PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

CARDURA® XL 4 mg TABLETS

CARDURA® XL 8 mg TABLETS

Doxazosin mesylate

Sugar free

Read all of this leaflet carefully before you start taking CARDURA XL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CARDURA XL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 belongs to a group of medicines called vasodilators. These substances reduce blood pressure by relaxing blood vessels. CARDURA XL also reduces tension in the muscle tissues of the prostate and the urinary tract. It is used to treat high blood pressure and benign prostatic hyperplasia (enlargement of the prostate which impairs the urine flow).

2. What you need to know before you take CARDURA XL

Do not take CARDURA XL:

- If you are hypersensitive (allergic) to doxazosin, or other quinazolines (such as prazosin and terazosin) or any of the other ingredients of CARDURA XL (listed in section 6).
- If you are pregnant or breastfeeding an infant.
- If you have previously experienced any form of obstruction of the digestive tract.

Warnings and precautions

Talk to your doctor or pharmacist before you take CARDURA XL:

- If you are pregnant or trying to become pregnant.
- If you have liver disease.
- If you are also taking other medicines.
- When you start to take CARDURA XL, you may experience feeling faint or dizzy 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.
- If you are taking PDE-5 inhibitors for erectile dysfunction, please tell your doctor before you start taking the tablets.
- If you have liver disease, please tell your doctor before you start taking the tablets.
- Please tell your eye surgeon in advance that you are taking or have previously taken CARDURA XL if you are about to undergo cataract or eye surgery. This is because CARDURA XL may cause complications during the surgery which can be managed if your specialist is prepared in advance.
- If you experience a persistent painful erection, you must seek immediate medical attention. If this is not treated immediately, penile tissue damage and permanent erectile dysfunction could result.

Other medicines and CARDURA XL

Always tell your health care provider if you are taking or have recently taken or might take any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may interact with CARDURA XL including the following:

- Medicines called PDE-5 inhibitors, which are used for the treatment of erectile dysfunction (impotence), as you may experience dizziness or light-headedness, which may be caused by low

blood pressure upon sitting or standing up quickly.

- Medicines used to treat bacterial or fungal infections (e.g. clarithromycin, itraconazole, ketoconazole, telithromycin or voriconazole).
- Medicines used in the treatment of HIV (e.g. indinavir, nelfinavir, ritonavir, saquinavir).
- Nefazodone, a medicine used to treat depression.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

There is minimal information on safety for CARDURA XL in pregnancy or breastfeeding.

Small amounts of doxazosin, the active substance of CARDURA XL, can get into your breast milk.

Driving and using machines

CARDURA XL may affect your ability to drive or operate machinery safely, especially when you first start to take the tablets. If you are affected, do not drive or operate machinery.

It is not always possible to predict to what extent CARDURA XL may interfere with the daily activities of the patient. Patients should ensure that they do not engage in the above activities until they are aware of the measures to which CARDURA XL affects them.

CARDURA XL contains sodium

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

Do not share medicines prescribed for you with any other person.

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

The usual dose of CARDURA XL is one 4 mg tablet once daily in the morning with food. Your doctor may wish to increase this dose to CARDURA XL 8 mg daily. This is the maximum dose of CARDURA XL.

Take CARDURA XL once a day, every day, at about the same time each day.

Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.

You should take CARDURA XL tablets with food. The tablets should be swallowed whole with a sufficient quantity of liquid. Do not chew, divide, cut or crush the tablets.

In CARDURA XL, the medicine is contained within a non-absorbable shell that has been specially designed to slowly release the medicine. When this process is completed, the empty tablet is eliminated from the body. You should not be concerned if you occasionally observe the empty tablet in your stool.

Your doctor will tell you how long your treatment with CARDURA XL will last. If you have the impression that the effect of CARDURA XL is too strong or too weak, tell your doctor or pharmacist.

If you take more CARDURA XL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CARDURA XL

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CARDURA XL can have side effects.

Not all side effects reported for CARDURA XL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CARDURA XL, please consult your health care provider for advice.

If any of the following happens, stop taking CARDURA XL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CARDURA XL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Respiratory tract infection.
- Urinary tract infection.
- Dizziness.
- Headache.
- Tiredness/sleepiness.
- Feeling of spinning or rotation of surroundings (vertigo).
- Increased/irregular rate in the heartbeat.
- Low blood pressure.
- Faintness (especially on getting up from a sitting or lying position).
- Bronchitis.
- Coughing.
- Difficulty in breathing.
- Nasal stuffiness and/or runny nose.
- Stomach pain.
- Heartburn or indigestion.
- Dry mouth.
- Nausea.
- Itching.
- Back pain.
- Muscle pain.
- Bladder inflammation (cystitis).
- Inability to control the bladder.
- Lack of energy.
- Chest pain.
- Flu like symptoms.
- Swelling of the feet or lower legs.

Other side effects

- Low number of white blood cells or blood platelets, which may result in bruising or easy bleeding.
- Allergic reactions.
- Loss of appetite (anorexia).
- Anxiety.
- Depression.
- Inability to sleep.
- Agitation.
- Nervousness.
- Stroke.
- Reduced sensitivity to touch.
- Fainting.
- Tremor.
- Tingling or numbness of the hands and feet.
- Blurred vision.
- Eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye).
- Ringing in the ears.
- Chest pain.
- Heart attack.
- Slow or irregular heartbeat.
- Hot flushes.
- Nose bleeds.
- Constipation.
- Diarrhoea.
- Excess air/gas in the stomach.
- Vomiting.
- Gastrointestinal blockage.
- Bile disorder.
- Inflammation of the liver.
- Yellowing of the skin and eyes (jaundice).

- Skin rash.
- Hair loss.
- Red or purple patches on the skin.
- Joint pain.
- Muscle cramps.
- Muscle weakness.
- Painful or difficulty in passing urine.
- Blood in the urine.
- More frequent urination.
- Sexual dysfunction.
- Enlargement of breasts in males.
- Prolonged and painful erection.
- No semen on ejaculation.
- Pain.
- Feeling weak.
- Abnormal liver function tests.
- Weight increase.

If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CARDURA XL.

5. How to store CARDURA XL

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original package to protect from light, moisture and humidity.

- Keep the blister in the outer carton.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CARDURA XL contains

The active substance is doxazosin mesylate.

Each CARDURA XL 4 mg tablet contains 5,093 mg doxazosin mesylate, which is equivalent to 4 mg of doxazosin.

Each CARDURA XL 8 mg tablet contains 10,185 mg doxazosin mesylate, which is equivalent to 8 mg of doxazosin.

The other ingredients are:

Tablet core: hydroxypropyl methylcellulose, magnesium stearate, polyethylene oxide, red ferric oxide, sodium chloride.

Film-coat: black ink (ammonium hydroxide, iron oxide black, isopropyl alcohol, modified pharmaceutical glaze, n-butyl alcohol, propylene glycol), cellulose acetate, polyethylene glycol, Opadry White (hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide).

What CARDURA XL looks like and contents of the pack

CARDURA XL 4 mg TABLETS: A round, biconvex shaped, white film-coated tablet, approximately 9,0 mm in diameter with an orifice on one side imprinted with “CXL 4”.

CARDURA XL 8 mg TABLETS: A round, biconvex shaped, white film-coated tablet, approximately 11,4 mm in diameter with an orifice on one side imprinted with “CXL 8”.

CARDURA XL TABLETS are available in blister packs containing 30, 60, 90, 120, 240, 360 or 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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CARDURA XL 4 mg TABLETS: 32/7.1/0556

CARDURA XL 8 mg TABLETS: 32/7.1/0557

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CARDURA XL 4 mg – Reg. No.: BOT0700932

CARDURA XL 8 mg – Reg. No.: BOT0700933

NAMIBIA: NS2

CARDURA XL 4 mg – Reg. No.: 04/7.1/1222

CARDURA XL 8 mg – Reg. No.: 04/7.1/1223

ZAMBIA: POM

CARDURA XL 4 mg – Reg. No.: 120/039

CARDURA XL 8 mg – Reg. No.: 120/040

ZIMBABWE: PP10

CARDURA XL 4 mg – Reg. No.: 2001/12.3.1/3952

CARDURA XL 8 mg – Reg. No.: 2001/12.3.1/3953