

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

The active substance in your tablets, doxazosin, belongs to a group of medicines known as alpha-1 antagonists. Doxadura XL is used to treat the following conditions:

- High blood pressure. If left uncontrolled, high blood pressure can increase the risk of heart disease or stroke.

Doxadura XL works by widening your blood vessels making it easier for your heart to pump blood through them. This helps to lower raised blood pressure and reduce the risk of heart disease.

- Symptoms of benign prostatic hyperplasia (BPH). This condition causes enlargement of the prostate gland, which is just underneath the bladder in men. This makes it difficult to pass urine.

Doxadura XL works by relaxing muscle around the bladder exit and prostate gland, making it easier to pass urine.

2. What you need to know before you take

Doxadura XL

Do not take Doxadura XL

- if you are allergic to doxazosin, to quinazolines (e.g. prazosin, terazosin) which is the chemical family of medicines to which doxazosin belongs, or any of the other ingredients of this medicine (in section 6). Allergic reactions may be, for example, itching, reddening of the skin or difficulty breathing
- if you have low blood pressure (hypotension) or have had a fall in blood pressure on standing up which caused dizziness, light-headedness or fainting (orthostatic hypotension)
- if you have or have had any form of obstruction of the digestive tract
- if you have benign prostatic hyperplasia (BPH) and additionally suffer from a blockage of your upper urinary tract, chronic urinary infections or bladder stones
- if you have an overflowing bladder, almost no production of urine (anuria) or if your kidneys fail to function properly (progressive renal insufficiency)
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxadura XL

- if you suffer from liver disease
- if you have suffered acute heart disease such as heart failure
- dizziness, weakness and in rare occasions fainting may occur, especially when you first start taking this medicine. You should therefore be careful in the beginning of treatment, and avoid situations that could lead to injury if these symptoms occur.

Your physicians will advise you what to do in the event of postural hypotensive symptoms (a decrease in blood pressure with symptoms when changing positions, e.g. from lying down or sitting to standing).

You should not be concerned if occasionally you observe remains in the stools that look like a tablet. This is because Doxadura XL has a non-absorbable coating that is designed to control the release of the medicine over a prolonged period.

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

Children and adolescents

Doxadura XL is not recommended for use in children or adolescents below 18 years as safety and efficacy have not been established.

Other medicines and Doxadura XL

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

Tell your doctor if you are already taking any of the following:

- Non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ibuprofen
- Other medicines used in the treatment of high blood pressure
- Oestrogens (female hormones)
- Dopamine, ephedrine, adrenaline, metaraminol, methoxamine, phenylephrine (medicines called sympathomimetics used e.g. for the treatment of heart problems, low blood pressure, asthma, or congestion of the nose)
- Doxazosin and the so-called phosphodiesterase-5 inhibitors (e.g. sildenafil, tadalafil or vardenafil). 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. Furthermore, it is recommended to respect a 6-hour time interval from intake of doxazosin and phosphodiesterase-5 inhibitors.

Doxadura XL with food and drink

Doxadura XL can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice.

Do not take Doxadura XL if you are 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.

Driving and using machines

Doxadura XL may cause dizziness or tiredness. If you feel tired, dizzy or light-headed, you must not drive or operate machinery. Be especially careful when you take your first dose or if your dose is increased.

Doxadura XL contains sodium

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

3. How to take Doxadura XL

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

Dosage

The dose of Doxadura XL is the same whether you are taking it for high blood pressure or to treat the symptoms of BPH. The usual dose is one tablet (4mg) each day. Your doctor may increase your dose to the maximum recommended dose of two tablets each day.

Choose any time of the day that 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. Doxadura XL releases the active substance slowly throughout the day.

For the treatment of high blood pressure, Doxadura XL can be used as single therapy, or in combination with other blood pressure-lowering medications (e.g. diuretics, water tablets).



Please read the back of this leaflet.

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It may take up to four weeks to reach the optimal blood pressure-lowering effect of Doxadura XL. Because high blood pressure is treated in order to prevent problems from arising, you may have no symptoms at all while taking Doxadura XL. Even if this is so and you feel well, you should not stop taking your medication unless instructed to by your doctor. Don't change the dose or stop taking the tablets without first checking with your doctor.

If you take more Doxadura XL 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 go to the nearest casualty department immediately.

If you forget to take Doxadura XL

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 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 Doxadura XL and call an ambulance immediately if you experience any of the following:

- Heart attack (uncommon)
- Weakness of arms, legs or problems speaking which may be symptoms of a stroke (uncommon)
- Swelling of the face, tongue or throat which may be the result of an allergic reaction to this medicine (uncommon)

Tell your doctor immediately if you experience any of the following symptoms after taking Doxadura XL:

- Chest pain (common), angina (uncommon)
- Shortness of breath, difficulty breathing, wheezing (very rare)
- Increased (common), decreased or irregular heartbeat (very rare)
- Feeling your heartbeat (palpitations) (common)
- Skin rash or itching (especially the whole body) (common)
- Fainting (uncommon)
- Yellowing of the skin or the eyes (jaundice) (very rare)
- Low numbers of white blood cells or blood platelets, which may result in bruising or easy bleeding (very rare)

Other side effects

Common (may affect up to 1 in 10 people):

- respiratory tract infection
- dizziness, headache, drowsiness
- loss of balance
- low blood pressure and low blood pressure as a result of getting up from a sitting or lying position (postural hypotension)
- inflammation of the air passages within the lungs, cough, shortage of breath, nasal stuffiness and/or runny nose
- abdominal pain, indigestion, dry mouth, feeling sick (nausea)
- back pain, painful muscles
- inflammation of the bladder (cystitis), urinary incontinence
- general weakness, influenza-like symptoms.

Uncommon (may affect up to 1 in 100 people):

- loss of appetite, gout, increased appetite
- anxiety, emotional instability (depression), sleeplessness (insomnia)
- reduced sense of touch or sensation, tremor, ringing or noise in the ears (tinnitus)
- nosebleed
- constipation, diarrhoea, flatulence, being sick (vomiting), inflammation of the gastrointestinal tract
- abnormal liver function test
- joint pain
- painful or difficult urination, presence of red blood cells in the urine (haematuria), frequent desire to urinate
- abnormal accumulation of fluid beneath the skin causing swelling of the face (facial oedema)
- difficulty to develop an erection (impotence)
- pain
- weight increase.

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

- reduced numbers of red cells
- dizziness postural
- restlessness, nervousness
- pins and needles

- blurred vision
- flushing
- blocked flow of bile (cholestasis), inflammation of the liver (hepatitis)
- hair loss (alopecia), rash caused by bleeding under the skin (purpura), hives
- muscle cramps, muscle weakness
- urination disorder, frequent urinating during the night, increased volume of urine passed
- temporary enlargement of the breasts (gynaecomastia)
- persistent painful erection of the penis. Seek urgent medical advice.
- feeling tired (fatigue), malaise

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

- intraoperative floppy iris syndrome
- taste disturbances
- retrograde ejaculation.

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 the Yellow Card Scheme at 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 Doxadura 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 the month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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 Doxadura XL contains

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

The other ingredients are

- polyethylene oxide, microcrystalline cellulose, povidone, butyl-hydroxytoluene (E321), all-rac- α -Tocopherol, colloidal anhydrous silica, sodium stearyl fumarate, methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30%, macrogol, and titanium dioxide (E171).

What Doxadura XL looks like and contents of the pack

The tablets are white, round, biconvex tablets with "DL" embossed on one side.

Your medicine is available in PVC/PVDC/aluminium blister packs:

Cartons with 10, 20, 28, 30, 50, 56, 60, 90, 98, 100, 140 (10 x 14) prolonged-release tablets.

Calendar packs of 28 and 98 prolonged-release tablets

Unit dose pack of 50 x 1 prolonged-release tablets

Not all pack sizes may be marketed

POM

PL 06831/0171 Doxadura XL 4mg prolonged-release tablets

Marketing Authorisation Holder and Manufacturer:

Genus Pharmaceuticals,
Linthwaite, Huddersfield, HD7 5QH, UK.

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

Estonia	Doxalfa
Latvia	Doxalfa 4 mg ilgstošās darbības tabletes
Lithuania	Doxalfa
The Netherlands	Doxazosine retard CF
Spain	DOXAZOSINA NEO STADA
Sweden	Doxastad
Great Britain	Doxadura XL

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