

PACKAGE LEAFLET : INFORMATION FOR THE USER

Cardura® XL 4mg Cardura® XL 8mg Prolonged-release Tablets doxazosin (as mesilate)

Important things that you SHOULD know about your medicine:

- Cardura XL is a treatment for high blood pressure
- 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.

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. How to Store 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.

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.

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 12 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.

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, 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.

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.

Taking other medicines:

There are some medicines that may interact with Cardura XL:

- Medicines for erectile dysfunction (impotence) such as sildenafil, tadalafil or vardenafil. 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 also increase the effects of drugs used to treat high blood pressure (hypertension). 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 and Breast-feeding:

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. 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 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.

3. HOW TO TAKE CARDURA XL

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.
- 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 miss a dose of 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.
- 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

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, cystitis, urinary incontinence (inability to control passing urine)
- sleepiness, general weakness
- indigestion, dry mouth
- itching
- 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, 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

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
- 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
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 your tablets out of the reach and sight of children.
- Do not store above 30° C.
- Store in the original package in order to protect from moisture
- Do not use Cardura XL after the expiry date which is stated on the carton, label and blister. The expiry date refers to the last day of the month.
- 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:

Cardura XL 4mg Prolonged Release Tablets contain 4mg of the active substance doxazosin (as doxazosin mesilate).

Cardura XL 8mg Prolonged Release Tablets contain 8mg of the active ingredient doxazosin (as doxazosin mesilate).

They also contain the following inactive ingredients : ammonium hydroxide (E527), propylene glycol, polyethylene oxide, sodium chloride, hypromellose, red iron oxide (E172), titanium dioxide (E171), magnesium stearate, cellulose acetate, macrogol 3350, pharmaceutical glaze, black iron oxide (E172).

The products imported from Spain also includes the following inactive ingredients: shellac, N-butyl alcohol, Isopropyl alcohol

Pharmaceutical form: Prolonged-release Tablets

Cardura XL 4mg Prolonged Release Tablets are white, round, biconvex tablets with an orifice in one side, marked 'CLX 4' on one side, plain on the other.

Cardura XL 8mg Prolonged Release Tablets are white, round, biconvex tablets with an orifice in one side, marked 'CLX 8' on one side, plain on the other.

Pack size: Cardura XL comes in packs of 28 or 30 tablets.

Manufacturer:

Pfizer Manufacturing Deutschland GmbH, Heinrich-Mack-Strasse 35, 89257 Illertissen, Germany or FARMASIERRA MANUFACTURING, S.L., Carretera N-I, Km. 26,200, 28700 San Sebastian de los Reyes (Madrid), Spain

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

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

Parallel Product Authorisation Numbers:

Cardura XL 4mg Prolonged-release Tablets-PPA 465/95/1
Cardura XL 8mg Prolonged-release Tablets-PPA 465/95/2

Cardura is a registered trademark of Pfizer Limited

Date of Leaflet Preparation by PCO Manufacturing: August 2014

As the days of the week are not listed on the blister foil in English, please use the following table should you require a translation:

English	Spanish
Mon (Monday)	Lu (Lunes)
Tue (Tuesday)	Ma (Martes)
Wed (Wednesday)	Mi (Miércoles)
Thu (Thursday)	Ju (Jueves)
Fri (Friday)	Vi (Viernes)
Sat (Saturday)	Sa (Sábado)
Sun (Sunday)	Do (Domingo)