

DOXAZOSIN 1 mg TABLETS DOXAZOSIN 2 mg TABLETS DOXAZOSIN 4 mg TABLETS

(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.
- DOXAZOSIN is a treatment for high blood pressure, or the symptoms caused by enlargement of the prostate gland in men.
- 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.
- You should take DOXAZOSIN regularly to get the maximum benefit, even if you are feeling well.
 - Most people do not have serious problems when taking DOXAZOSIN 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 and tell your doctor or pharmacist.

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

The name of your medicine is DOXAZOSIN 1 mg Tablets, DOXAZOSIN 2 mg Tablets, DOXAZOSIN 4 mg Tablets (referred to as DOXAZOSIN throughout this leaflet).

1. What DOXAZOSIN is and what it is used for

Doxazosin, the active ingredient in Doxazosin tablets, is one of a group of medicines called alpha-blockers.

DOXAZOSIN tablets are used to treat high blood pressure (hypertension) or the symptoms caused by enlargement of the prostate gland in men.

In patients taking DOXAZOSIN to treat high blood pressure (hypertension) DOXAZOSIN works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

In patients with enlargement of the prostate gland, DOXAZOSIN is taken to treat frequent and/or poor passing of urine. This is common in patients with enlargement of the 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

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.
- 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 bladder stones
- If you have an enlarged prostate gland (benign prostatic hyperplasia) and have low blood pressure
- If 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
- If you have liver disease
- If you are also taking other medicines
- If you 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:

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

Please refer to section 3.

Pregnancy, breast-feeding and fertility

Pregnancy

The safety of using DOXAZOSIN during pregnancy has not been established. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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. 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 you are affected, do not drive or operate machinery and contact your doctor immediately.

DOXAZOSIN contains 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.

Sodium

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



3. How to take DOXAZOSIN

Use in adults and elderly

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. DOXAZOSIN is usually taken once daily. DOXAZOSIN may be taken in the morning or the evening.

You can take your tablets before or after food.

You should take your tablets at the same time each day with a small amount of water.

The initial dose of DOXAZOSIN is 1mg once daily. Thereafter the dose may be gradually increased (within 1-2 weeks interval) to the recommended dose (2mg or 4mg daily).

In some circumstances the dose 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.

You have been given a calendar pack that will help you remember to take your tablets. If you are taking more than one tablet a day, you must ignore the marking for the day, printed on the back of the blister.

Because high blood pressure is treated in order to prevent problems from arising, you may have no symptoms at all while taking DOXAZOSIN. Even if this is so and you feel well, you

should not stop taking your blood pressure medication unless instructed to by your doctor.

Don't change the dose or stop taking the tablets without first checking with your doctor.

Don't wait until your tablets are finished before seeing your doctor.

If you have impression that the effect of DOXAZOSIN is too strong or too weak, talk to your doctor or pharmacist.

Use in children and adolescents

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

If you take more DOXAZOSIN 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

Do not worry. If you forget to take a tablet, leave that dose out completely. Then go on as before. Do not take

a double dose to make up for a forgotten tablet.

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
- 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 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 increasing frequency of infection, 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

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

Store below 25°C. 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 label after EXP.

The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What DOXAZOSIN contains

The active substance is doxazosin. Each tablet contains 1mg, 2mg, or 4mg of doxazosin (as mesilate).

The other ingredients are: Lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycolate (type A) and colloidal anhydrous silica.

What DOXAZOSIN looks like and contents of the pack

DOXAZOSIN comes in three different strengths:

Doxazosin 1 mg tablet is a round white to off-white tablet scored on one side.

Doxazosin 2 mg tablet is a white to off-white capsule-shaped tablet scored on one side.

Doxazosin 4 mg tablet is a white to off-white capsule-shaped tablet, scored on both sides, with embossment "D4" on one side.

Doxazosin 1 mg, 2 mg and 4 mg tablets are available in calendar packs of 28 tablets in foil blister strips.

Marketing Authorisation Holder and Manufacturer:

Dexcel[®]-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK

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