingredient  
Doxazosin

- Inactive ingredients  
Polyethylene oxide, sodium chloride, hydroxypropyl methylcellulose, red ferric oxide (E172), titanium dioxide (E171), magnesium stearate, cellulose acetate, macrogol, pharmaceutical glaze and black iron oxide (E172).

### - MAL number:

| Product Name           | Registration Number |
|------------------------|---------------------|
| CARDURA XL 4 mg Tablet | MAL20040550ARZ      |

### Manufacturer

Viartis Pharmaceuticals LLC  
KM 58.2 Road #2  
Barceloneta, Puerto Rico 00617  
United States

### Product Registration Holder

Viartis Sdn Bhd  
15-03 & 15-04, Level 15, Imazium,  
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### Date of revision

16/10/2023

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