

PACKAGE LEAFLET: INFORMATION FOR THE USER

CARDURA ® XL 4mg and 8mg Tablets Doxazosin mesilate

Important things that you SHOULD know about your medicine:

- CARDURA XL 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 XL regularly to get the maximum benefit, even if you are feeling well.
- Most people do not have serious problems when taking CARDURA XL 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 XL and tell your doctor.

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. This leaflet was last updated in December 2011.

In this leaflet:

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

1. What CARDURA XL is and what it is used for

CARDURA XL 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 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.

In patients with an enlarged prostate gland, CARDURA XL is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate gland. CARDURA XL works by relaxing muscle around the bladder exit and prostate gland so urine is passed more easily.

2. Before you take CARDURA XL

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 (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 have any form of obstruction of the digestive tract
- 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.

Take special care with CARDURA XL:

The following are reasons why CARDURA XL 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 of the eye) please inform your eye specialist before the operation that you are using or have previously used CARDURA XL. This is because CARDURA XL may cause complications during the surgery which can be managed if your specialist is prepared in advance.

If any of these apply to you speak to your doctor before taking this medicine.

When you start to take CARDURA XL 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.

Taking other medicines:

There are some medicines that may interact with CARDURA XL:

- 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 XL may lower your blood pressure even more if you are already taking other medicines to treat your 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.

☒ Taking CARDURA XL with food and drink:

CARDURA XL can be taken with or without food.

☒ Pregnancy:

The safety of using CARDURA XL during pregnancy has not been established. If you are pregnant or trying to become pregnant speak to your doctor and he/she will decide if CARDURA XL is suitable for you.

☒ Breast-feeding:

Do not take CARDURA XL 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. They may make you feel weak or dizzy. If affected, do not drive or operate machinery and contact your doctor immediately.

3. How to take CARDURA XL

CARDURA XL is a modified release tablet. The medicine is contained within a non-absorbable shell that has been specially designed to slowly release the medicine. Once swallowed, doxazosin is slowly released into the body from the tablet, until the tablet is empty.

Since the empty tablet is eliminated from the body in bowel movements, you may occasionally observe in the stools, something that looks like a tablet. This is to be expected and you should not be concerned.

How to take your medicine

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

each day.

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

- Swallow CARDURA XL whole with water. **Do not chew, divide or crush** the tablets.

- Take your tablets as your doctor told you or by following the days and arrows on the blister foil.

- If you are still not sure, ask your doctor or pharmacist.

- 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 XL than you should:

Taking 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 immediately.

If you forget to take CARDURA XL:

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 XL can cause side effects although not everybody gets them.

STOP taking CARDURA XL 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 XL:

- Chest pain, angina
- Shortness of breath, difficulty breathing, wheezing
- Increased, decreased or irregular heartbeat
- Feeling your heartbeat (palpitations)
- Skin rash or itching (especially the whole body)
- 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 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

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 infection, urinary incontinence (inability to control passing urine), inflammation of the bladder (cystitis)
- sleepiness, general weakness
- indigestion, heartburn, dry mouth
- 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, needing to pass urine more often than usual, blood in urine
- inflammation of the joints (gout), painful joints, general pain
- swelling of the face
- sleeplessness, anxiety, depression
- reduced or altered sense of touch or sensation of the hands and feet
- increased appetite or loss of appetite, weight gain
- nose bleeds
- ringing in the ears, tremor
- failure/ inability to achieve penile erection
- abnormal results for blood tests which show changes in the way the liver is working

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
- agitation, nervousness
- tiredness, generally feeling unwell
- aggravated wheezing
- muscle cramps, muscle weakness
- blurred vision
- flushing
- disorder in passing urine, needing to pass urine at night, increased volume of urine passed, increased production of urine causing an increase in the number of times of passing urine
- 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 XL”.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store CARDURA XL.

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

Do not use CARDURA XL 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.

Store in the original package.

The tablets should be whole to work effectively, if you notice any defects (such as broken tablets) consult your pharmacist immediately.

6. Further information

What CARDURA XL contains and its package:

The active substance is Doxazosin. Each tablet contains either 4.85mg doxazosin mesilate equivalent to 4mg doxazosin or 9.70mg doxazosin mesilate equivalent to 8mg doxazosin within a shell that has been specially designed to slowly release the drug.

The other ingredients in each tablet are: polyethylene oxide, sodium chloride, hypromellose, red ferric oxide (E172), titanium dioxide (E171), magnesium stearate, cellulose acetate, Macrogol, pharmaceutical glaze, black iron oxide (E172), ammonium hydroxide and propylene glycol.

CARDURA XL tablets are white, round, biconvex shaped with a hole in one side and marked CXL 4 for the 4mg and CXL 8 for the 8mg

They are available in strengths of 4mg and 8mg modified release tablets and in packs of 28 tablets.

Marketing Authorisation Holder

Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom.

Manufacturer

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

This leaflet was last revised in 10/2014