

Package leaflet: Information for the user

Doxazosin Aurobindo 1 mg tablets

Doxazosin Aurobindo 2 mg tablets

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

1. What doxazosin aurobindo is and what it is used for

Doxazosin belongs to the group known as vasodilators. These substances cause the blood vessel to widen, which reduces the blood pressure. Doxazosin can also reduce tension in the muscle tissues of the prostate and the urinary tract.

Doxazosin is used to treat:

- high blood pressure;
- symptoms of an enlarged prostate.

2. What you need to know before you take Doxazosin Aurobindo

Do not take Doxazosin Aurobindo

- 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);
- 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 are breast-feeding
- 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 Aurobindo:

- suffer from serious heart problems such as e.g. severely reduced cardiac function or a restrictive and painful sensation in the chest (angina pectoris);
- are on a strict low-salt diet;

- are using diuretics;
- have kidney or liver problems.

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 Aurobindo. This is because Doxazosin Aurobindo may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Important information about Doxazosin Aurobindo

The likelihood of your blood pressure dropping too fast is greatest at the start of treatment or when the dosage is increased. You may observe this as dizziness or more rarely fainting when changing position. To reduce the risk of this happening, your doctor will check your blood pressure thoroughly at the start of treatment and when the dosage is increased. You should therefore avoid situations at the start of treatment in which dizziness or faintness could cause injury.

Doxazosin Aurobindo may also affect the results of some blood and urine tests. If you are due to have a blood or urine test make sure that you tell you are taking Doxazosin Aurobindo.

Children and adolescents

Doxazosin Aurobindo is not recommended for use in children or adolescents below 18 years as safety and efficacy have not yet been established.'

Other medicines and Doxazosin Aurobindo

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

- 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 drugs for erectile dysfunction (impotence) with alpha-blockers. 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 Aurobindo may lower your blood pressure even more if you are already taking other medicines to treat high blood pressure such as terazosin and prazosin;
- nitrates (medicines for heart problems) such as nitroglycerine and isosorbide nitrate: these can exacerbate the hypotensive effect;
- certain painkillers for rheumatism (known as non-steroidal anti-inflammatory drugs) such as naproxen, ibuprofen or any other anti-inflammatory painkiller: these can reduce the hypotensive effect;
- medications that could also possibly affect the liver metabolism, e.g. cimetidine (a medicine for stomach problems);

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

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

Doxazosin Aurobindo should only be used during pregnancy if your doctor decides that the benefits for the mother outweigh the possible risk for the foetus.

Do not breast feed while taking Doxazosin Aurobindo.

Driving and using machines

Doxazosin can sometimes cause dizziness or fainting. In such an event, you should exercise care during activities that require attentiveness, such as driving, operating machinery and working at heights. If you are unsure whether Doxazosin is having a negative effect on your ability to drive, discuss this with your doctor.

Doxazosin Aurobindo 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.

3. HOW TO TAKE DOXAZOSIN AUROBINDO

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

HIGH BLOOD PRESSURE

The initial dose is 1mg daily (= 24 hours) in a single dose. After 1 to 2 weeks, the dose is generally increased to 2mg in a single daily dose (= 24 hours). This dose is also retained for 1 to 2 weeks. If necessary, the dosage can be further increased to 4, 8 or 16mg per day, until the desired reduction in blood pressure is achieved. The maximum daily dose is 16mg.

An initial dose should preferably be taken before going to bed; this means that any dizziness you may experience is less of a problem.

ENLARGED PROSTATE

The initial dose is 1mg daily (= 24 hours) in a single dose. After this the usual dose is 2mg or 4mg daily. In some circumstances this may be increased to a maximum of 8mg daily.

The tablets should be taken as a single dose each day (= 24 hours). The tablets must be taken with plenty of water.

If you take more Doxazosin Aurobindo than you should

If you have taken more than the prescribed dose, you should consult your doctor and/or pharmacist immediately. If you feel extremely dizzy or think you might faint, you should lie down immediately with your head down.

If you forget to take Doxazosin Aurobindo

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 tablet dose.

If you stop taking Doxazosin Aurobindo

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.

Some side effects could be serious:

If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions such as wheezing, shortness of breath, extreme dizziness or collapse, swelling of the face or throat, or a serious skin rash with red spots or blisters (especially affecting the whole body).
- Chest pain (angina pectoris), increased or irregular heartbeat, heart attack or stroke (symptoms may include collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech, and loss of speech).

- Yellowing of the skin or whites of the eyes, caused by liver problems (jaundice).
- Unusual bruising or bleeding caused by low blood platelets.
- Presence of blood in the urine
- Hepatitis (liver disease with nausea, vomiting, loss of appetite, generally feeling unwell, fever)
- Cholestasis (blocked flow of bile - can cause itchy skin, pale stool, and dark urine)
-

These side effects are uncommon (affects 1 to 10 users in 1,000) or rare (affects 1 to 10 users in 10,000)

Other side effects:

Common: (may affects up to 1 to in 10 users in 100people):

- respiratory tract infection (nose, throat, lung)
- urinary tract infection (symptoms may include: pain or a burning sensation when you urinate or a frequent need to urinate), urinary incontinence (inability to control passing urine)
- dizziness sleepiness (somnolence), headache
- feeling of dizziness or “spinning” (vertigo)
- feeling or sensation of irregular heartbeat (palpitation), increased heart rate
- low blood pressure and low blood pressure as a result of getting up from a sitting or lying position (postural hypotension)
- inflammation of the air passages within the lungs, cough, shortage of breath, nasal stuffiness and/or runny nose
- abdominal pain, indigestion, dry mouth, feeling sick (nausea)
- itching (pruritus)
- back pain, muscle pain (myalgia)
- inflammation of the bladder (cystitis)
- feeling of weakness (asthenia), chest pain, influenza like symptoms
- swelling of the ankles, feet or fingers (peripheral oedema)

Uncommon (affects 1 to 10 users in 1,000):

- gout, increased appetite, anorexia
- agitation, depression, anxiety, sleeplessness (insomnia), nervousness, tremor
- stroke, reduced sense of touch or sensation, fainting
- ringing or noise in the ears (tinnitus)
- nosebleed
- constipation, flatulence, vomiting (being sick), inflammation of the gastrointestinal tract, diarrhoea
- abnormal liver function test
- skin rash
- joint pain
- painful or difficult urination
- difficulty to develop an erection (impotence)
- pain, swelling of the face
- weight increase.

Very Rare (may affects up to less than 1 user in 10,000 people):

- dizziness postural (dizziness as a result of getting up from a sitting or lying position), tingling or numbness of the hands and feet (paraesthesia)
- reduced number of white blood cells (symptoms may include frequent infections such as fever, severe chills, sore throat or mouth ulcers)
- blurred vision
- reduced heart rate
- hot flushes
- bronchial spasm (difficulty in breathing, wheezing or coughing)
- muscle cramps, muscle weakness
- polyuria (passing large volumes of urine)
- increased blood levels of urea and creatin

- hives (urticaria) , hair loss (alopecia), rash caused by bleeding under the skin (purpura)
- disorder in passing urine, needing to pass urine at night, increased volume of urine passed
- temporary enlargement of the breasts in men (gynaecomastia)
- feeling tired (fatigue), malaise (general feeling of being unwell)
- Persistent painful erection of the penis. Seek urgent medical advice.

Not known (frequency cannot be estimated from available data):

- eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye). See section “Take special care with Doxazosin Aurobindo”.
- little or no semen ejaculated at sexual climax, cloudy urine following sexual climax (retrograde ejaculation)

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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store doxazosin aurobindo

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 blister, , label, bottle and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Doxazosin Aurobindo contains

- The active substance is doxazosin. Each tablet contains 1mg, 2mg or 4mg doxazosin (as doxazosin mesilate).
- The other ingredients are: Cellulose microcrystalline, lactose anhydrous, sodium starch glycolate, magnesium stearate

What Doxazosin Aurobindo looks like and contents of the pack

Doxazosin Aurobindo 1mg tablets:

White to off white coloured, circular biconvex shaped uncoated tablet debossed with H on one side and 01 on other side.

Doxazosin Aurobindo 2mg tablets:

White to off-white coloured, caplet shaped uncoated tablet debossed with H02 on one side and breakline on other side.

The tablet can be divided into equal halves.

Doxazosin Aurobindo 4mg tablets:

White to off-white coloured, diamond shaped uncoated tablet debossed with H03 on one side and breakline on other side.

The tablet can be divided into equal halves.

PVC-PVDC Aluminium blisters:

Pack size: 10, 14, 15, 20, 28, 30, 50, 56, 60, 90, 98, 100 and 140 tablets

HDPE bottle:

Pack size: 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma (Malta) Limited

Vault 14, Level 2, Valletta Waterfront, Floriana FRN 1913

Malta

Manufacturer

Milpharm Limited

Ares, Odyssey Business Park, West End Road,

South Ruislip HA4 6QD.

United Kingdom

or

APL Swift Services (Malta) Limited

HF26, Hal Far Industrial Estate

Hal Far, Birzebbugia, BBG 3000

Malta

or

Adamed Sp. z o.o.

Pieńków 149

05-152 Czosnów

Polska

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria: Doxazosin Aurobindo 1mg/ 2mg/ 4mg таблетки

Czech Republic: Doxazosin Aurobindo 4mg tablety

Germany: Doxazosin Aurobindo 1mg/ 2mg/ 4mg/ 8mg Tabletten

Hungary: Doxazosin Aurobindo 2mg/ 4mg tabletta

Ireland: Doxazosin Aurobindo 1mg/ 2mg/ 4mg tablets

Italy: Doxazosin Aurobindo 2mg/ 4mg compresse

Poland: Adadox, 2 mg/4 mg

Doxazosin Aurobindo, 1 mg

Spain: DOXAZOSINA AUROBINDO 2mg/ 4mg comprimidos

United Kingdom: Doxazosin 1mg/ 2mg/ 4mg/ 8mg tablets

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