

Package leaflet: Information for the patient

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

1. What Doxacar is and what it is used for

Doxacar tablets contain doxazosin, which belongs to a group of medicines called alpha-blockers. Doxacar can be used to treat high blood pressure (hypertension) by relaxing the blood vessels in the body so that the blood passes through more easily. This helps to lower blood pressure.

In patients with an enlarged prostate gland (benign prostatic hyperplasia), Doxacar is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate gland. Doxacar works by relaxing muscle around the bladder exit and prostate gland so urine is passed more easily.

2. What you need to know before you take Doxacar

Do not take Doxacar

- If you are allergic to doxazosin, other types of quinazolines (e.g. prazosin, terazosin), or to 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 or have had any form of obstruction of the digestive tract.
- If you have an enlarged prostate with one of the following: a longstanding infection of the urinary tract, any kind of congestion or blockage in your urinary tract or bladder stones.
- If you have an enlarged prostate gland and 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
- If you have low blood pressure (hypotension) and have been prescribed this medicine for benign prostatic hyperplasia.

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxacar:

- if you have heart disease or a heart condition
- if you have problems with your liver or kidneys

Tell your doctor if any of the above applies to you.

When you start to take Doxacar 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.

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. This is because doxazosin 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 Doxacar your doctor may perform tests to rule out other conditions such as prostate cancer that may cause the same symptoms as benign prostatic hyperplasia.

Children and adolescents

Doxacar is not recommended for use in children and adolescents under the age of 18 years due to a lack of data on its efficacy and safety.

Other medicines and Doxacar

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important that you tell your doctor if you are taking any of the following:

- other medicines to lower blood pressure
- medicines for erectile dysfunction (impotence) (e.g. sildenafil, tadalafil or vardenafil); you may feel dizzy and lightheaded, which may be caused by low blood pressure upon sitting or standing up quickly, if you are also taking Doxacar tablets. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of Doxacar before you start drugs for impotence
- medicines to treat of bacterial or fungal infections (e.g. clarithromycin, itraconazole, ketoconazole, telithromycin or voriconazole)
- medicines to treat of HIV (e.g. indinavir, nelfinavir, ritonavir or saquinavir)
- nefazodone, a medicine used to treat depression

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 before taking this medicine.

There is not sufficient experience from the use of doxazosin during pregnancy, therefore its use is not recommended.

Do not take Doxacar if you are breast-feeding.

Driving and using machines

Do not drive or operate machinery if you feel dizzy, tired or have blurred vision while taking this medicine. This is more likely at the start of treatment.

Doxacar 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 Doxacar

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

Doxacar is a prolonged-release tablet. The medicine is contained within a non-absorbable shell that has been specially designed to slowly release the medicine. Once swallowed, the medicine (doxazosin) is slowly released into the body from the tablet, until the tablet is empty. Since the empty tablet is eliminated from the body in bowel movements, you may occasionally observe in the stools, something that looks like a tablet. This is to be expected and you should not be concerned.

Doxacar can be taken at any time of the day. Choose a time that is convenient for you and take your tablets at this time each day. Swallow your medicine whole with water. **Do not chew, divide or crush** the tablets. The prolonged release tablets may be taken with or without food.

Adults (including elderly people)

The recommended dose of doxazosin is one tablet (4 mg doxazosin) once a day. If necessary, your doctor may increase this dose to the maximum of two tablets (8 mg doxazosin) once a day.

Your doctor has decided which dose is best for you. Follow your doctor's instructions and do not change the dose yourself.

Use in children and adolescents

Doxacar is not recommended for use in patients under the age of 18 years due to a lack of data on its efficacy and safety.

Use in patients with liver problems

Your doctor may reduce your dose or monitor your progress closely. Doxacar is not recommended for use in patients with severe liver problems.

If you take more Doxacar than you should

Contact your doctor or nearest hospital casualty department immediately. Take any remaining tablets and the container with you.

Symptoms of overdose include feeling light-headed or dizzy due to a drop in your blood pressure.

If you forget to take Doxacar

If you forget to take a dose of Doxacar do not worry and leave that dose out completely. Then continue as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Doxacar

It is important to keep taking your tablets. They help to control your blood pressure.

Do not change the dose or stop taking the tablets without first checking with your doctor. Do not suddenly stop taking your medicine as this may cause serious changes in your blood pressure. Do not wait until your tablets are finished before seeing your doctor.

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

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

- chest pain that spreads to the arms or back, which may be signs of a heart attack
- collapse, numbness or weakness of arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, or problems speaking such as slurred speech and loss of speech which may be signs of stroke
- swelling of the face, tongue or throat, causing difficulty breathing, which may be the result of a serious allergic reaction to this medicine

Tell your doctor **immediately** if you experience any of the following:

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

- Blockage of the digestive tract

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

- sudden pain or a feeling of tightness in the chest (angina pectoris)

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

- liver disease causing dark urine, pale stools, yellowing of the skin or the eyes, nausea, fever and stomach pain (hepatitis)
- frequent infections causing fever, sore throat or mouth ulcers, which may be a sign of reduced 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
- sleepiness
- flu-like symptoms
- indigestion
- breathlessness
- swelling of the feet or hands
- runny or blocked nose
- headache
- chest pain
- infection of the kidney or bladder (urinary tract infection, cystitis)
- nose, throat or lung infection (respiratory tract infection)
- spinning sensation (vertigo)

- unusual weakness
- low blood pressure
- feeling sick
- light-headedness when standing up. This is more likely to happen at the beginning of treatment
- back pain
- muscle pain
- abdominal pain
- dry mouth
- inflammation of the airways (bronchitis)
- coughing
- itching
- inability to control passing urine (urinary incontinence)
- feeling your heartbeat (palpitations)

Uncommon (may affect up to 1 to 100 people)

- nose bleeds
- feeling faint
- being sick
- painful, swollen joints due to accumulation of uric acid crystals (gout)
- tremor
- less frequent urge to pass urine
- joint pain
- ringing in the ears
- increase in appetite
- difficulty in sleeping
- loss of appetite
- anxiety
- diarrhoea
- constipation
- wind
- inflammation of the stomach and intestines (gastroenteritis)
- abnormal liver function tests
- skin rash
- depression
- decreased feeling or sensitivity, especially in the skin
- passing blood in the urine (haematuria)
- failure or inability to get and maintain erection
- pain
- painful urination
- Weight gain
- Facial oedema

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

- bruising or bleeding more easily or for longer than usual (signs of low platelets in the blood)
- agitation
- nervousness
- blurred vision
- aggravated wheezing and coughing (bronchospasm)
- passing more urine than normal
- difficulty passing urine
- passing urine at night

- enlargement of breasts in men
- sensation of tingling, pricking or numbness of skin (paraesthesia)
- hair loss
- hives
- bruising because of bleeding into the skin (purpura)
- muscle cramps
- muscle weakness
- hot flushes
- fatigue
- generally feeling unwell
- an increased, decreased or irregular heartbeat

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

- eye problems during eye surgery for cataract which is a condition with cloudiness of the lens of the eye (intraoperative floppy iris syndrome -IFIS). See section 2 “Warnings and precautions”.
- abnormal ejaculation where semen passes into the bladder

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 Doxacar

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 and carton.

The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

The tablets should be whole to work effectively, if you notice any defects (such as broken tablets) do not take them and consult your pharmacist immediately.

Do not throw 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 Doxacar contains

The active substance is doxazosin. Each prolonged-release tablet contains 4 mg doxazosin (as doxazosin mesilate).

The other ingredients are:

Tablet core: macrogol, microcrystalline cellulose, povidone, butylhydroxytoluene (E321), alpha-tocopherol, colloidal anhydrous silica and sodium stearyl fumarate (see section 2 ‘Doxacar contains sodium’).

Tablet coat: methacrylic acid – ethyl acrylate copolymer, colloidal anhydrous silica, macrogol, and titanium dioxide (E171).

What Doxacar looks like and contents of the pack

Doxacar 4 mg prolonged-release tablets are white, round, biconvex tablets marked with “DL” on the one side.

Contents of the pack:

Cartons containing blisters with 10, 20, 28, 30, 50, 56, 60, 90, 98, 100, 140 (10x14) prolonged-release tablets

Calendar packs of 28 and 98 prolonged-release tablets

Unit dose pack of 50 x 1 prolonged-release tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

McDermott Laboratories Ltd, t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13.

Other Manufacturer

Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary

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