

Package leaflet: Information for the patient
CARDURA® 1mg and 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.
- 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 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 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 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.

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 are also taking other medicines
- you have 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.

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 (enlargement of the prostate gland).

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 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. 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 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, breast-feeding and fertility

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.

CARDURA contains lactose and small amounts of sodium

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.

This medicine contains less than 23 mg per tablet of sodium, 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 recommended 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.
- CARDURA can be taken with or without food.
- Take your tablet as your doctor told you or by following the days and arrows on the blister foil.
- It is important to keep taking your tablets. They help to control your 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.

Use in children

The safety and efficacy of CARDURA in children have not been established.

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
- 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

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

- Shortness of breath, difficulty breathing (common: may affect up to 1 in 10 people)
- Increased or decreased heartbeat (common: may affect up to 1 in 10 people)
- Feeling your heartbeat (palpitations) (common: may affect up to 1 in 10 people)
- Chest pain, angina (uncommon: may affect up to 1 in 100 people)
- Irregular heartbeat (very rare: may affect up to 1 in 10,000 people)
- Yellowing of the skin or the eyes (jaundice) (very rare: may affect up to 1 in 10,000 people)
- Low numbers of white blood cells or blood platelets, which may result in bruising or easy bleeding (very rare: may affect up to 1 in 10,000 people)
- Persistent painful erection of the penis. Seek urgent medical advice (very rare: may affect up to 1 in 10,000 people)

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: 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
- Chest cold, 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 bladder (cystitis)
- Sleepiness, general weakness
- Indigestion, heartburn, dry mouth
- Itching
- Back pain, painful muscles
- Flu-like symptoms

Uncommon: 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
- Swelling of the face
- 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
- Liver enzyme increases which may have an effect on some medical tests
- Stroke

Rare: may affect up to 1 in 1,000 people

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

Very Rare: 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
- Aggravated wheezing
- 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

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 via the relevant national reporting system detailed below:

UK

Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

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.

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

The other ingredients in each tablet are: magnesium stearate, microcrystalline cellulose, sodium lauril sulfate, sodium starch glycollate and lactose (see section 2 “**CARDURA contains lactose**”, **This medicine contains less than 1 mmol (23 mg) sodium**”).

What CARDURA looks like and the contents of the pack

The 1mg tablets are white round, biconvex and marked with CN1 on one side and ‘VLE’ on the other. The 2mg tablets are white oblong, biconvex and marked with CN2 on one side and ‘VLE’ on the other. They are available in calendar packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

United Kingdom

Upjohn UK Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom

Manufacturer

Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79108 Freiburg Im Breisgau, Germany

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