

Package leaflet: Information for the patient

Doxazosin 0.4 mg/ml Oral Suspension

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.
- ▶ Doxazosin 0.4 mg/ml oral suspension is a treatment for high blood pressure, or the symptoms caused by enlargement of the prostate gland in men.
- ▶ You should take Doxazosin 0.4 mg/ml oral suspension regularly to get the maximum benefit, even if you are feeling well.
- ▶ Most people do not have serious problems when taking Doxazosin 0.4 mg/ml Oral Suspension but side effects can occur. If you experience swelling of the face, tongue or windpipe, see your doctor immediately. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- ▶ Taking other medicines may sometimes cause problems. Check with your doctor or pharmacist before taking this or any other medicines.
- ▶ If you are, or are trying to become, pregnant, do not take Doxazosin 0.4 mg/ml oral suspension and tell your doctor or pharmacist.

The name of your medicine is Doxazosin 0.4 mg/ml oral suspension but it will be referred to as 'Doxazosin' throughout this leaflet.

What is in this leaflet

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

1. What Doxazosin is and what it is used for

Doxazosin contains active substance doxazosin mesilate, which belongs to 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 is 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Doxazosin

Do not take Doxazosin if:

- ▶ You are allergic to doxazosin, other types of quinazolines (such as prazosin or 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.
- ▶ You are under 18 years of age.
- ▶ You have low blood pressure.
- ▶ 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.
- ▶ 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 bladder stones.
- ▶ You 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 Doxazosin if:

- ▶ You are pregnant or trying to become pregnant
- ▶ You have liver disease
- ▶ You have heart disease
- ▶ 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 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

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 use 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 up quickly. Certain patients have experienced these symptoms when taking medicines called PDE-5 inhibitors for the treatment of 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.
- ▶ 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

Refer to section 3.

Pregnancy and breast-feeding

Pregnancy

The safety of using Doxazosin during pregnancy has not been established. If you are pregnant or trying to become pregnant speak to your doctor, who will decide if it is suitable for you.

Breast-feeding

Small amounts of doxazosin, the active substance of Doxazosin, can get into your breast milk. You should not use Doxazosin during breast-feeding unless your doctor advises you to do so.

Driving and using machines

Take care if you drive or operate machinery. Doxazosin may affect your ability to drive or operate machinery safely, particularly when you first start to take them. It may cause drowsiness, make you feel weak or dizzy. If you are affected, do not drive or operate machinery and contact your doctor immediately.

Doxazosin contains

Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).

Propylene glycol (E1520): This medicine contains 4.75 mg propylene glycol in each 5 ml dose which is equivalent to 0.95 mg/ml.

Sodium: This medicine contains less than 1mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’

Benzoic acid: This medicinal product contains 0.055 mg benzoic acid in each 5 ml dose which is equivalent to 0.011 mg/ml.

3. How to take Doxazosin

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 usual dose of Doxazosin is 2 mg (5 ml) taken once a day.
- ▶ If you are taking Doxazosin for the first time the normal dose is 1 mg (2.5 ml) daily. Your doctor may increase this after a couple of weeks to the usual dose of 2 mg (5 ml) or 4 mg (10 ml) daily. In some circumstances this may be increased to a maximum of 8 mg (20 ml) daily if you are being treated for prostate enlargement, or to a maximum of 16 mg (40 ml) if you are being treated for high blood pressure.
- ▶ Doxazosin may be taken in the morning or the evening.
- ▶ Doxazosin can be taken with or without food.
- ▶ It is best to take your oral suspension at about the same time each day with a drink of water.
- ▶ Take Doxazosin as your doctor told you - It is important to keep taking Doxazosin. It helps to control your blood pressure.
- ▶ Don't change the dose or stop taking Doxazosin without first checking with your doctor.
- ▶ Don't wait until your Doxazosin is finished before seeing your doctor.

Route and Method of administration:

- ▶ This medicine must be taken orally.
- ▶ Use the measuring syringe provided in the pack to deliver the required dose.
- ▶ Doses of 10 ml or below should be administered using the 10ml syringe. For doses greater than 10ml, the 20 ml syringe should be used.

Instructions for the use of syringe:

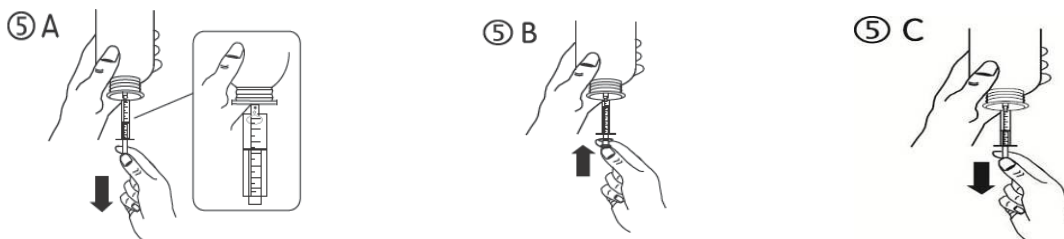
a) Open the bottle: press the cap and turn it anticlockwise (figure 1).



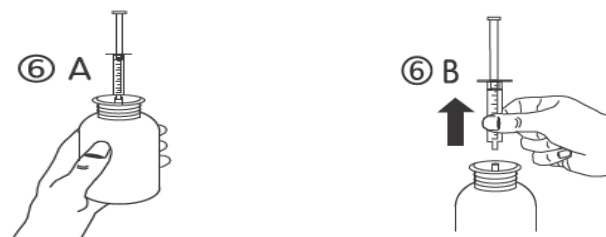
b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



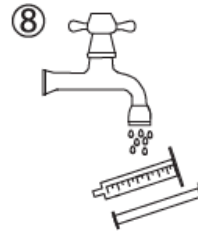
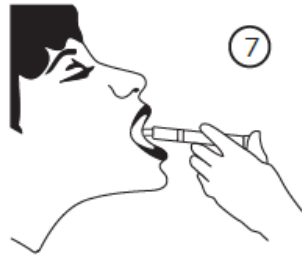
c) Turn the bottle upside down. Fill the syringe with a small amount of suspension by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic cap. Wash the syringe with water (figure 8).



If you take more Doxazosin than you should:

Taking too much Doxazosin may make you unwell. If too much is taken it may be dangerous. Tell your doctor immediately or go to your nearest hospital casualty department.

If you forget to take Doxazosin:

If you forget to take a dose, leave that dose out completely. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Doxazosin:

Do not suddenly stop taking your medicine as this may cause serious changes in your blood pressure.

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

- ▶ Heart attack
- ▶ Increased, decreased or irregular heartbeat
- ▶ Weakness of arms, legs or problems speaking which may be symptoms of a stroke
- ▶ Allergic reactions (hypersensitivity). Symptoms include sudden wheeziness, tightness in chest, difficulty in 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 symptoms after taking Doxazosin:

- ▶ 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)

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 side effects 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 the bladder (cystitis)
- ▶ Sleepiness, general weakness
- ▶ Indigestion, dry mouth
- ▶ Itching
- ▶ Back pain, painful muscles
- ▶ Flu-like symptoms

Uncommon side effects 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 side effects may affect up to 1 in 1,000 people

- ▶ Increased number of times of passing urine
- ▶ Muscle cramps, muscle weakness

Very Rare side effects 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
- ▶ 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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

- ▶ 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 bottle label and on the carton after 'EXP'. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ Discard 30 days after first opening.
- ▶ Do not use this medicine if you notice any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 contains

The active substance is doxazosin (as mesilate).

Each ml of oral suspension contains 0.4 mg doxazosin (as mesilate).

The other ingredients are:

methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate, (E216), simethicone emulsion 30% (contains benzoic acid (E210), low volatile simethicone intermediate, polyoxyethylene sorbitan tristearate, methylcellulose, poly (ethylene oxide), stearate, glyceryl stearate, xanthan gum, sorbic acid, sulfuric acid 98% & purified water), microcrystalline cellulose and carmellose sodium, glycerol (E422), sucralose (E955), citric acid anhydrous (E 330), lemon flavour (contains propylene glycol (E1520)) and purified water.

What Doxazosin looks like and contents of the pack

Doxazosin is a white to off white coloured suspension with lemon flavour supplied in amber glass bottles fitted with a tamper evident, child resistant white plastic (polyethylene/polypropylene) cap with EPE liner. The pack also contains 20 ml syringe with 0.5 ml graduation marks and 10 ml oral syringe with 0.25 ml graduation marks and a syringe adaptor.

Doxazosin is supplied in a bottle containing 150 ml oral suspension.

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If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This leaflet was last revised in 11/2025