

Package Leaflet: Information for the patient

Slocinx XL 4 mg prolonged-release tablets Doxazosin

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.
- 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.

What is in this leaflet

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

The name of this product is Slocinx XL 4 mg prolonged-release tablets (referred to as Slocinx XL throughout this leaflet). It contains the active substance doxazosin mesilate and is one of a group of medicines called alpha-blockers.

It 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 Slocinx XL is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate. Slocinx 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 Slocinx XL

Do not take Slocinx XL and tell your doctor 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). Signs of an allergic reaction include itching, reddening of the skin or difficulty in breathing.
- you are breast-feeding.
- you have any form of obstruction of the digestive tract.
- you have an enlarged prostate gland (benign prostatic hyperplasia) **and** have low blood pressure.
- 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.
- 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 had bladder stones.
- 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 Slocinx XL as it may not be suitable for you if you

- are pregnant or trying to become pregnant.

- have liver disease.
- have something called ‘diabetic autonomic neuropathy’. This is a disease related to diabetes which affects your nervous system.
- have heart disease.
- 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 Slocinx XL. This is because Slocinx 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 Slocinx 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 Slocinx 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

Slocinx 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 Slocinx XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may interact with Slocinx 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 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.
- Slocinx 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.
- Painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) – such as ibuprofen.
- Other medicines which lower blood pressure.
- Medicines containing oestrogen – such as the contraceptive pill or hormone replacement therapy (HRT).
- Medicines containing dopamine, metaraminol, methoxamine, adrenaline (epinephrine). Also, medicines for coughs and colds (as they may contain ephedrine, phenylephrine).

Slocinx XL with food and drink

Slocinx XL can be taken with or after food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The safety of using Slocinx XL during pregnancy has not been established.

Do not take this medicine if you are breast-feeding.

Driving and using machines

Take care if you drive or operate machinery. Slocinx XL 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.

Slocinx 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 Slocinx 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.

Slocinx 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 Slocinx XL is one 4 mg 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 Slocinx XL.
- Swallow the tablet whole with water. Do not chew, divide or crush the tablets.
- Take your tablets as your doctor told you.
- 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.

If you take more Slocinx 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 Slocinx 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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Slocinx XL and call an ambulance immediately if you experience any of the following:

- Heart attack (uncommon: may affect up to 1 in 100 people).
- Weakness of arms, legs or problems speaking which may be symptoms of a stroke (uncommon: may affect up to 1 in 100 people).
- 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) (uncommon: may affect up to 1 in 100 people).

Tell your doctor immediately if you experience any of the following symptoms after taking Slocinx 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).
- If you feel nervous, shaky or sweaty. These may be signs of low blood sugar levels (hypoglycaemia) (rare: may affect up to 1 in 1,000 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) (rare: may affect up to 1 in 1,000 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 doxazosin. If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Dizziness, feeling of spinning or rotation of surroundings (vertigo), headache.
- Problems with focussing your eyes
- Low blood pressure (hypotension), feeling faint or dizzy when standing up from sitting or lying position (orthostatic hypotension). This happens especially at the beginning of your treatment or if you restart your treatment after a break. If these symptoms last for a long time or become a problem, talk to your doctor or pharmacist.
- Water retention.
- 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).
- Lack of interest or emotion (apathy).
- Sleepiness, general weakness.
- Indigestion, stomach ache, dry mouth.
- Back pain, pain of muscles.
- Flu like symptoms.

Uncommon (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.
- Low levels of potassium in the blood, feeling more thirsty than usual.
- Inflammation of the joints (gout), painful joints, general pain.
- Flushing, high temperature (fever), shivers.
- Swelling of the face.
- Nightmares, forgetfulness (amnesia), feeling emotionally unstable.

- Sleeplessness, anxiety, depression.
- Watery eyes, being more sensitive to light than usual.
- Reduced or altered sense of touch or sensation of the hands and feet.
- Increased appetite or loss of appetite, weight gain.
- Reduced blood supply to the limbs.
- Nose bleeds, sore throat.
- 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 (may affect up to 1 in 1,000 people)

- Blockage of the digestive tract.
- Swelling of the voice box.
- Low body temperature (especially in the elderly).

Very rare (may affect up to 1 in 10,000 people)

- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness.
- 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.
- A blood or urine test may show changes to the way your kidneys are working.
- 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”.
- Changes in the way things taste.

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: 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 Slocinx XL

Keep this medicine out of the sight and reach of children

Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Slocinx XL contain

- The active substance is doxazosin mesilate. Each tablet contains the active ingredient doxazosin mesilate equivalent to 4 mg of doxazosin.
- The other ingredients are blends of polyethylene oxide preparations containing butylhydroxytoluene (E321), microcrystalline cellulose, povidone, α -tocopherol, colloidal anhydrous silica and sodium stearyl fumarate. The tablet coating contains methacrylic acid copolymer, colloidal anhydrous silica, macrogol and titanium dioxide (E171).

What Slocinx XL looks like and contents of the pack

Your medicine is in the form of a round biconvex white prolonged release tablet marked “DL” on one side.

Tablets are available in blister packs of 28, 30 and 100 tablets.

Not all pack size may be marketed.

Marketing Authorisation Holder:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

Manufacturer:

Zentiva Pharma UK Limited, One Onslow Street, Guildford, Surrey, GU1 4YS, United Kingdom

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