

PATIENT INFORMATION LEAFLET (CLEAN)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

CARZIN XL 4 mg prolonged-release film coated tablet

Doxazosin

CARZIN XL contains sugar (lactose monohydrate 74,27 mg)

Read all of this leaflet carefully before you start taking/using CARZIN XL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- CARZIN 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 CARZIN XL is and what it is used for
2. What you need to know before you take/use CARZIN XL
3. How to take/use CARZIN XL
4. Possible side effects

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5. How to store CARZIN XL
6. Contents of the pack and other information

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

CARZIN XL contains the active substance doxazosin mesylate and is one of a group of medicines called alpha-blockers.

CARZIN XL is indicated for the treatment of:

- mild to moderate high blood pressure (hypertension)
- symptoms associated with benign (non-cancerous) enlargement of the prostate (benign prostatic hyperplasia) and for reduced urinary flow due to BPH. CARZIN XL may be used in patients with BPH who have normal or high blood pressure.

2. What you need to know before you take/use CARZIN XL

Do not take/use CARZIN XL:

- if you are hypersensitive (allergic) to doxazosin, other quinazolines or to any of the other ingredients of CARZIN XL (listed in section 6)
- if you suffer from gastrointestinal (gullet, stomach, and intestines) obstruction. If you take CARZIN XL, you may have an increased risk of side-effects
- if you are pregnant or breastfeeding an infant

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- 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 (benign prostatic hyperplasia) and have low blood pressure.

Warnings and precautions

Take special care with CARZIN XL:

The presence of other medical problems may affect the use of CARZIN XL. Make sure to tell your doctor if you have other conditions, especially:

- if you have low blood pressure, as you may feel dizzy, weak, or faint after the first dose of CARZIN XL or after a dose increase.

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

- if you are taking PDE-5 inhibitors, such as sildenafil (to treat impotence)

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- [~~Kidney or~~] if you have liver disease. You may experience more of the side-effects of CARZIN XL
- if you have heart problems. CARZIN XL may make the condition worse
- if you are undergoing eye surgery due to cataract(s) (cloudiness of the lens of the eye), please inform your eye specialist before the operation that you are using or have previously used CARZIN XL. This is because CARZIN XL may cause complications during the surgery, which can be managed if your specialist is alerted in advance
- persistent painful erections may occur very rarely in men taking CARZIN XL. If this happens you should contact a doctor immediately
- before starting treatment with CARZIN 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 CARZIN XL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- 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

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- tell your doctor if you are using medication that lowers your blood pressure, such as diuretics, beta-blockers, and calcium channel blockers. Dizziness, light headedness, or sudden fainting is more likely when you take CARZIN XL together with these medicines, or with alcohol
- 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, or any other medicines used to treat mental disorders known as antidepressants or antipsychotics.

CARZIN XL with food, and drink and alcohol

You can take the tablet with or without food.

Taking alcohol while using CARZIN XL may increase your risk to become dizzy or faint.

Pregnancy, breastfeeding, and fertility

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 healthcare provider for advice before using CARZIN XL.

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CARZIN XL has not been studied in pregnant and breast-feeding women. It is not known whether the tablet is safe for use during pregnancy and lactation.

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

Driving and using machines

Your ability to drive or operate machinery may be impaired by CARZIN XL, especially when you are at the start of treatment. You should drive or operate machinery with caution.

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

CARZIN XL contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take/use CARZIN XL

Do not share medicines prescribed for you with any other person. Always use CARZIN XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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You can take the tablet with or without food. Swallow the tablet whole with a sufficient amount of water – do not chew or crush it.

Hypertension

The usual dose is one tablet daily. Your doctor may increase the dosage to two tablets once daily.

If your hypertension is not adequately controlled, your doctor may combine CARZIN XL with a thiazide diuretic or a beta-blocking medicine.

Benign Prostatic Hyperplasia

The usual dose is one tablet daily. Your doctor may increase the dosage to two tablets once daily.

Your doctor will tell you how long your treatment with CARZIN XL will last. Do not stop treatment early because your symptoms may return.

If you have the impression that the effect of CARZIN XL is too strong or too weak, tell your doctor or pharmacist.

If you take/use more CARZIN XL than you should

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

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Symptoms of overdose may include:

- light-headedness, dizziness or fainting upon standing.

If you forget/use to take CARZIN XL

If you miss a dose of CARZIN XL, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking/using CARZIN XL

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.

4. Possible side effects

CARZIN XL can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth, or throat, which may cause

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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 allergic reaction to CARZIN XL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- yellow eyes and skin, also called jaundice
- chest pain, discomfort, or tightness in the chest (angina), changes in the way your heart beats (for example, if you notice it beating faster), difficulty breathing, shortness of breath, wheezing
- bladder pain, cloudy or dark urine, painful urination, trouble in holding or releasing urine
- painful or prolonged erection of the penis (called priapism)
- weakness of arms, legs or problems speaking which may be symptoms of a stroke.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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Frequent side effects:

- respiratory tract (nose, throat, lungs) infection, wheezing
- difficult or painful urination, blood in urine, increased urge to urinate during the night, increased volume of pale dilute urine, lower back, or side pain. These are symptoms of a urinary tract infection
- frequent urination or changes in frequency of urination, frequent urge to urinate
- “flu-like” symptoms including fever, cough, runny nose, sneezing, sore throat
- faintness or light headedness including when getting up from a lying or sitting position, and sudden fainting
- dizziness, headache, sleepiness, sleep disturbances, drowsiness, general weakness
- sensation that the room is spinning (vertigo)
- acid stomach, belching, heartburn, indigestion, stomach pain or discomfort, dry mouth, nausea
- skin rash or itching
- back pain, muscle pain or stiffness
- swelling of feet or lower legs, lack or loss of strength.

Less frequent side effects:

- inflammation of the joints (gout), increased appetite
- abnormal results for blood tests which show changes in the way the liver is

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working

- facial swelling.

The following side effects have been reported but the frequency for them to occur is not known:

- unusual bleeding or bruising
- loss of appetite, weight loss, excessive sweating
- anxiety, trouble sleeping, nervousness, restlessness, unusual irritability, depression, paranoia, hallucinations (hearing or seeing things which are not there) or confusion
- tremor, reduced or altered sense of touch or sensation of the hands and feet, shaking, feeling dizzy when standing still, a sensation of burning, crawling, itching, numbness, prickling, or “pins and needles” feeling
- blurred vision, eye problems may occur during eye surgery for cataract(s) (cloudiness of the lens of the eye)
- ringing in the ears
- hot flushes, low blood pressure
- nose bleeds, blocked nose, wheezing
- vomiting, constipation, wind, diarrhoea, faecal incontinence (lack of control over bowel movements), gastrointestinal blockage
- hepatitis (liver inflammation) or bile disorder, inflammation of the pancreas, liver

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problems

- hair loss, pinpoint red or purple spots on skin, hives or welts, redness of skin, ulcers or white spot on lips or mouth
- joint pain, swollen joints, muscle aching or cramping, muscle weakness
- swelling of breast or breast soreness, failure/ inability to achieve penile erection (impotence), little or no semen ejaculated at sexual climax, cloudy urine following sexual climax
- pain, general tiredness or weakness, general feeling of discomfort or illness
- weight gain, abnormal liver test results.

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, pharmacist, or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of CARZIN XL.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

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5. How to store CARZIN XL

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from light and moisture.

Keep blisters in carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the 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 CARZIN XL contains

The active ingredient is doxazosin.

Each film coated tablet contains doxazosin mesylate equivalent to 4 mg doxazosin.

The other ingredients are:

Tablet cores:

Calcium hydrogen phosphate anhydrous, hypromellose, lactose monohydrate, magnesium stearate

Film coating - Composition of Opadry White Y-1-7000:

Hypromellose, macrogol 400 and titanium dioxide (E171)

Carzin XL (4 mg)
Pharma Dynamics (Pty) Ltd
Submitted: 30 September 2022
Implementation (67 working days): 05 January 2023

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What CARZIN XL looks like and contents of the pack

White, round, slightly biconvex, film coated tablet.

CARZIN XL is available in pack sizes of 30 tablets, packed in blister strips of OPA/AL/PVC film and aluminium foil, in an outer carton.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

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www.pharmadynamics.co.za

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