PIL_0162/03

Package leaflet: Information for the patient

Cardura® XL 8mg Prolonged release tablets

(doxazosin mesilate)

Your medicine is known by the above name, but will be referred to as Cardura XL throughout this leaflet. This medicine is also available in 4mg.

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.
- 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 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. If you experience swelling of the face, tongue or windpipe, see your doctor immediately. If you get any side effects, talk to your doctor or pharmacist. 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 XL and tell your doctor or pharmacist.

What is in this leaflet

1. What Cardura XL is and what it is used for
2. What you need to know before you take Cardura XL
3. How to take Cardura XL
4. Possible side effects
5. How to store Cardura XL
6. Contents of the pack and other information

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

Cardura XL contains the active substance doxazosin mesilate and 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. What you need to know before you take Cardura XL

Do not take Cardura XL:

- If you are allergic to doxazosin, other quinazolines (e.g. prazosin or terazosin), or to 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 any form of obstruction of the digestive tract
- 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 XL as it 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.

Persistent painful erections may occur very rarely. If this happens, you should contact a doctor immediately. Before starting treatment with Cardura XL your doctor may perform tests to rule out other conditions such as prostate cancer that may cause the same symptoms as benign prostatic hyperplasia.

Children and adolescents

Cardura XL 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 XL

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 XL. Ask your doctor or pharmacist before use if you are taking any of these medicines as they may change the effect of 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 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 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.
- 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 XL with food and drink

See section 3 How to take Cardura XL

Pregnancy, breast-feeding and fertility

Pregnancy

The safety of using Cardura XL during pregnancy has not been established. If you are pregnant or are 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 XL, can get into your breast milk. You should not use Cardura XL 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 affected, do not drive or operate machinery and contact your doctor immediately.

Information about the ingredients of Cardura XL

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Cardura XL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Cardura XL is a prolonged 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 recommended dose of Cardura XL is one 4mg prolonged 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.
- 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.

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. 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 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
- Allergic reactions (hypersensitivity). Symptoms include sudden wheeziness, tightness in the chest, difficulty in breathing, swelling of the face, tongue or throat, rash or itching (especially the whole body)

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

- Feeling your heartbeat (palpitations) (common: may affect up to 1 in 10 people)
- Increased or decreased heartbeat (common: may affect up to 1 in 10 people)
- Shortness of breath, difficulty breathing, wheezing (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)
- Skin rash or itching (especially the whole body) (uncommon: may affect up to 1 in 100 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 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: 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 the bladder (cystitis)
- sleepiness, general weakness
- indigestion, heartburn, dry mouth
- back pain, painful muscles
- flu-like symptoms

Uncommon side effects: 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, 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

Rare side effects: may affect up to 1 in 1,000 people
- blockage of the digestive tract

Very Rare side effects: 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
- 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

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 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 XL

- Keep out of the sight and reach of children.
- Do not use after the expiry date printed on the carton label or blister strip after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package in order to protect from moisture.
- The tablets should be whole to work effectively, if you notice any defects (such as broken tablets) consult your pharmacist immediately.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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.

6. Contents of the pack and other information

What Cardura XL contains
The active substance is doxazosin mesilate.
Each prolonged release tablet contains 9.7mg doxazosin mesilate equivalent to 8mg doxazosin within a shell that has been specially designed to slowly release the drug.
The other ingredients are: sodium chloride, hypromellose, red iron oxide (E172), titanium dioxide(E171), magnesium stearate, cellulose acetate, macrogol, pharmaceutical glaze and black iron oxide (E172).

What Cardura XL looks like and contents of the pack
Cardura XL 8mg tablets are white, round, biconvex shaped and printed 'CXL8' in black ink with a hole on one side.

They are available in calendar blister packs of 28 tablets.

PL: 56830/0076 POM

Manufacturer
Manufactured by: R-PHARM GERMANY GMBH,
89257 Illertissen, Germany
or
PFIZER MANUFACTURING DEUTSCHLAND GMBH,
79090 Freiburg, Germany

Procured from within the EU and repackaged by:
BModesto B.V., Minervaweg 2, 8239 DL, Lelystad, Netherlands.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name:
Cardura XL 8mg
Prolonged release Tablets
Reference No: 56830/0076

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