

**Package leaflet: Information for the patient**

**Doxazosine Syri Pharma 0,4 mg/ml, suspensie voor oraal gebruik**  
doxazosin 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.
- ▶ 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.
- ▶ Doxazosine Syri Pharma 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 Doxazosine Syri Pharma 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 Doxazosine Syri Pharma 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.
- ▶ 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 Doxazosine Syri Pharma 0.4 mg/ml Oral Suspension and tell your doctor or pharmacist.

The name of your medicine is Doxazosine Syri Pharma 0,4 mg/ml, suspensie voor oraal gebruik but it will be referred to as 'Doxazosine Syri Pharma' throughout this leaflet.

**What is in this leaflet**

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

**1. What Doxazosine Syri Pharma is and what it is used for**

Doxazosine Syri Pharma 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. Doxazosine Syri Pharma 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, Doxazosine Syri Pharma is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate gland. Doxazosine Syri Pharma 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 Doxazosine Syri Pharma**

**Do not take Doxazosine Syri Pharma 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 Doxazosine Syri Pharma 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 Doxazosine Syri Pharma. This is because Doxazosine Syri Pharma may cause complications during the surgery which can be managed if your specialist is prepared in advance.

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

Before starting treatment with Doxazosine Syri Pharma your doctor may perform tests to rule out other conditions such as prostate cancer that may cause the same symptoms as benign prostatic hyperplasia.

When you start to take Doxazosine Syri Pharma 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.

### **Children and adolescents**

Doxazosine Syri Pharma is not recommended for use in children or adolescents below 18 years as safety and efficacy have not yet been established.

### **Other medicines and Doxazosine Syri Pharma**

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 Doxazosine Syri Pharma:

- ▶ 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.

- ▶ Doxazosine Syri Pharma 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.

#### **Doxazosine Syri Pharma 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 Doxazosine Syri Pharma, can get into your breast milk. You should not use Doxazosine Syri Pharma during breast-feeding unless your doctor advises you to do so.

#### **Driving and using machines**

Take care if you drive or operate machinery. Doxazosine Syri Pharma 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.

#### **Doxazosine Syri Pharma 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 Doxazosine Syri Pharma**

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 Doxazosine Syri Pharma is 2 mg (5 ml) taken once a day.
- ▶ If you are taking Doxazosine Syri Pharma 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.
- ▶ Doxazosine Syri Pharma may be taken in the morning or the evening.
- ▶ Doxazosine Syri Pharma 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 Doxazosine Syri Pharma as your doctor told you - It is important to keep taking Doxazosine Syri Pharma. It helps to control your blood pressure.
- ▶ Don't change the dose or stop taking Doxazosine Syri Pharma without first checking with your doctor.
- ▶ Don't wait until your Doxazosine Syri Pharma is finished before seeing your doctor.

**Route and Method of administration:**

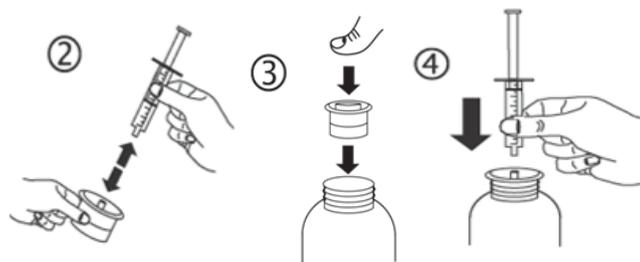
- ▶ This medicine must be taken orally.
- ▶ Use the measuring syringe provided in the pack to deliver the required dose.
- ▶ Doses of 10 ml or below should be administered using the 10ml syringe. For doses greater than 10ml, the 20 ml syringe should be used.

*Instructions for the use of syringe:*

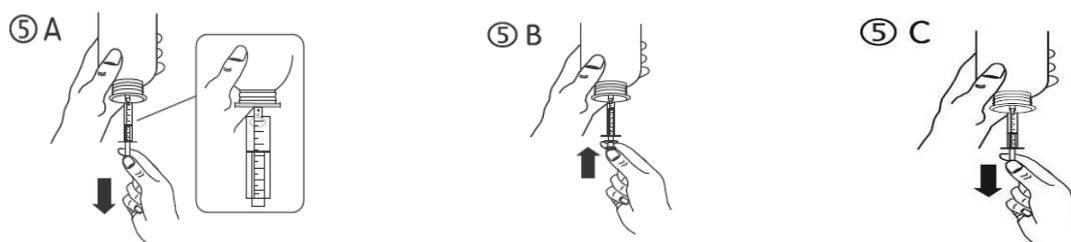
a) Open the bottle: press the cap and turn it anticlockwise (figure 1).



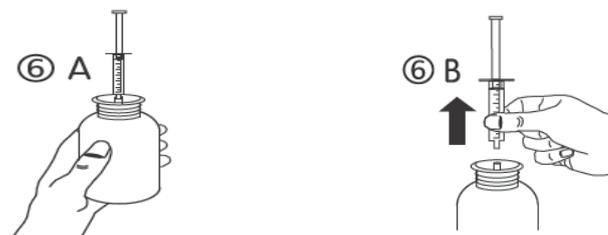
b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



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).

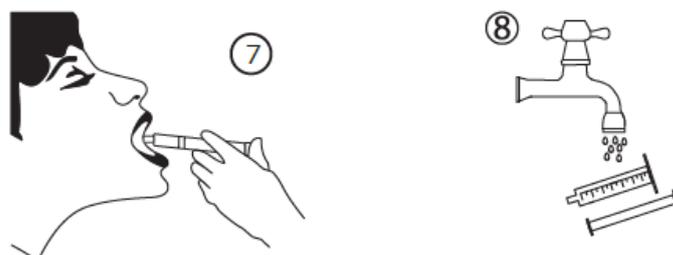


d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



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 Doxazosine Syri Pharma than you should:**

Taking too much Doxazosine Syri Pharma 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 Doxazosine Syri Pharma:**

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 Doxazosine Syri Pharma:**

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 Doxazosine Syri Pharma 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 Doxazosine Syri Pharma:

- ▶ Chest pain (angina), wheezing, shortness of breath, difficulty breathing
- ▶ Feeling your heartbeat (palpitations)
- ▶ Fainting
- ▶ Yellowing of the skin or the eyes (jaundice)
- ▶ Low numbers of white blood cells or blood platelets, which may result in bruising or easy bleeding

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
- ▶ Bronchitis, 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
- ▶ 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
- ▶ Swollen face
- ▶ 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 Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Doxazosine Syri Pharma

- ▶ 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 Doxazosine Syri Pharma 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 Doxazosine Syri Pharma looks like and contents of the pack

Doxazosine Syri Pharma 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.

Doxazosine Syri Pharma is supplied in a bottle containing 150 ml oral suspension.

### Marketing Authorisation Holder and Manufacturer:

#### Marketing Authorisation Holder:

Syri Pharma Limited  
1 Windmill Lane  
Dublin 2, D02 F206  
Ierland.

#### Manufacturer:

Pharmadox Healthcare Ltd.  
KW20A Kordin Industrial Park,  
Paola PLA 3000, Malta.

**In het register ingeschreven onder: RVG 133857**

**This medicine is authorised in the Member States of the European Economic Area under the following name:**

**NL:** Doxazosine Syri Pharma 0,4 mg/ml, suspensie voor oraal gebruik

**MT:** Doxazosin Syri Pharma 0.4 mg/ml Oral Suspension

**If this leaflet is hard to see or read, please call +353 1437 0882 for help.**

**Deze bijsluiter is voor het laatst goedgekeurd in november 2025.**