

DOXATAN XL 4 mg

Prolonged-release Tablets

Doxazosin (as mesilate)

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 Doxatan XL 4 mg is and what it is used for
2. What you need to know before you take Doxatan XL 4 mg
3. How to take Doxatan XL 4 mg
4. Possible side effects
5. How to store Doxatan XL 4 mg
6. Contents of the pack and other information

1. What Doxatan XL 4 mg is and what it is used for

Doxatan XL contains Doxazosin which belongs to a group of medicines called alpha-blockers. It works by relaxing blood vessels so that the blood passes through them more easily.

Your doctor may have prescribed Doxatan XL because your blood pressure is high. High blood pressure (hypertension), if left uncontrolled, can increase the risk of heart disease or stroke. Doxatan XL 4mg helps to lower your blood pressure, which reduces this risk.

2. What you need to know before you take Doxatan XL 4 mg

Do not take Doxatan XL 4 mg

- if you are allergic to doxazosin or any of the other ingredients of this medicine (listed in section 6). Symptoms of an allergic reaction can include itching, reddening of the skin or difficulty in breathing
- if you are allergic to other types of quinazolines (such as prazosin or terazosin)
- if you are breast-feeding
- if you have any form of obstruction of the digestive tract
- 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 stones in your bladder
- if you have an enlarged prostate gland and 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.
- Doxatan XL is not recommended for use in children or adolescents below 18 years as safety and efficacy have not yet been established.

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxatan XL 4 mg

- if you are pregnant, or planning to become pregnant
- if you have liver, kidney or heart disease
- if you are also taking other medicines

If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Doxatan XL 4 mg. This is because Doxatan XL 4 mg may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Prolonged and sometimes painful erections – this occurs very rarely. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

When you start taking Doxatan XL 4 mg you may have a condition called 'orthostatic hypotension', where you experience faintness or dizziness due to 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.

Other medicines and Doxatan XL 4 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Medicines for erectile dysfunction (impotence) for example sildenafil, tadalafil or vardenafil. Some patients who are taking 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. To reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha blocker before you start to take drugs for erectile dysfunction.
- The effects of drugs used to treat high blood pressure (hypertension) may also be increased by Doxatan XL 4 mg.

You should always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed, because they might interact with Doxatan XL 4 mg.

Doxatan XL 4 mg with food and drink

Doxatan XL 4 mg can be taken with or without food.

Pregnancy and breast-feeding

The safety of using Doxatan XL 4 mg during pregnancy has not been 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.

Driving and using machines

Doxatan Tablets can affect your ability to drive, usually when you first start taking your medicine or if the doctor increases your dose. If you feel dizzy or light-headed when taking Doxatan, you must not drive or operate machinery. You should also be careful if you are starting to take your medicine again after not having taken it for some time.

Doxatan XL contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Doxatan XL 4 mg

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

Adults and the elderly

The recommended dose is one tablet (4 mg) each day. Your doctor may increase your dose to the maximum recommended dose of two tablets each day.

Use in children and adolescents

Doxatan XL 4mg should not be used in children and adolescents.

Choose any time of the day that it is convenient for you and take your tablets at this time each day. The tablets must be swallowed whole with a sufficient amount of water. **Do not chew, divide or crush the tablets.** Doxatan XL 4 mg has been specially designed to release the active ingredient slowly throughout the day.

If you take more Doxatan XL 4 mg than you should

If you take too many tablets you should lie down on your back with your feet higher than your head. The most likely symptoms of overdose would be a feeling of light-headedness or dizziness due to a fall in blood pressure. If you have any of these symptoms you should tell your doctor or pharmacist or telephone your nearest casualty department immediately.



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If you forget to take Doxatan XL 4 mg

If you miss a dose, do not worry. Simply take the next day's tablet when it is due. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Doxatan XL 4 mg

Keep taking your tablets until your doctor tells you to stop, even if you are feeling well.

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.

STOP taking Doxatan XL 4 mg and call your doctor or hospital emergency department immediately if you experience any of the following

- Heart attack
- Increased, decreased or irregular heartbeat
- Weakness of the arms, legs or problems speaking which may be symptoms of a stroke
- Allergic reactions (hypersensitivity). Symptoms include sudden wheeziness, tightness in chest, difficulty breathing, swelling of the face, tongue or throat, rash or itching (especially affecting the whole body).

Tell your doctor **immediately** if you experience any of the following after taking Doxatan XL 4 mg

- Chest pain (angina), wheezing, shortness of breath, difficulty breathing
- Feeling your heartbeat (palpitations)
- Fainting
- Yellowing of the skin or the whites of your eyes (jaundice)
- Low numbers of white blood cells or blood platelets, which may result in bruising or bleeding more easily.

When you start taking Doxatan XL 4 mg you may experience faintness or dizziness due to 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.

The following side effects have been reported in patients taking Doxatan XL 4 mg.

Common: may affect up to 1 in 10 people

- nasal stuffiness, sneezing and/or runny nose caused by inflammation of the lining of the nose (rhinitis)
- stomach/abdominal pains, feeling/being sick
- dizziness, feeling of spinning or rotation of surroundings (vertigo), headache
- low blood pressure
- swelling of feet, ankles or fingers
- bronchitis, coughing, respiratory tract (nose, throat, lungs) infection
- urinary tract infection, cystitis, urinary incontinence (inability to control passing urine)
- sleepiness, general weakness
- indigestion, dry mouth
- itching
- back pain, painful muscles
- flu-like symptoms

Uncommon: may affect up to 1 in 100 people

- inflammation of the joints (gout), painful joints, general pain
- sleeplessness, anxiety, depression
- reduced or altered sense of touch or sensation of the hands and feet
- increased appetite or loss of appetite, weight gain
- constipation, wind, inflammation of the stomach and intestines (gastroenteritis) which can cause diarrhoea and vomiting
- pain or discomfort on passing urine, increased frequency in passing urine, blood in urine
- nose bleeds
- skin rash
- ringing or noise in the ears, tremor
- failure/inability to achieve penile erection
- increase in liver enzymes which may have an effect on some medical tests
- stroke

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

- 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
- tiredness, generally feeling unwell
- faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position
- agitation or nervousness
- blurred vision
- hot flushes
- muscle cramps, muscle weakness
- disorder in passing urine, needing to pass urine at night, increased frequency of passing urine, increased volume of urine passed

- discomfort or enlargement of the breasts in men
- Persistent painful erection of the penis. Seek urgent medical advice.

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'.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA 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 Doxatan XL 4 mg

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 blister strip and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine 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 Doxatan XL 4 mg contains

The active substance is doxazosin (as mesilate). Each prolonged-release tablet contains 4 mg doxazosin (as mesilate).

The other ingredients are polyethylene oxide, microcrystalline cellulose, povidone, butylhydroxytoluene (E321), α -tocopherol, silica colloidal anhydrous and sodium stearyl fumarate. The film coat contains methacrylic acid copolymer, silica colloidal anhydrous, macrogol 1300 – 1600 and titanium dioxide (E171).

What Doxatan XL 4 mg looks like and contents of the pack

Doxatan XL 4 mg tablets are white round biconvex tablets marked with DL.

Doxatan XL 4 mg tablets are available in transparent PVC/PVdC and aluminium blister strip packs containing 10, 14, 15, 28, 30, 56, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation holder/

Manufacturer:

Clonmel Healthcare Ltd,
Clonmel, Co. Tipperary, Ireland

This leaflet was last revised in May 2018.