

Package leaflet: Information for the user

Raporsin 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 Raporsin is and what it is used for
2. What you need to know before you take Raporsin
3. How to take Raporsin
4. Possible side effects
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1 What Raporsin is and what it is used for

Raporsin is one of a group of medicines called alpha-blockers. It is used to treat high blood pressure in both male and female patients or the symptoms caused by enlargement of the prostate gland in male patients. Raporsin can be 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 male patients with an enlarged prostate gland, Raporsin is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate gland. Raporsin works by relaxing muscle around the bladder exit and prostate gland so that urine is passed more easily.

2 What you need to know before you take Raporsin

Do not take Raporsin:

- If you are **allergic** to doxazosin, other quinazolines (e.g. prazosin, terazosin) or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you are suffering from **benign hyperplasia** (an enlarged prostate gland) together with **bladder stones** or **blockages or infections** of the urinary tract.
- If you are suffering from **benign hyperplasia (an enlarged prostate gland) and bladder leakage, problems producing urine** or worsening **kidney problems**.
- If you have any form of obstruction of the digestive tract.
- If you have a history of orthostatic hypotension (a drop in blood pressure caused by standing or sitting up too quickly).
- If you have abnormally low blood pressure (only applicable if you are being treated for enlargement of the prostate gland).
- If you are **breastfeeding**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Raporsin

- If you have had a surgical procedure.

- At the start of treatment, 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. Your doctor will monitor your blood pressure at the start of treatment.
- If you have acute **heart disease such as swelling and/or fluid accumulation in the lungs (pulmonary oedema) and heart failure.**
- Be careful if you have acute heart failure due to a blood clot or build up of fluid around the heart.
- If you have severe liver problems.
- If you are male and use medicines to treat impotence such as sildenafil, tadalafil and vardenafil as taking these medicines at the same time with doxazosin may lead to low blood pressure. Your doctor will advise you with respect to interval required between taking these medicines with doxazosin.
- If you are undergoing eye surgery for cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Raporsin. This is because Raporsin may cause complications during the surgery which can be managed if your specialist is prepared in advance.
- If you have your blood or urine tested, remember to tell the doctor or nurse that you are being treated with Raporsin.

Raporsin is a modified release tablet. The medicine is contained within a non absorbable shell that has been specially designed to slowly release the medicine. Since the empty shell is removed 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.

Children and adolescents:

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

Other medicines and Raporsin

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Your treatment can be affected if Raporsin is taken with certain other medicines.

- It is especially important for your doctor to know if you are already being treated with the following medicines: Medicines to treat impotence in men (sildenafil, tadalafil and vardenafil) taken at the same time as doxazosin may lead to low blood pressure.
- 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.
- Other blood pressure lowering medicines - as the blood pressure lowering effect of these medicines may be increased.
- Anti-inflammatory medicines of the NSAID types (Non Steroidal Anti Inflammatory Drugs) – as they can reduce the effects of Raporsin.
- Cimetidine, a medicine used in the treatment of stomach ulcers taken at the same time with doxazosin will increase the effect of doxazosin. Speak with your doctor about this.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Raporsin tablets must not be used during breastfeeding.

Driving and using machines

Take care if you drive or operate machinery. Your tablets may affect your ability to drive or operate machinery safely, particularly when you first start to take them. If affected, do not drive or operate machinery and contact your doctor immediately.

3 How to take Raporsin

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

For oral use.

The tablets must be swallowed whole with a glass of water. Do not chew, divide or crush the tablets.

The tablets can be taken **with or without food**.

Raporsin can be used if you suffer from high blood pressure as well as prostatic hyperplasia (enlargement of the prostate gland). It will treat both conditions at the same time.

Adults including the elderly:

- **Treatment of high blood pressure for adult male and female patients**

The recommended dose is 4 mg doxazosin (1 prolonged-release tablet) once a day. If needed, the dosage may be increased to 8 mg doxazosin (2 prolonged-release tablets) once a day. It may take up to 4 weeks to attain the optimal effect.

- **Treatment of symptoms of prostatic hyperplasia (enlargement of the prostate gland) for adult male patients**

The recommended dose is 4 mg doxazosin (1 prolonged-release tablet) once a day. If needed, the dosage may be increased to 8 mg doxazosin (2 prolonged-release tablets) once a day.

- **Patients with loss of liver function:**

A reduction of the dose may be needed. Always follow the doctor's recommendations.

If you take more Raporsin than you should

If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

If an overdose has been taken there may be signs such as headache, dizziness, fainting, unconsciousness, difficulty breathing, low blood pressure, palpitations, fast or irregular heart beat or feeling of being sick.

If you forget to take Raporsin

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. **Do not take a double dose to make up for a forgotten dose.** Take the next dose at the correct time.

If you stop taking Raporsin

Continue taking Raporsin for as long as recommended by the doctor and you should not stop taking Raporsin or change the dosage without checking with 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.

Tell your doctor immediately and stop taking your medicine if you experience an **allergic drug reaction**. **If you get a skin rash, swelling of the face, lips, tongue, throat, difficulty breathing or swallowing. Stop taking Raporsin and contact your doctor immediately, you may need urgent medical attention or hospitalisation.**

Contact your doctor immediately if you develop a heart attack. This is a very serious but uncommon side effect.

Contact your doctor immediately if you develop hepatitis (liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of skin and eyes, and dark coloured urine) or jaundice (yellowing of the skin and whites of the eyes) or narrowing of the airways. This is a very serious but rare side effect.

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

- Respiratory tract infection
- Urinary tract infection
- Dizziness and weakness and rarely fainting
- Headache
- Drowsiness
- Imbalance when getting upright quickly
- Palpitations (greater awareness of the heart beat) or faster heart beat
- Low blood pressure
- Dizziness/spinning sensation especially when you stand up abruptly
- Bronchitis
- Cough
- Shortness of breath
- Runny or blocked nose, sneezing, facial pressure or pain
- Abdominal pain (stomach pain and discomfort)
- Indigestion and heartburn
- Dry mouth
- Nausea
- Itching
- Back pain
- Muscle pain
- Inflammation of the urinary bladder (cystitis)
- Involuntary leakage of urine
- Chest pain
- Weakness and loss of strength
- Water retention in legs
- Influenza-like symptoms

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

- Loss of appetite
- Gout
- Increased appetite
- Generalised fear
- Anxiety
- Mental state characterised by extreme sadness (depression)
- Difficulty in sleeping
- Stroke (inability to move one or more limbs on one side of the body, inability to understand or formulate speech, or inability to see one side of the visual field)
- Reduced sense of touch
- Loss of consciousness
- Fainting
- Tremor

- Involuntary shakiness
- Ringing or buzzing in the ears
- Pain in the centre of the chest (angina pectoris)
- Constipation
- Nose bleed
- Wind
- Vomiting
- Diarrhoea
- Abnormal liver function tests (detected by a blood test)
- Stomach flu
- Skin rash
- Joint pain
- Blood in the urine
- Pain when passing urine
- Urinating more frequently
- Reduced sexual potency in men (impotence)
- Pain
- Swelling of the face
- Weight increase

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

- Reduction in white blood cells (may cause more infections (such as fever, severe chills, sore throat or mouth ulcers)) or platelets (may cause more bruising or bleeding) in the blood
- Excitement or restlessness (agitation)
- Nervousness
- Numbness
- Posture-related dizziness
- Blurred vision
- Slower heart beat
- Irregular heart beat
- Narrowing of the airways e.g. asthma (may cause difficulty breathing, wheezing or coughing)
- Failure in the flow of bile
- Sudden blush
- Hair loss, baldness (alopecia)
- Itchy skin rash
- Red or purple discolouring to the skin (purpura)
- Muscle cramps
- Muscle weakness
- Tingling or pins and needles
- Frequent urination at night
- Producing more urine than normal
- Problems passing urine
- Persistent painful erections of the penis, seek urgent medical advice
- Enlarged breasts in men
- Tiredness
- Feeling of general discomfort and illness (malaise)

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

- Intraoperative floppy iris syndrome (IFIS) which can develop during operation for cataract.
- Taste disturbances
- Retrograde ejaculation - occurs when semen is redirected to the urinary bladder instead of as normally being ejaculated via the urethra.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Raporsin

This medicinal product does not require any special storage conditions.
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.

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 Raporsin contains

- The active substance is doxazosin (each tablet contains doxazosin mesilate 4.85 mg corresponding to 4 mg doxazosin).
- The other ingredients are: polyethylene oxide I, microcrystalline cellulose, povidone K 29-32, butylhydroxytoluene (E321), all-rac-alpha-tocopherol, colloidal anhydrous silica, sodium stearyl fumarate, methacrylic acid –ethyl acrylate copolymer, macrogol 1300-1600 and titanium dioxide (E171).

What Raporsin looks like and contents of the pack

Raporsin prolonged-release tablets are white, round biconvex tablets with embossing “DL”.

The packs contain 10, 28, 30, 50, 90, 98 or 100 prolonged-release tablets.
Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf, Reykjavikurvegi 76-78, 220 Hafnarfjordur, Iceland

Manufacturer

Actavis UK Ltd, Whiddon Valley, Barnstaple, N Devon EX32 8NS, UK
Actavis Group PTC ehf, Reykjavikurvegur 76-78, 220 Hafnarfjordur, Iceland

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

Austria	Doxazosin Actavis 4 mg Tabletten
Bulgaria	Hyxazin
Denmark	Cardosin retard
Estonia	Doxazosin Actavis
Iceland	Cardosin Retard
Ireland	Raporsin 4mg Prolonged-release Tablets
Latvia	Doxazosin Actavis
Lithuania	Doxazosin Actavis 4 mg pailginto atpalaidavimo tabletės
Netherlands	Doxazosine Aurobindo Retard 4 mg tabletten met verlengde afgifte
Poland	Doxar XL
Portugal	Doxazosina RitiscaSlovenia Cardosin Retard 4 mg tablete s podaljšanim sproščanjem
Spain	Doxazosina Neo Aurovitas Spain 4 mg comprimidos de liberacion prolongada EFG

Sweden Doxazosin Actavis United
United Kingdom Raporsin XL 4 mg Prolonged-release Tablets

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