Package leaflet: Information for the user

Doxatan 1mg, 2mg and 4mg 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.

In this leaflet:

1. What Doxatan is and what it is used for

The active ingredient in your tablets, doxazosin, belongs to a group of medicines known as alpha-1 antagonists. Doxatan is used to treat the following conditions.

- High blood pressure (essential hypertension). If left uncontrolled, high blood pressure can increase the risk of heart disease or stroke.

Doxatan works by widening your blood vessels making it easier for your heart to pump blood through them. This helps to lower raised blood pressure and reduce the risk of heart disease.

2. What you need to know before you take Doxatan

DO NOT take Doxatan
- if you are allergic to doxazosin or any of the other ingredients of this medicine (listed in section 6). Allergic reactions may be, for example, itching, reddening of the skin or difficulty breathing.
- if you know that you are allergic to quinazolines (e.g. prazosin, terazosin). Quinazolines are a chemical family of medicines to which doxazosin belongs to.
- if you have or have had a fall in blood pressure on standing up which caused dizziness, light-headedness or fainting (orthostatic hypotension).
- if you have benign prostatic hyperplasia (BPH) and additionally suffer from a blockade of your upper urinary tract, chronic urinary infection or bladder stones.
- if you are breast-feeding (see section “Pregnancy and breast-feeding”).
- if you have overflow bladder, decreased production of urine (anuria) or if your kidneys fail to function properly (progressive renal insufficiency).

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxatan
- if you are going to have eye surgery. It is important that you tell the surgeon if you are currently taking doxazosin or if you have taken it in the past, as it may cause an increased risk of complications during cataract surgery.
- if you suffer from liver disease (please ask your doctor before taking Doxatan)
- if you are taking other medicines (see section “Other medicines and Doxatan”).

– if you have suffered acute heart disease such as heart failure. If you know that you have any heart disease please tell your doctor before taking Doxatan.
– if you are under 18 years of age.

Some patients may experience symptoms such as low blood pressure on standing up which can cause dizziness, light-headedness or fainting (orthostatic hypotension). This is more likely at the beginning of the treatment or if you are on a low-sodium diet or if you are treated with diuretics (water tablets). If any of those conditions apply to you your doctor will monitor you carefully.

Before surgery and anaesthesia (even at the dentist), you should tell the doctor or dentist that you are taking Doxatan.

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

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

If you are not sure about what to do, ask your doctor or pharmacist.

Other medicines and Doxatan
Tell your doctor if you are taking, have recently taken or might take any other medicines:
– Non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ibuprofen
– Other medicines used in the treatment of high blood pressure, such as vasodilators
– Nitrates (e.g. to treat chest pain)
– Oestrogens (female hormone)
– Dopamine, ephedrine, adrenaline, metaraminol, methoxamine, phenylephrine (medicines used for the treatment of heart problems)
– Cardiovascular stimulating medicines (sympathomimetics; they all raise blood pressure),
– Cimetidine (used to treat gastrointestinal diseases) and other medicines which may influence the effect of Doxatan; please ask your doctor if the medicines you are already taking belong to this group.
– 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. Furthermore, it is recommended to initiate drugs for erectile dysfunction treatment with the lowest possible dose and to respect a 6-hour time interval from intake of doxazosin.

Please note that Doxatan may influence some laboratory results. Your doctor should consider this.

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.

Doxatan should only be used in pregnant women after the doctor has carefully looked at the expected benefits against potential risks.

Doxazosin must not be used during breast-feeding, because it passes into human breast milk. If

therapy with doxazosin is unavoidable, breast-feeding must be stopped.

Driving and using machines
Doxatan may result in decreased alertness. Therefore the ability to drive, operate machines or work may be impaired. These effects especially occur at the start of therapy, when increasing the dose, switching medications or in combination with alcohol.

Doxatan 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.

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

3. How to take Doxatan

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

Doxatan may be prescribed as a monotherapy or in combination with other medicines which also lower the blood pressure.

Always take your tablets in the morning with a glass of water. The Doxatan 2 mg and 4 mg tablets can be divided into equal halves.
Your doctor will decide for how long you have to take the tablets.

Hypertension
For hypertension, the starting dose of doxazosin is 1 mg once daily. This dose must not be exceeded for at least one week or your blood pressure could fall too low. Depending on your response, the dosage may be increased after one or two weeks to 2 mg of doxazosin taken once daily. This dosage may be further increased to 4 mg and then eventually to 8 mg doxazosin once daily.

The recommended dose is 2-4 mg of doxazosin once daily.

The maximum daily dose for hypertension is 16 mg of doxazosin.

Elderly patients/patients suffering from impaired kidney function
Those patients should be treated with the lowest dosage possible and must be monitored carefully.

If you take more Doxatan than you should
If you take too many tablets you should lie down on your back with your feet higher than your head. The most likely symptoms of overdose would be a feeling of light-headedness, dizziness or fainting due to a fall in blood pressure. If you have any of these symptoms you should tell your doctor or pharmacist or telephone your nearest casualty department immediately.

If you forget to take Doxatan
If you miss a dose, do not worry. Simply take the next day's tablet when it is due. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Doxatan
Keep taking your tablets until your doctor tells you to stop.

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. The evaluation of the side effects is based on the following frequencies:

Very common (may affect more than 1 in 10 people)

- dizziness
- headache

Common (may affect up to 1 in 10 people)

- dizziness as a result of getting up from a sitting or lying position (postural dizziness)
- light-headedness (vertigo)
- low blood pressure as a result of getting up from a sitting or lying position (postural hypotension)
- low blood pressure (hypotension)
- nasal congestion
- runny nose (rhinitis)
- bronchitis
- respiratory tract infection
- breathlessness (dyspnoea)
- cough
- influenza like symptoms (e.g. fever/shivering)
- feeling sick (nausea)
- swelling of the voice box, facial/general swellings (oedema)
- drowsiness (somnolence)
- tiredness
- apathy
- nervousness
- itching (pruritus)
- tingling or numbness (paraesthesia)
- eyes cannot focus properly (accommodation disturbances)
- feeling your heart beat (palpitations)
- increased heart rate (tachycardia)
- giddiness
- decreased appetite (anorexia)
- constipation
- diarrhoea
- abdominal pain
- indigestion (dyspepsia)
- dry mouth
- muscle cramps
- painful muscles (myalgia)
- back pain
- urinary incontinence
- inflammation of the bladder (cystitis)
- urinary tract infection
- increased frequency and/or increased volume of urine passed
- ejaculation disorders (e.g. retrograde ejaculation)
- weakness (asthenia)
- chest pain

Orthostatic hypotension (low blood pressure as a result of getting up from a sitting or lying position) and fainting (syncope) have been observed shortly after the beginning of the treatment,

especially at high doses and also after the therapy is restarted after a short break.

Uncommon (may affect up to 1 in 100 people)
- thirst
- weight increase
- low blood levels of potassium (hypokalaemia)
- nightmares
- sleeplessness (insomnia)
- memory loss
- emotional lability
- anxiety
- agitation
- depression
- muscle stiffness
- vomiting
- inflammation of the gastrointestinal tract (gastroenteritis)
- flatulence
- abnormal tear flow
- excessive sensitivity to light (photophobia)
- having less than normal sensitivity to stimulation (hypoaesthesia)
- fainting (syncope)
- inflammation of the throat (pharyngitis)
- hair loss (alopecia)
- rash
- rash caused by bleeding under the skin(purpura)
- allergic drug reaction
- urinary disturbances
- painful urination (dysuria)
- presence of red blood cells in the urine (haematuria)
- impotence
- paleness
- gout
- shaking (tremor)
- ringing or noise in the ears (tinnitus)
- feeling of irregular heart beat (arrhythmia)
- chest pain (angina pectoris)
- heart attack (myocardial infarction)
- stroke (cerebrovascular accident)
- disturbed blood flow in the extremities (peripheral ischaemia)
- bronchial spasms
- nosebleed (epistaxis)
- increased appetite
- painful joints (arthralgia)
- joint swelling
- muscle weakness
- general pain
- facial flushing
- hot flushes
- abnormal liver function test

Rare (may affect up to 1 in 1,000 people)
- blurred vision

- low blood sugar level (hypoglycaemia)
- cerebrovascular disturbances
- decreased body temperature in the elderly
- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)
- increased liver enzymes

Very rare (may affect up to 1 in 10,000 people)
- slower heart beat (bradycardia)
- hives (urticaria)
- malaise
- fatigue
- low level of platelets, which may result in easy bleeding (thrombocytopenia)
- low level of white blood cells (leukopenia)
- low level of red blood cells
- blocked flow of bile (cholestasis)
- inflammation of the liver (hepatitis)
- increased levels of blood urea nitrogen (BUN) and creatinine in the plasma
- increased urination at night (nocturia)
- temporary enlargement of the breasts (gynaecomastia)
- persistent painful erection of the penis. Seek urgent medical advice.

Not known (frequency cannot be estimated from the available data)
- increased risk of complications during cataract surgery (Intra-operative Floppy Iris Syndrome; IFIS)
- disturbed taste (dysgeusia)

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
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Doxatan
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 carton and blister after Exp. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Doxatan contains
The active substance is doxazosin (as mesilate).

Doxatan 1 mg, 2 mg or 4 mg tablets
Each tablet contains either
- 1 mg doxazosin (as mesilate),
- 2 mg doxazosin (as mesilate) or
- 4 mg doxazosin (as mesilate).

The other ingredients are microcrystalline cellulose, lactose, magnesium stearate, sodium laurilsulfate, sodium starch glycolate (type A), colloidal anhydrous silica.

What Doxatan looks like and contents of the pack
Doxatan 1 mg tablets
White, round convex tablet, embossed 'D1' on one side.

Doxatan 2 mg tablets
White, oblong tablet, scored on one side, embossed 'D2' on one side.

Doxatan 4 mg tablets
White, oblong tablet, scored on one side, embossed 'D4' on one side.

PVC/PVDC/Aluminium blisters

Pack sizes: 10, 20, 28, 30, 40, 50, 56, 98, 100, 150, 200, 250, 300, 400, 500 or 1000 tablets.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
STADA M&D SRL, Str. Trascăului, nr 10, RO-401135, Turda, Romania

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

Ireland	Doxatan 1mg/2 mg/4 mg tablets
Italy	Doxazosina EG 2 mg/4 mg compresse
Germany	Doxazosin STADA 1 mg/2 mg/4 mg Tabletten
Austria	Doxazosin Genericon 2 mg/4 mg – Tabletten

This leaflet was last revised in March 2024.