

PACKAGE LEAFLET

Package leaflet: Information for the patient

Doxazosin Mylan 1 mg, 2 mg and 4 mg Tablets (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.

What is in this leaflet

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

1. What Doxazosin Mylan is and what it is used for

Your medicine belongs to a group of medicines called alpha-blockers. Doxazosin Mylan can treat high blood pressure (hypertension) by relaxing the blood vessels in the body and lowering blood pressure. Doxazosin Mylan can also be given to men suffering from an enlarged prostate gland, as it can relax the muscles allowing urine to be passed more easily.

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

Do not take Doxazosin Mylan if you

- are allergic to doxazosin, or other types of quinazolines (e.g. prazosin, terazosin) or any of the other ingredients of this medicine (listed in section 6).
- 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 (benign prostate hyperplasia) and problems with your bladder, a long standing infection of the urinary tract or difficulty in passing urine.
- have low blood pressure
- are breast-feeding (see Pregnancy and breast-feeding)
- 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 Mylan if you:

- have heart disease or a heart condition
- have liver problems
- have kidney disease or kidney problems
- have diabetes
- are on a low-salt diet

- are elderly
- need a blood test as Doxazosin Mylan can affect some test results
- are undergoing eye surgery because of cataract (cloudiness of the lens). Please inform your eye specialist before the operation that you are taking or have previously taken medicine containing doxazosin. This is because doxazosin may cause complications during the surgery, which can be managed if your eye specialist is informed in advance.

When you start to take Doxazosin Mylan or when your dose is increased 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 or when your dose is increased to reduce the possibility of these effects happening.

Children and adolescents

Doxazosin mesilate 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 Mylan:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, or the following:

- other medicine to lower blood pressure such as beta-blockers (e.g. atenolol) or vasodilators (e.g. hydralazine)
- medicine to treat a heart condition such as nitrates (e.g. glyceryl trinitrate)
- painkillers called non-steroidal anti-inflammatory medicine (NSAIDs) e.g. ibuprofen
- medicine containing oestrogen such as HRT or oral contraceptive medicines.
- cimetidine, used to treat stomach ulcers
- diuretics or 'water tablets'
- medicine containing dopamine, metaraminol, methoxamine, adrenaline (epinephrine), cough and cold remedies as they may contain ephedrine, phenylephrine
- medicine for erection problems, such as sildenafil, tadalafil, vardenafil. You should not take such medicines until your blood pressure is well controlled. You should take the lowest possible dose of medicine for erection problems.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Doxazosin Mylan should not be given to pregnant women unless the benefits to the mother outweigh the risks to the baby.

Do not breast-feed your baby, as small amounts of doxazosin can pass into breast milk.

Driving and using machines

Do not drive or operate machinery if you feel less alert while taking this medicine. They make you feel weak or dizzy. This is more likely at the start of the treatment or if the doctor increases your dose.

Doxazosin Mylan contains lactose

Doxazosin Mylan contains **lactose**. If your doctor has told you that you have intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Doxazosin Mylan

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

Adults including the elderly

High blood pressure: The usual starting dose is 1 mg once a day. If necessary, your doctor may gradually increase the dose (e.g. 2 mg, 4 mg, 8 mg) at intervals of 1 to 2 weeks until the desired blood pressure is achieved. The maximum daily dose is 16 mg. Your doctor may give you another medicine to take along with Doxazosin Mylan

Enlarged prostate: The usual starting dose is 1 mg once a day. If necessary, your doctor may gradually increase the dose at intervals of 1 to 2 weeks until your symptoms are controlled. The maximum daily dose is 8 mg.

Take your tablets at about the same time each day with a drink of water.

If you take more Doxazosin Mylan than you should:

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include headache, dizziness, confusion, fainting, breathlessness, low blood pressure, palpitations (feeling your heartbeat), racing heartbeat, irregular heartbeat, slow heartbeat, feeling sick, vomiting, low levels of sugar and potassium in your blood.

If you forget to take Doxazosin Mylan:

Take the next dose as soon as you remember. Unless it is almost time for your next dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Doxazosin Mylan:

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

Uncommon (may affect up to 1 in 100 people):

- Pressure, tightness, pain or a squeezing sensation in your chest or arms that may spread to your neck, jaw or back which may be signs of a 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

Seek urgent medical advice **immediately** if you experience any of the following symptoms after taking Doxazosin Mylan:

Uncommon (may affect up to 1 in 100 people):

- Angina
- Fainting
- Shortness of breath, difficulty breathing

Very rare (may affect up to 1 in 10, 000 people):

- Decreased or irregular heartbeat
- Liver disease (hepatitis) or a condition in which the flow of bile from the liver is blocked (cholestasis) causing dark urine, pale stools, nausea, fever and yellowing of the skin or the eyes (jaundice).
- Increase in the number of infections that you get such as sore throat, mouth ulcers, with chills and fever, which may be caused by low numbers of white blood cells.
- Persistent painful erection of the penis

Other possible side effects:

Common (may affect up to 1 in 10 people):

- Dizziness
- Headache
- Respiratory tract (nose, throat, lungs) infection
- Urinary tract infection
- Feeling of dizziness or spinning (vertigo)
- Sleepiness
- Weakness
- Feeling sick
- Feeling indifferent or lacking interest
- Swelling of the ankles
- Low blood pressure or a drop in blood pressure when standing up from a sitting or lying position
- Chest pain
- Increased heartbeat
- Feeling your heartbeat (palpitations)
- Light-headedness
- Back pain
- Muscle pain
- Abdominal (stomach) pain
- Dry mouth
- Indigestion
- Bronchitis
- Coughing
- Itching
- Breathlessness
- Blocked nose
- Runny nose
- Delayed ejaculation
- Bladder infection
- Urinary incontinence (inability to control passing urine)
- Difficulty in focussing
- Flu-like symptoms

Uncommon (may affect up to 1 in 100 people):

- Shaking (tremor)
- Feeling anxious
- Loss of appetite or increased appetite.
- Difficulty in sleeping
- Feeling nervous
- Diarrhoea
- Swelling of the face and body

- Paleness or redness of the face
- Fever or shivering
- Cold fingers and toes
- Muscle pain
- Constipation
- Wind
- Being sick
- Inflammation of the stomach and intestines (gastroenteritis)
- Abnormal liver function tests
- Muscle stiffness
- Painful inflammation of the joints (gout)
- Joint pain (arthralgia)
- Skin rash
- Nose bleeds
- Sore swollen throat
- Low blood potassium levels
- Feeling thirsty
- Changes in taste
- Agitation
- Depression
- Nightmares
- Loss of memory
- Reduced or altered sense of touch or sensation
- Mood changes
- Change in frequency of passing urine
- Passing blood in the urine (haematuria)
- Failure / inability to achieve penile erection
- General pain
- Painful urination
- Sensitivity of your eyes to light
- Changes in tear flow
- Ringing in the ears
- Weight increase

Rare (may affect up to 1 in 1,000 people):

- Lower body temperature in the elderly
- Change in the blood flow in the brain
- Swelling of the throat
- Sweating
- Swollen runny eyes (conjunctivitis)
- Increase of urea and creatinine levels in your blood
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- Low blood sugar
- Change in volume of urine (polyuria)
- Muscle cramps
- Muscle weakness

Very Rare (may affect up to 1 in 10,000 people):

- Reduction in blood platelets, which increases risk of bleeding or bruising.
- Blurred vision
- Aggravated wheezing
- Itchy red skin
- Increased volume of urine passed, disorder in passing urine, needing to pass urine at night
- Enlargement of breasts in men

- Sensation of tingling, pricking or numbness of skin (paraesthesia)
- Dizziness on standing. This is more likely to happen at the beginning of the treatment
- Hair loss
- Bruising because of bleeding into the skin (purpura)
- Hot flushes
- Fatigue, and malaise (feeling out of sorts)

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

- Intraoperative floppy iris syndrome (IFIS)
- Taste disturbances
- Retrograde ejaculation (little or no semen released at sexual climax, cloudy urine following sexual climax).

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 [To be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Doxazosin Mylan

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Mylan contains:

Each Doxazosin Mylan 1 mg, 2 mg or 4 mg tablet contains either 1 mg, 2 mg or 4 mg of the active ingredient doxazosin as doxazosin mesilate. The other ingredients are microcrystalline cellulose, anhydrous lactose, sodium starch glycolate Type A, magnesium stearate and sodium laurilsulfate.

What Doxazosin looks like and contents of the pack:

Doxazosin Mylan 1 mg Tablets are white, round tablets with “DX1” marked on one side.

Doxazosin Mylan 2 mg Tablets are white, scored, capsule-shaped tablets with “DX|2” marked on one side.

Doxazosin Mylan 4 mg Tablets are white, scored, capsule-shaped tablets with “DX|4” marked on one side.

Doxazosin Mylan is available in plastic bottles with tamper-proof plastic cap of 10, 20, 28, 30, 50, 60, 90, 100, 250, 500, 1000 tablets and in blister packs of 10, 20, 28, 30, 50, 60, 90, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

[To be completed nationally]

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

Austria: Doxazosin “Arcana” 2 mg & 4 mg Tabletten

Germany: Doxazosin dura 1 mg, 2 mg & 4 mg Tabletten

Spain: Doxazosina Mylan 2 mg & 4 mg, comprimidos
Sweden: Doxazosin Mylan 1 mg, 2 mg & 4 mg Tabletter
United Kingdom: Doxazosin 1 mg, 2 mg and 4 mg Tablets

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