

PACKAGE LEAFLET: INFORMATION FOR THE USER

Doxane XL 4mg 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.

What is in this leaflet

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1. What Doxane XL 4mg Prolonged-Release Tablets are and what they are used for

Doxane XL 4mg Prolonged-Release Tablets are 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 4mg Prolonged-Release Tablets

Do not take this medicine

- if you are allergic (hypersensitive) to doxazosin, related quinazolines e.g. prazosin or terazosin, or any of the other ingredients of this medicine (see 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 (bladder overflow), an inability to urinate, or kidney failure
- if you are breast-feeding
- 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 before taking this medicine:

- if you have liver disease
- if you have heart disease
- if you undergo a surgery of cataract (clouding of eye lens)
- If you are pregnant or trying to become pregnant
- If you are also taking other medicines.

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.

Other medicines and Doxane XL

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. 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 they may lower your blood pressure
- medicines for high blood pressure (called anti-hypertensives).

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.

Pregnancy and breast-feeding

- If you are pregnant do not take this medicine without consulting your doctor first. The safety of this medicine in pregnancy is not sufficiently established.
- You should not take this medicine if you are breast-feeding (see section 2 “Do not take this medicine”).

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.

3. How to take Doxane XL 4mg Prolonged-Release Tablets

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

The recommended dose of Doxane XL 4mg Prolonged-Release Tablets 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 4mg Prolonged-Release Tablets.

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.

Children and adolescents:

This medicine is not recommended for patients under the age of 18 years.

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.

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 effect

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

Some side effects could be serious:

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

- allergic reactions such as wheezing, shortness of breath, extreme dizziness or collapse, swelling of the face or throat, or a serious skin rash with red spots or blisters
- chest pain, increased or irregular heartbeat, heart attack or stroke
- yellowing of the skin or whites of the eyes and itching, caused by liver problems
- unusual bruising or bleeding caused by low blood platelets.

These side effects are uncommon (affects less than 1 in 100 patients) or rare (affects less than 1 in 1000 patients).

Other side effects:

Common (affects less than 1 in 10 patients):

- infections of the respiratory and urinary tract
- dizziness, headache, sleepiness
- feeling of strong heartbeats, increased heartbeat
- 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)
- bronchitis, cough
- abdominal pain, indigestion, dry mouth, feeling/ being sick
- back pain, muscle pain
- painful and frequent urination, inability to control urination (urinary incontinence)
- weakness, chest pain, flu-like symptoms, swollen hands, ankles or feet.

Uncommon (affects less than 1 in 100 patients):

- loss of appetite, increased appetite
- gout
- anxiety, depression, difficulty in sleeping
- decreased skin sensitivity, fainting, shaking (tremor)
- ringing or noise in the ears
- nose bleeds
- constipation, diarrhoea, flatulence, vomiting, 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
- weight increase.

Very rare (affects less than 1 in 10,000 patients):

- low level of white blood cells
- agitation, nervousness
- tingling or altered sensitivity of the hands and feet
- blurred vision

- slowing of the heart rate
- flush
- difficulty in breathing or wheezing
- 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, persistent painful erection of the penis - Seek urgent medical advice.
- tiredness, generally feeling unwell, swelling of the skin.

Frequency not known:

- taste disturbances
- ejaculation backwards into the bladder instead of forward through the urethra (retrograde ejaculation)
- a certain complication that may occur during cataract surgery (intraoperative floppy iris syndrome, see also section 2 “Take special care with this medicine”).

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 4mg Prolonged-Release Tablets

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

Do not use Doxane XL 4mg Prolonged-Release Tablets after the expiry date which is stated on the carton 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 4mg Prolonged-Release Tablets contain

- The active substance is doxazosin . Each tablet contains 4 mg doxazosin (as mesilate).
- Other ingredients are:

Core:

Macrogol 200

Macrogol 900

Butylhydroxytoluene (E321)

Cellulose microcrystalline

Povidone K 30
 α -Tocopherol (E307)
Colloidal anhydrous silica
Sodium stearyl fumarate

Coating:

Methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30%
Colloidal silica, hydrated
Macrogol,(1300-1600)
Titanium dioxide (E171).

What Doxane XL 4mg Prolonged-Release Tablets look like and contents of the pack

Doxane XL 4mg Prolonged-Release Tablets are white, round, biconvex tablets marked with “DL”

Doxane XL 4mg Prolonged-Release Tablets are packed in blisters.

The blisters are packed in a carton box containing 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:

United Kingdom	Dosano XL 4 mg prolonged-release tablets
Ireland	Doxane XL 4mg Prolonged-Release Tablets

This leaflet is last approved in 04/2019.