

Package leaflet: Information for the patient

Doxane 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

1. What Doxane XL is and what it is used for
2. What you need to know before you take Doxane XL
3. How to take Doxane XL
4. Possible side effects
5. How to store Doxane XL
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1. What Doxane XL is and what it is used for

Doxane XL is one of a group of medicines called alpha-blockers.

It is used to treat:

- high blood pressure
- symptoms caused by enlargement of the prostate gland in men.

In patients taking this medicine to treat high blood pressure (hypertension), it works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

In patients with enlargement of the prostate gland, this medicine is taken to treat poor and/or frequent passing of urine. This is common in patients with enlargement of the prostate gland (benign prostatic hyperplasia). This medicine 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 Doxane XL

Do not take Doxane XL

- if you are allergic to doxazosin, related quinazolines e.g. prazosin or terazosin, or any of the other ingredients of this medicine (listed in section 6)
- if you have had any form of obstruction of the digestive tract

- if you have an enlarged prostate gland together with congestion of the upper urinary tract, chronic urinary tract infections or bladder stones
- if you suffer from a loss of bladder control (overflow incontinence) or anuria (your body is not producing any urine) with or without kidney problems
- if you are being treated for an enlarged prostate gland and you have low blood pressure
- if you have or have ever had a fall in blood pressure on standing up, causing dizziness, light-headedness or fainting.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you have liver disease
- if you have heart disease and in particular cardiac insufficiency or pulmonary oedema (water deposits in the lungs)
- if you are pregnant or trying to become pregnant
- if you are also taking medicines that are used to treat erection problems (PDE-5 inhibitors, e.g. sildenafil, tadalafil, vardenafil) (see section “Other medicines and Doxane XL.”)

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

Dizziness, weakness and in rare cases fainting may occur, especially when you first start taking this medicine. You should therefore be careful at the beginning of treatment, and avoid situations that could lead to injury if these symptoms occur. Should you feel dizzy or faint, lie down and the symptoms should disappear rapidly. Your doctor may want to measure your blood pressure regularly at the start of therapy to reduce the possibility of these effects happening.

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

Before starting treatment with Doxane XL for an enlarged prostate gland, 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 Doxane XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to mention the following before taking this medicine:

- medicines used to treat difficulties in getting an erection (e.g. sildenafil, tadalafil or vardenafil) together with Doxane XL may lower your blood pressure. Certain patients may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of Doxane XL before you start medicines for erectile dysfunction (impotence). Your doctor may start you on the lowest possible dose of medicines for erectile dysfunction, and it is recommended to take it at least 6 hours away from the intake of Doxane XL.
- medicines for high blood pressure (called antihypertensives), including terazosin and prazosin
- 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.

Pregnancy and breast-feeding

The safety of this medicine in pregnancy is not sufficiently established. 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.

Small amounts of doxazosin, the active substance of this medicine, can get into your breast milk. You should not take this medicine if you are 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 make you feel weak or dizzy. If affected, do not drive or operate machinery and contact your doctor immediately.

Doxane 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 Doxane 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.

The recommended dose of Doxane XL is 4 mg taken as a single daily dose.

Your doctor may wish to increase your dose to 8 mg once daily. This is the maximum dose of Doxane XL.

Doxane 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.

Method of administration:

- Do not chew, divide or crush the tablets.
- Swallow the tablets whole with a drink of water.
- You can take these tablets with or without food.

Elderly

Normal adult dose is recommended for elderly, however the dose should be kept as low as possible.

Patients with liver disorders

If you have liver problems your doctor will monitor you closely during treatment. This medicine is not recommended for use in patients with severe liver problems.

Use in children and adolescents

This medicine is not recommended for patients under the age of 18 years. Benign prostate hyperplasia is not relevant in children.

If you take more of Doxane XL than you should

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.

If you forget to take Doxane XL

Do not worry. If you forget to take a tablet, leave that dose out completely. Then go back to your usual schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Doxane XL

It is important to keep taking your tablets. Do not change the dose or stop taking the tablets without first checking with your doctor.

Do not wait until your tablets are finished before seeing your doctor.

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

4. Possible side effects

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

Some side effects could be serious:

Stop taking this medicine and call an ambulance immediately:

- Allergic reactions such as wheezing, shortness of breath, extreme dizziness or collapse, swelling of the face or throat, skin rash or itching (especially the whole body).
- Heart attack or stroke (weakness of arms, legs or problems speaking).

These side effects are uncommon (may affect up to 1 in 100 people).

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

- Feeling your heartbeat (palpitations) (common: may affect up to 1 in 10 people)
- Increased heartbeat (common: may affect up to 1 in 10 people)
- Chest pain, angina (uncommon: may affect up to 1 in 100 people)
- Shortness of breath, difficulty breathing, wheezing (very rare: may affect up to 1 in 10,000 people)
- Irregular heartbeat (very rare: may affect up to 1 in 10,000 people)
- Slower heartbeat (very rare: may affect up to 1 in 10,000 people)
- Yellowing of the skin or whites of the eyes, itching, loss of appetite, and dark-coloured urine, caused by liver problems or bile disorders (very rare: may affect up to 1 in 10,000 people).
- Reduction in the number of white blood cells or blood platelets which makes infections more likely or unusual bruising or bleeding (very rare: may affect up to 1 in 10,000 people)
- Persistent painful erection of the penis (very rare: may affect up to 1 in 10,000 people).

Other side effects:

Common (may affect up to 1 in 10 people)

- infections of the respiratory and urinary tract
- dizziness, headache, sleepiness
- low blood pressure
- fall in blood pressure on standing up which may cause dizziness, light-headedness or fainting
- spinning sensation
- itching
- shortness of breath, nasal stuffiness or runny nose (rhinitis)
- cough with phlegm, chest pain, fever (bronchitis), cough
- abdominal pain, indigestion, dry mouth, feeling sick
- back pain, muscle pain
- painful and frequent urination (cystitis), inability to control urination (urinary incontinence)
- weakness, chest pain, flu-like symptoms, swollen hands, ankles or feet.

Uncommon (may affect up to 1 in 100 people)

- loss of appetite, increased appetite
- gout (painful and swollen joints)
- anxiety, depression, difficulty in sleeping
- decreased skin sensitivity, fainting, shaking (tremor)
- ringing or noise in the ears
- nose bleeds
- constipation, diarrhoea, wind, vomiting, inflammation of stomach and gut (gastroenteritis)
- abnormal liver function tests
- skin rash
- painful joints
- blood in urine, difficulty or pain on passing urine, abnormal urination frequency
- failure/ inability to achieve penile erection
- pain, swelling of the face (facial oedema)
- weight increase.

Rare (may affect up to 1 in 1,000 people)

- blockage of the digestive tract.

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

- agitation, nervousness
- dizziness when getting up from a sitting or lying position
- tingling or altered sensitivity of the hands and feet
- blurred vision
- flushing
- hair loss, purple skin patches, itchy rash
- muscle cramps, muscle weakness
- micturition disorder, frequent need to urinate, increased urination, need to get up during the night in order to urinate (nocturia)
- enlargement of male breasts
- tiredness, generally feeling unwell.

Not known (frequency cannot be estimated from the available data)

- ejaculation backwards into the bladder instead of forward through the urethra (retrograde ejaculation, “dry orgasm”)
- a certain complication that may occur during cataract surgery (intraoperative floppy iris syndrome, see also 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, 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 Doxane XL

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

Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”. 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 Doxane XL contains

The active substance is doxazosin.

Each tablet contains 4 mg of doxazosin (as mesilate).

Other ingredients are macrogol 200, macrogol 900, butylhydroxytoluene (E321), cellulose microcrystalline, povidone K30, all-rac- α tocopherol, colloidal anhydrous silica, sodium stearyl fumarate, methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30%, colloidal silica, hydrated Macrogol 1300-1600, titanium dioxide (E171).

What Doxane XL looks like and contents of the pack

White, round, biconvex prolonged-release tablets marked with “DL”.

The prolonged-release tablets are packed in Alu/PVC/PVDC-blisters which are inserted in a carton folder.

Pack sizes:

Blister: 14, 28, 30, 56 or 98 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland Doxane XL 4 mg prolonged-release tablets

This leaflet was last revised in 07/2019.