

Package leaflet: Information for the user

DOXAZOSIN 1 MG, 2 MG AND 4 MG 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 Doxazosin tablets are and what they are used for
2. What you need to know before you take Doxazosin tablets
3. How to take Doxazosin tablets
4. Possible side effects
5. How to store Doxazosin tablets
6. Contents of the pack and other information

1. What Doxazosin tablets are and what they are used for

Doxazosin is one of a group of medicines called alpha-blockers. It is used to treat high blood pressure, or the symptoms caused by enlargement of the prostate gland in men.

Doxazosin can be used to treat high blood pressure (hypertension), by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

In patients with an enlarged prostate gland, doxazosin is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate gland.

Doxazosin 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 Doxazosin tablets

Do not take Doxazosin Tablets if you:

- are allergic to doxazosin, other medicines from the same group (known as quinazolines, such as e.g. prazosin and terazosin) or any of the other ingredients of this medicine (listed in section 6). This may have been itching, reddening of the skin or difficulty in breathing.
- 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.
- 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 bladder stones.
- are breast-feeding.
- have an enlarged prostate gland (benign prostatic hyperplasia) and have low blood pressure.
- 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.

Warnings and Precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- are pregnant or trying to become pregnant
- have liver disease
- are also taking other medicines
- have heart disease

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.

Before starting treatment with Doxazosin your doctor may perform tests to rule out other conditions such as prostate cancer that may cause the same symptoms as benign prostatic hyperplasia (enlargement of the prostate gland).

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

When you start to take Doxazosin you may experience faintness or dizziness caused by 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. Your doctor may want to measure your blood pressure regularly at the start of therapy to reduce the possibility of these effects happening.

Children and adolescents

Doxazosin is not recommended for use in children or adolescents below 18 years as safety and efficacy have not yet been established. Benign prostate hyperplasia is not relevant in children.

Other medicines and Doxazosin tablets

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

There are some medicines that may interact with Doxazosin. Ask your doctor or pharmacist before used if you are taking any of these medicines as they may change the effect of Doxazosin:

- 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 too quickly. Certain patients have experienced these symptoms when taking medicines called PDE 5 inhibitors for the treatment of drugs for erectile dysfunction (impotence): with alpha-blockers e.g. sildenafil, tadalafil, vardenafil (please see section "Warnings and precautions". 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.
- Doxazosin may lower your blood pressure even more if you are already taking other medicines to treat high blood pressure such as 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.

Doxazosin with food and drink

This medicine can be taken with or without food.

Pregnancy, breastfeeding and fertility

- 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. The safety of using Doxazosin during pregnancy has not been established.
- Do not breast feed while taking Doxazosin.

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.

Doxazosin tablets contain 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 tablets

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 tablets should be swallowed with a drink of water.**

- The scoreline on 2mg and 4mg tablets is not intended for breaking the tablets.
- The recommended dose of doxazosin is one tablet taken as a single daily dose each day.
- If you are taking doxazosin for the first time the normal dose is 1mg daily. Your doctor may increase this after a couple of weeks to the usual dose of 2mg or 4mg daily. In some circumstances this may be increased to a maximum of 8mg daily if you are being treated for prostate enlargement, or to a maximum of 16mg if you are being treated for high blood pressure.
- This medicine may be taken in the morning or the evening.
- It is best to take your tablets at about the same time each day.
- Doxazosin can be taken with or without food.
- Take your tablet as your doctor told you or by following the days and arrows on the blister foil.
- It is important to keep taking your tablets. They help to control your blood pressure.
- 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.

Use in children

The safety and efficacy of Doxazosin in children have not been established.

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If you take more Doxazosin Tablets 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 Doxazosin Tablets

If you have forgotten to take a tablet, then skip it and take the next tablet at the usual time. You should check with your doctor or pharmacist if you are unsure. Do not take a double dose to make up for a forgotten dose.

If you stop taking Doxazosin Tablets

If you suddenly stop taking doxazosin, the complaints you suffered prior to the start of treatment may recur. It is therefore better not to stop taking this medication suddenly. Your doctor will decrease the dosage gradually. You should always check with your doctor or pharmacist if you are unsure. If you have any further questions on the use of this product, 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 this medicine and call an ambulance immediately if you experience any of the following:

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

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

- Shortness of breath, difficulty breathing (common: may affect up to 1 in 10 people)
- Increased or decreased heartbeat (common: may affect up to 1 in 10 people)
- Feeling your heartbeat (palpitations) (common: may affect up to 1 in 10 people)
- Chest pain, angina (uncommon: may affect up to 1 in 100 people)
- Irregular heartbeat (very rare: may affect up to 1 in 10,000 people)
- Yellowing of the skin or the eyes (jaundice) (very rare: may affect up to 1 in 10,000 people)
- Low numbers of white blood cells or blood platelets, which may result in bruising or easy bleeding (very rare: may affect up to 1 in 10,000 people)
- Persistent painful erection of the penis. Seek urgent medical advice (very rare: may affect up to 1 in 10,000 people)

Other side effects:

The following events have been reported in patients being treated with Doxazosin. If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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

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

Uncommon (may affect up to 1 in 100 people)

- 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
- inflammation of the joints (gout), painful joints, general pain
- swelling of the face
- sleeplessness, agitation, anxiety, depression or nervousness
- reduced or altered sense of touch or sensation of the hands and feet
- increased appetite or loss of appetite, weight gain
- nose bleeds
- skin rash
- ringing or noise in the ears, tremor
- failure/ inability to achieve penile erection
- liver enzyme increases which may have an effect on some medical tests
- stroke

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

- increased number of times of passing urine
- muscle cramps, muscle weakness

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

- faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position
- 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
- aggravated wheezing
- blurred vision
- hot flushes
- disorder in passing urine, needing to pass urine at night, 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 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 Doxazosin tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not use the tablets after the expiry date (exp.) shown on the carton or label. The expiry date refers to the last day of that month.
- 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 Doxazosin Tablets contain**

- The active substance is:
- Doxazosin Mesylate 1.2125 mg equivalent to 1mg Doxazosin in Doxazosin 1mg Tablets
- Doxazosin Mesylate 2.425 mg equivalent to 2 mg Doxazosin in Doxazosin 2mg Tablets
- Doxazosin Mesylate 4.85 mg equivalent to 4 mg Doxazosin in Doxazosin 4mg Tablets
- The other ingredients are: Anhydrous lactose, magnesium stearate, microcrystalline cellulose, colloidal anhydrous silica, sodium lauryl sulfate and sodium starch glycolate.

What Doxazosin Tablets look like and the contents of the pack

- Doxazosin Tablets are white and are available in three strengths.
- Doxazosin Tablets 1mg tablet is round, convex, uncoated tablets marked 'D1' on one side.
- Doxazosin Tablets 2mg tablet is oblong, uncoated tablets marked 'D2' and scoreline on one side.
- Doxazosin Tablets 4mg tablet is oblong, uncoated tablets marked 'D4' and scoreline on one side.
- Doxazosin Tablets are available in packs of 28 tablets.

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Doxazosin 4 mg Tablets; PL 17907/0257

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