

PACKAGE LEAFLET: INFORMATION FOR THE USER

Doxazosin 1, 2, 4 mg tablets

Doxazosin mesilate

Read all of this leaflet carefully before you start taking/using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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- 1. What Doxazosin 1, 2, 4 mg is and what it is used for**
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1. WHAT DOXAZOSIN IS AND WHAT IT IS USED FOR

Doxazosin belongs to the group of medicines called vasodilators (alpha-blockers).

Doxazosin is used to treat:

- high blood pressure
- the symptoms caused by an enlarged prostate gland in men.

Doxazosin works by widening the blood vessels, making it easier for the heart to pump blood around the body. This helps to lower blood pressure.

In patients with enlargement of the prostate gland, Doxazosin works by relaxing the muscles around the bladder and prostate gland so that urine may be passed more easily.

2. BEFORE YOU TAKE DOXAZOSIN

DO NOT take Doxazosin if you:

- are allergic (hypersensitive) to doxazosin, or to other medication from the same medicine category (the so-called quinazolines, such as prazosin or terazosin), or to any of the other ingredients of Doxazosin
- suffer from dizziness when standing up from a lying or sitting position due to decrease in blood pressure (orthostatic hypotension)
- have experiences problems with urinating:
 - have a loss of urinary control (overflow bladder)
 - decreased or absent production of urine (anuria)
 - progressive kidney insufficiency
- are breastfeeding

Additionally, patients prescribed doxazosin for an enlarged prostate should not take this medication as monotherapy if you:

- have low blood pressure
- have congestion of the upper urinary tract
- suffer from chronic infections of the urinary tract
- have bladder stones.

Take special care with Doxazosin

- at start of the treatment or when the dose is increased. The blood pressure reducing influence may be stronger, which is noticeable by dizziness and weakness or sometimes

fainting. Your doctor may check your blood pressure to minimize the risk. Avoid situations in which you could be hurt when you experience dizziness or weakness

- if you are suffering from acute heart disease
- if you have liver problems. In patients with severe liver function impairment, use of Doxazosin is not recommended.
- if you are using certain medication for erectile dysfunction (PDE5 inhibitors) such as sildenafil, tadalafil and vardenafil (see section “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 Doxazosin. This is because Doxazosin may cause complications during the surgery which can be managed if your specialist is prepared in advance.
- Use in children below the age of 12 years is not recommended.

If any of these apply to you, talk to your doctor before you start to take this medicine.

Taking other medicines

Some medicines may influence each other's activity and/or side effects if taken simultaneously (known as interaction). An interaction can occur when this medication is taken at the same time with:

- other antihypertensives or other alpha-blockers (e.g. prazosin, terazosin); the blood pressure lowering effect can be increased
- medicines which may influence the metabolism of the liver such as cimetidine, a H₂-receptor antagonist (which acts to decrease the natural production of acid in the stomach) medication for erectile dysfunction (PDE5 inhibitors) such as sildenafil, tadalafil, 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.

If you are taking any of these medicines, make sure you talk to you doctor or pharmacist before you start to take doxazosin.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

These remarks can also be applicable to medicines you have taken in the recent past or you will take in the near future as well as medicines you are already taking. Medicines mentioned in this section may be known to you under another name, usually a branded name. In this section only the name of the active ingredient is mentioned and not the branded name. Look at the package or in the patient information leaflet of your other medicines to see what the active ingredient is of the medication you take.

Pregnancy and breast-feeding

- Do not take doxazosin if you are breast-feeding. See also section ‘Do not take Doxazosin’.
- Alternatively, mothers should stop breast-feeding when treatment with doxazosin is necessary.
- If you are pregnant or are planning to become pregnant, talk to your doctor before taking this medicine. Doxazosin is not recommended for use during pregnancy unless your doctor decides that the potential benefit of treatment outweighs the risks. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Sometimes this medication can make you feel sleepy, dizzy and/or weak, especially when you first start taking the tablets, or can affect your vision. If you are affected do not engage in activities which require concentration, such as driving, operating machines and working at heights.

Important information about some of the ingredients of Doxazosin

Patients who are intolerant to **lactose** should note that Doxazosin tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. HOW TO TAKE DOXAZOSIN

Always take Doxazosin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be taken in a once-daily dosage with a glass of water (one glass).

The usual dose is:

Adults

- **High Blood Pressure**

The usual starting dose is 1 mg a day before going to bed.

After 1 to 2 weeks the dose may be increased to 2 mg a day for a further 1 to 2 weeks.

Your doctor may continue to increase your dose up to a maximum of 16 mg a day depending on how your blood pressure responds to treatment.

- **Enlarged Prostate**

The usual starting dose is 1 mg a day before going to bed.

Your doctor may increase your dose in steps at 1 to 2 week intervals up to a maximum of 8 mg a day depending on the effects of the medicine.

If you take more Doxazosin than you should

If you have taken more than the dosage prescribed or if you think a child or someone else has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause low blood pressure, which may make you feel dizzy or faint. In case of serious dizziness or imminent fainting you should lie down immediately with your head downward.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Doxazosin

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. Take the remaining doses at the correct time. In case of doubt you should always consult your pharmacist or doctor.

If you stop taking Doxazosin

You should continue to take these tablets for as long as your doctor tells you to. If the use of this medication is suddenly stopped, the symptoms that existed before the start of the treatment may reoccur.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if you experience any of the following effects:

- allergic reactions, this can be recognized by e.g. rash and/or itch
- swelling of the face due to fluid accumulation (facial oedema).

These are very serious but uncommon side effects. You may need urgent medical attention or hospitalisation.

Very common (occurring in more than 1 in 10 patients)

- dizziness, headache.

Common (occurring in less than 1 in 10 patients)

- infection of the respiratory tract
- infection of the urinary tract
- lack of appetite
- anxiety, nervousness
- sleepiness
- low blood pressure (hypotension), faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position (postural hypotension)
- sensation that one's self or the surroundings are moving or spinning (vertigo)
- tingling without apparent cause (paresthesia)
- palpitations, rapid heart rate (tachycardia)
- inflammation of the airway (bronchitis), cough, shortness of breath, runny nose (rhinitis)
- abdominal pain, pain or discomfort in the upper abdomen (dyspepsia), dry mouth, feeling sick, diarrhoea
- severe itching (pruritus)
- back pain, muscle pain
- bladder infection (cystitis), urinary incontinence
- weakness and loss of strength
- chest pain
- flu-like symptoms
- swelling of tissue due to fluid accumulation, usually in the lower limbs (peripheral oedema)
- tiredness
- general feeling of being unwell (malaise).

Uncommon (occurring in less than 1 in 100 patients)

- allergic drug reaction
- gout
- increased appetite
- agitation, depression
- stroke
- reduced sense of touch (hypoesthesia)
- fainting
- tremor
- ringing in the ears (tinnitus)
- chest pains (angina pectoris)
- heart attack (myocardial infarction)
- abnormal heart rhythms (cardiac arrhythmia)
- hot flushes
- nose bleeds
- constipation, flatulence, being sick
- inflammation of the mucous membrane of the stomach and intestines (gastroenteritis)
- skin rash
- hair loss (alopecia)
- red or purple discolorations of the skin (purpura)
- joint pain, muscle cramps, muscle weakness
- painful urination (dysuria)
- more frequent need to urinate, more frequent urination of large volumes of urine (polyuria), blood in urine (haematuria)

- inability to have or maintain an erection (impotence)
- weight increase.
- abnormal liver function tests
- pain

Very rare (occurring in less than 1 in 10000 patients)

- decrease in white blood cells; this may cause a higher susceptibility to infections
- decrease in blood platelets, which may result in bruising or easy bleeding
- blurred vision
- slow heart rate (bradycardia)
- increased tightness of the chest caused by cramp of the respiratory tract muscles (aggravated bronchospasm)
- jaundice; this can be recognized by a yellow colour of the skin
- inflammation of the liver that can cause a yellow colour of skin and eyes (hepatitis)
- bile disorder (cholestasis)
- hives (urticaria)
- increased urine volume (increased diuresis), urination disorders, the need to wake and pass urine at night (nocturia)
- discomfort or enlargement of the breast tissue in men (gynaecomastia)
- persistent, usually painful erection of the penis (priapism).

Unknown frequency

- complications during surgery for cataract (see section "take special care with doxazosin")
- taste disturbances
- little or no semen ejaculated at sexual climax, cloudy urine following sexual climax (retrograde ejaculation).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DOXAZOSIN

Keep out of the reach and sight of children.

Store dry in a well closed packaging. Do not store above 30°C.

Do not use Doxazosin after the expiry date which is stated on the package. The term "Exp." on the strip means: "do not use after". The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Doxazosin contains

- The active substance is doxazosin mesylate. Each tablet contains doxazosin mesylate equivalent to 1 mg, 2 mg or 4 mg doxazosin.
- The other ingredients are microcrystalline cellulose, lactose anhydrous, starch sodium glycolate, magnesium stearate, sodium laurilsulfate, colloidal anhydrous silica.

What Doxazosin looks like and contents of the pack .

- 1 mg: round convex tablet
- 2 mg: oblong scored tablet
- 4 mg: oblong scored tablet
- The product is available packed in PVC/PVDC-Aluminium blister strips in pack sizes of, 2, 3, 5, 10, 20 or 50 x 10 tablets or 1, 2 or 7 x 14 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Will be addressed locally.

Manufacturer

Pharmachemie B.V., Swensweg 5, Postbus 552 2003, RN Haarlem, the Netherlands
TEVA UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG,
United Kingdom
TEVA Pharmaceutical Works Private Ltd. Co., Pallagi Street, 13H-4042, Debrecen,
HUNGARY

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

The Netherlands: Doxazosine 1 PCH, tabletten 1 mg
 Doxazosine 2 PCH, tabletten 2 mg
 Doxazosine 4 PCH, tabletten 4 mg

United Kingdom: Doxazosin 1 mg Tablets
 Doxazosin 2 mg Tablets
 Doxazosin 4 mg Tablets

Germany: Doxazoflo® 1 mg Tabletten
 Doxazoflo® 2 mg Tabletten
 Doxazoflo® 4 mg Tabletten

This leaflet was last approved in {06/2010}.