Package leaflet: Information for the user

Raporsin 8 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

Your doctor may have prescribed Raporsin because you have high blood pressure, which can increase your risk of heart disease or stroke if it is not treated. The active substance in the tablets, doxazosin, belongs to a group of medicines known as alpha-1 antagonists. These medicines work 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.

You may also have been given Raporsin to treat the symptoms of benign prostate enlargement (benign prostatic hyperplasia, BPH). This condition means that the prostate, which is directly underneath the bladder in men, is enlarged. This makes it more difficult to empty your bladder. Raporsin works by relaxing muscles around the bladder exit and the prostate gland, making it easier to empty your bladder.

Doxazosin, which is in Raporsin prolonged-release tablets, may also be approved to treat other diseases that are not listed in this leaflet. Ask your doctor, pharmacist or another healthcare professional if you have any further questions and always follow their instructions.

2. What you need to know before you take Raporsin

Do not take Raporsin
- if you are allergic to doxazosin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other medicines in the same class of doxazosin, such as prazosin and terazosin.
- if you have low blood pressure or if you have ever had a fall in blood pressure causing dizziness or fainting when standing up from a sitting or lying position.
- if you have benign prostate enlargement and at the same time an obstruction of the upper urinary tract, chronic urinary tract infection or bladder stones.

- if you have or have had an obstruction of your digestive tract.
- if you are taking this medicine to treat hypertension and you are breast-feeding.
- if you are taking this medicine to treat the symptoms of Benign Prostatic Hyperplasia (BPH) and have low blood pressure.
- if you have overflow incontinence or no production of urine with or without an increasing deterioration of kidney function.

Warnings and precautions
Talk to your doctor or pharmacist before taking Raporsin:
- at the start of treatment. You may experience a fall in blood pressure accompanied by dizziness, weakness and in rare cases fainting fits. Avoid any situations that could lead to injuries if these symptoms occur.
- if you suffer from any acute heart disease such as heart failure.
- if you have any liver disease. In cases of severe liver disease, use of Raporsin is not recommended.
- if you are also taking medicines that are used to treat erection problems (PDE-5 inhibitors, e.g. sildenafil, tadalafil, vardenafil), as this can result in a significant drop in blood pressure. This is likely to occur soon after you take the PDE-5 inhibitor. This means that you should be stable in your treatment with doxazosin before starting treatment with PDE-5 inhibitors. Your doctor may consider using a lower start dose of the PDE-5 inhibitor.
- if you are to undergo eye surgery because of a cataract (cloudiness of the lens), inform your eye specialist before the operation that you are taking or have previously taken Raporsin. This is because Raporsin may cause complications during the surgery, which can be managed if your specialist has been informed.

You may occasionally notice in your stool something that looks like a tablet. This is normal. The active substance in the prolonged-release tablets is contained in a non-absorbable shell that has been specially designed to slowly release the substance in the body. When this process is completed, the empty shell is removed from the body with the stool.

Ask your doctor or pharmacist if you are uncertain.

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

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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor in particular if you are taking any of the following:
- Other alpha-blockers and other medicines used in the treatment of high blood pressure.
- Non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ibuprofen

Pregnancy, breast-feeding and fertility
Only for the hypertension indication:

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. Experience of use of doxazosin during pregnancy is limited.

Do not take Raporsin if you are breast-feeding.
Alternatively, you should stop breast-feeding when treatment with doxazosin is necessary.

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

There are no records of any effects caused by doxazosin in male human reproduction.

Driving and using machines
Raporsin may cause drowsiness. Be particularly careful when you take your first dose, if your dose is increased or if you start to take this medicine again after a break in medication. If you feel dizzy or light-headed, you must not drive a car or operate machinery.

It is your own responsibility to assess whether you are in a condition to drive a vehicle or carry out work that requires heightened vigilance. One of the factors that can affect your ability in this respect is the use of medicines, due to their effects and/or side effects. The description of these effects and side effects is set out in other sections. Therefore read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are not sure.

3. How to tale Raporsin

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

Method of administration
Raporsin has been produced in a special way, which causes the active substance to be slowly released throughout the day. Choose a time in the day that is convenient for you and always take your tablets at this time. The tablets must be swallowed whole with a sufficient amount of liquid. Do not chew, divide or crush the tablets.

To treat high blood pressure and the symptoms of benign prostatic hyperplasia:

Adults (including the elderly)
The usual dose of doxazosin is 4 mg doxazosin daily although your doctor may increase your dose to the maximum of 8 mg doxazosin (one tablet) each day.

The maximum recommended dose is 8 mg doxazosin once daily. It may take up to four weeks to achieve an optimal effect.

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

If you take more Raporsin than you should
If you take too many tablets or if, for example, a child has taken the medicine by mistake, contact your doctor, or hospital emergency department immediately. If you have taken too many tablets, light-headedness or dizziness may occur due to a fall in blood pressure. Lie down on your back with your feet higher than your head.

If you forget to take Raporsin

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 Raporsin
Continue to take 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.

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 (may affect up to 1 in 100 people).
- Chest pain (angina pectoris; may affect up to 1 in 100 people), increased or irregular heart beat (may affect up to 1 in 10,000 people), heart attack or stroke (may affect up to 1 to 100 people)
- Yellowing of the skin or whites of the eyes (jaundice), caused by liver problems (may affect up to 1 in 10,000 people)

Common side effects (may affect up to1 in 10 people):

- palpitation (strong heart beat), increased heart beat
- light-headedness, headache, sleepiness
- a feeling of dizziness or 'spinning'
- inflammation of the airways (bronchitis), cough, shortness of breath (dyspnoea), rhinitis (itchy, running and congested nose)
- abdominal discomfort, stomach discomfort (dyspepsia), dry mouth, nausea
- inflammation of the bladder (cystitis), uncontrolled urination
- itching skin
- back pain, muscle pain
- lung infection (respiratory tract infection), infection of the kidneys or bladder (urinary tract infection)
- low blood pressure, a sudden drop in blood pressure when standing up
- weakness, flu-like symptoms, swelling particularly of the feet and lower limbs (oedema)

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

- weight increase
- reduced sensation, fainting, tremor
- tinnitus (ringing in the ears)
- nose bleeds
- constipation, diarrhoea, wind, vomiting, inflammation of stomach and gut
- painful urination, blood in the urine, increased frequency of urination
- skin rash
- joint pain and stiffness (arthralgia)
- increased or decreased appetite, gout (painful form of arthritis)
- pain, swelling particularly of the face (facial oedema)
- increased levels of liver enzymes
- inability to obtain an erection

- anxiety, depression, insomnia

Very rare side effects (may affect up to 1 in 10,000 people):
- decreased heart beat
- decrease in the levels of certain blood cells (leucopoenia, thrombocytopenia)
- dizziness when standing up, tingling sensation with numbness
- blurred vision
- narrowing of the airways with difficulty breathing or wheezing (bronchospasm)
- urination problems, increased need for urination at night, increased urine production and volume
- hair loss, unusual bleeding or bruising under the skin, rash
- muscle cramps, muscle weakness
- flushing
- fatigue, generally feeling unwell
- blocked bile excretion from the liver (cholestasis), inflammation of the liver (hepatitis)
- enlargement of male breast
- persistent painful erection of the penis. Seek urgent medical advice
- agitation, nervousness

Not known (frequency cannot be estimated from the available data):
- complications ('Intraoperative Floppy Iris Syndrome') during cataract surgery (see section 2 "Warnings and precautions")
- retrograde ejaculation – occurs when semen is redirected to the urinary bladder instead of as normally 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

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 label and blister 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 Raporsin contains
The active substance is doxazosin (as mesilate). Each prolonged-release tablet contains 8 mg doxazosin (as mesilate).

The other ingredients are:

Tablet core: polyethylene oxide (MW 900,000), polyethylene oxide (MW 200,000), microcrystalline cellulose, povidone (K29-32), butylhydroxytoluene (E321), all-rac-α-tocopherol, colloidal anhydrous silica, sodium stearyl fumarate.

Tablet coating: Methacrylic acid - ethyl acrylate copolymer (1:1), dispersion 30 %, colloidal anhydrous silica, macrogol 1300-1600, titanium dioxide (E171).

What Raporsin look*s* like and contents of the pack
The tablets are white, round, biconvex and embossed with 'DH' on one side.

The medicine is packaged in:
- PVC/PVDC/aluminium blister packs of 7, 10, 14, 15, 28, 30, 50, 56, 60, 98, 100 tablets
- Calendar packs: 7, 14, 28, 56 and 98 tablets
- Single-dose packs: 50 x 1 tablet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer
Acino AG,
Leopoldstraße 115,
80804 München,
Germany

This leaflet was last revised in May 2022.