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.

1. What DOXAZOSIN is and what it is used for

DOXAZOSIN is one of a group of medicines called alpha-blockers. DOXAZOSIN tablets are used to treat high blood pressure (hypertension) and the symptoms caused by enlargement of the prostate gland in men. This medicine may be prescribed when other medicines, such as diuretics, have been established. If you are already taking other medicines to treat high blood pressure or prostate enlargement, DOXAZOSIN may be used to help control your blood pressure more effectively.

2. What you need to know before you take DOXAZOSIN

• Are allergic to doxazosin, other types of quinazolines (such as prazosin or terazosin) or any of the other ingredients of DOXAZOSIN tablets listed in section 6.

• Have an enlarged prostate gland (benign prostatic hyperplasia) and have low blood pressure.

• 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 long-standing infection of the urinary tract or you have bladder stones.

• Have overactive bladder (you do not feel the urge to urinate), or anuria (your body is not producing any urine) with or without kidney problems.

3. How to take DOXAZOSIN

Take your tablets with or without food. Your doctor or pharmacist may have told you to take your tablets in the morning or at bedtime. They may tell you to start at a low dose and increase gradually. For example, you may start taking one tablet each night and increase to two tablets each night after a few weeks. DOXAZOSIN is usually taken once a day at the same time each day. Follow the instructions on your tablet box. DOXAZOSIN tablets may be used in combination with other medicines to treat high blood pressure. DOXAZOSIN tablets are used to treat high blood pressure, which is a condition in which your blood pressure is too high. Your blood pressure should be checked regularly while taking DOXAZOSIN. Your doctor may want to measure your blood pressure regularly at the start of therapy to reduce the possibility of these effects happening.

4. Possible side effects

Most possible side effects do not usually mean that you have to stop taking DOXAZOSIN. However, you should report any side effects to your doctor or pharmacist as they may change the effect of DOXAZOSIN.

• 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.

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 muscles around the bladder exit and prostate gland so urine is passed more easily.

5. How to store 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 DOXAZOSIN tablets listed in section 6.

- Have an intolerance to some sugars, contact your doctor before taking this medicine. Do not take DOXAZOSIN if you:

- Have heart disease

- Have a history of a condition known as "orthostatic hypotension" which is a form of low blood pressure that causes you to feel dizzy 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 prostatic hyperplasia is not relevant in children.

Other medicines and DOXAZOSIN: Tell your doctor or pharmacist if you are taking any of these medicines as they may change the effect of DOXAZOSIN.

• 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.

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 muscles 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 DOXAZOSIN tablets listed in section 6.

This may have been itching, reddening of the skin or difficulty in breathing.

• Are breastfeeding.

• Have an enlarged prostate gland (benign prostatic hyperplasia) and have low blood pressure.

• 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 long-standing infection of the urinary tract or you have bladder stones.

• Have overactive bladder (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 have liver disease.
Always take DOXAZOSIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. 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 large 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 to remember to take your tablets. If you are taking more than one tablet a day, you must ignore the marking for that dose out completely. Then go on as before. Do not take a double dose to make up for a forgotten tablet.

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 10 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 infected infections, 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 are 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/becoming 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
- Sleepiness, 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):

- Fainting 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 2. “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 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

Store below 25°C. Keep out of the sight and reach of children. Check the expiry date on the label. Do not use the tablets if the expiry date has passed.

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.

The manufacturer/holder of the marketing authorization is: Dexelz-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Davenport, Northamptonshire, NN11 8PB, UK.

This leaflet was last revised in February 2019.