

Package leaflet: Information for the patient

CARDURA® XL 8 mg

Prolonged-release Tablets

doxazosin (as 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.
- 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, 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 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 is one of a group of medicines called alpha-blockers. It is used to treat high blood pressure.

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 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 any form of obstruction of the digestive tract
- If you are under 18 years of age
- 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 an enlarged prostate gland and 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, kidney or heart disease
- If you are also taking other medicines
- If you have problems with your heart

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 XL. This is because this medicine may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Persistent painful erections may occur very rarely. If this happens you should contact a doctor immediately.

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.

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.

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 or 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 also increase the effects of drugs used to treat high blood pressure (hypertension).
- 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 and breast-feeding

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, who will decide if this medicine is suitable for you.

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 cause drowsiness and could also make you feel weak or dizzy. If you are 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 (23 mg) 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, the medicine (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 prolonged-release tablet taken once a day. Your doctor may wish to increase your dose to 8mg. This is the maximum dose of this medicine.
- Cardura XL can be taken with or without food.
- Swallow your medicine whole with water. **Do not chew, divide or crush** the tablets.
- Take your tablets as your doctor told you.
- 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 are still not sure how to take your tablets, ask your doctor or pharmacist.

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
- Increased, decreased or irregular heartbeat
- Weakness of arms, legs or problems speaking which may be symptoms of a stroke
- Allergic reactions (hypersensitivity). Symptoms include sudden wheeziness, tightness in chest, difficulty in breathing, swelling of the face, tongue or throat, rash or itching (especially affecting the whole body)

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

- Chest pain (angina), wheezing, shortness of breath, difficulty breathing
- Feeling your heartbeat (palpitations)
- 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: 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
- 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, dry mouth
- Itching
- 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, increased frequency in passing urine, blood in urine
- Inflammation of the joints (gout), painful joints, general pain
- 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
- 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 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
- Agitation or nervousness
- 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
- Blurred vision
- Hot flushes
- Muscle cramps, muscle weakness
- Disorder in passing urine, needing to pass urine at night, increased number of times of passing urine, increased volume of urine passed
- Discomfort or enlargement of the breasts in men
- Persistent painful erection of the penis. Seek urgent medical advice

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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cardura XL

Keep this medicine out of the sight and reach of children.

Do not use Cardura XL after the expiry date which is stated on the carton and tablet blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C. Keep your tablets in the original packaging 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.

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 XL contains

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

The other ingredients are sodium chloride (see section 2 "Information about the ingredients of Cardura XL"), hypromellose, red ferric oxide (E172), titanium dioxide (E171), magnesium stearate, cellulose acetate, macrogol, pharmaceutical glaze, black iron oxide (E172).

What Cardura XL looks like and contents of the pack

Cardura XL 8 mg tablets are white film coated, round biconvex shaped with a hole in one side, marked 'CXL8'.

Cardura XL 8 mg tablets are available in cartons containing blister strips of 28 tablets.

Manufacturer

Pfizer Manufacturing Deutschland GmbH, 79090 Freiburg, Germany

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

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