

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

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1. What Raporsin is and what it is used for

Your doctor may have prescribed Raporsin because you have high blood pressure (hypertension), 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-blockers. These medicines work by relaxing 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, other types of quinazolines (such as prazosin or terazosin), or any of the other ingredients of this medicine (listed in section 6). This may have been itching, reddening of the skin or difficulty in breathing.
- if you are allergic to other medicines in the same class of doxazosin, such as prazosin and terazosin.

- 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 a sitting or lying position.
- if you have an enlarged prostate gland with one of the following: any kind of congestion or blockage in your urinary tract, a longstanding infection of the urinary tract or you have bladder stones.
- if you have enlarged prostate gland and have overflow incontinence (you do not feel the urge to urinate), or unuria (your body is not producing any urine) with or without kidney problems.
- 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 are under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Raporsin as it may not be suitable for you:

- if you pregnant or trying to become pregnant
- 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 and avoid situations where you might fall or hurt yourself.
- if you suffer from any acute heart disease such as heart failure.
- If you have any liver or kidney 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. Persistent painful erections may occur very rarely. If this happens you should contact your doctor immediately.
- if you are to undergo eye surgery because of a cataract (cloudiness of the lens), please 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.

Before starting treatment with Raporsin your doctor may perform tests to rule out other conditions such as prostate cancer that may cause the same symptoms as benign prostatic hyperplasia.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. There are some medicines that may interact with Raporsin. Ask your doctor or pharmacist before use if you are taking any of these medicines as they may change the effect of 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 medicines called PDE-5 inhibitors for the treatment of erectile dysfunction (impotence) with alpha blockers e.g. sildenafil, tadalafil or vardenafil (please see Section “Warnings and precautions”.

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.

- Raporsin may also increase the effects of drugs used to treat high blood pressure (hypertension)
- Medicines to treat bacterial or fungal infections e.g. clarithromycin, itraconazole, ketoconazole, telithromycin, voriconazole.
- Medicines used in the treatment of HIV e.g. indinavir, nelfinavir, ritonavir, saquinavir.
- Nefazodone, a medicine used to treat depression
- Non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ibuprofen

Pregnancy, breast-feeding and fertility

Only for the hypertension indication:

Pregnancy

The safety of Raporsin during pregnancy has not been established. If you are pregnant, 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.

Breast-feeding

Small amounts of doxazosin, the active substance of Raporsin, can get into your breast milk. You should not use Raporsin during breast-feeding unless your doctor advises you to do so.

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.

Information on sodium content

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

3. How to take Raporsin

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

Raporsin 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.

How to take your medicine

The usual dose of Raporsin is one 4 mg prolonged-release tablet taken once a day. Your doctor may wish to increase your dose to 8 mg. This is the maximum dose of this medicine.

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.

- Raporsin can be taken with or without food.
- The tablets must be swallowed whole with a sufficient amount of liquid. Do not chew, divide or crush the tablets.
- Take your tablets as your doctor told you
- It is important to keep taking your tablets. They help to control your blood pressure.
- Don't change the dose or stop taking the tablets without first checking with your doctor.
- Don't wait until your tablets are finished before seeing your doctor.
- If you are still not sure how to take your tablets, ask your doctor or pharmacist.

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.

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, call an ambulance or go to the casualty department at your nearest hospital:

- Allergic reactions (hypersensitivity) such as wheezing, tightness in the chest, shortness of breath, difficulty breathing, extreme dizziness or collapse, swelling of the face or throat, or a serious skin rash with red spots or blisters, itching (may affect up to 1 in 100 people).
- Chest pain (angina pectoris; may affect up to 1 in 100 people), increased, decreased or irregular heart beat (may affect up to 1 in 10,000 people), heart attack or stroke (weakness of arms, legs or problems speaking), (may affect up to 1 in 100 people)
- Fainting

- Yellowing of the skin or whites of the eyes (jaundice), caused by liver problems (may affect up to 1 in 10,000 people)
- Low numbers of white blood cells or blood platelets, which may result in bruising or easy bleeding.

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

- palpitation (strong heart beat), increased heart beat
- light-headedness, headache, sleepiness
- a feeling of dizziness or 'spinning' or rotating of surroundings (vertigo)
- inflammation of the airways (bronchitis), coughing, shortness of breath (dyspnoea), rhinitis (itchy, running and congested nose), respiratory tract (nose, throat, lungs) infection
- abdominal/stomach discomfort or pain, feeling/being sick, indigestion, dry mouth, nausea
- inflammation of the bladder (cystitis)
- itching skin
- back pain, muscle pain
- lung infection (respiratory tract infection)
- infection of the kidneys or bladder (urinary tract infection), urinary incontinence (inability to control passing urine), inflammation of the bladder (cystitis)
- low blood pressure, a sudden drop in blood pressure when standing up
- general weakness, sleepiness, flu-like symptoms
- swelling particularly of the fingers, feet and lower limbs (oedema)

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

- weight increase
- reduced or altered sense of touch or sensation of the hands and feet, tremor
- tinnitus (ringing in the ears)
- nose bleeds
- constipation, wind, inflammation of stomach and gut (gastroenteritis) which can cause diarrhoea and vomiting
- painful urination, blood in the urine, increased frequency of urination
- skin rash
- joint pain and stiffness (arthralgia)
- increased or decreased appetite
- gout (inflammation of the joints), general pain
- pain, swelling particularly of the face (facial oedema)
- increased levels of liver enzymes which may have an effect on some medical tests
- failure/inability to obtain an erection
- anxiety, depression, sleeplessness
- stroke

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

- Blockage of the digestive tract

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

- faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position
- decreased heart beat
- decrease in the levels of certain blood cells (leucopenia, thrombocytopenia)
- tingling sensation with numbness of the hands and feet
- 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
- hives, hair loss, red or purple patches on the skin, unusual bleeding or bruising under the skin, rash
- muscle cramps, muscle weakness
- hot flushes
- tiredness (fatigue), generally feeling unwell
- blocked bile excretion from the liver (cholestasis), inflammation of the liver (hepatitis)
- discomfort or 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 (cloudiness of the lens of the eye). 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. Little or no semen ejaculated at sexual climax, cloudy urine following sexual climax.

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 HPRRA 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 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 hydrated silica, macrogol 1300-1600, titanium dioxide (E171).

What Raporsin looks 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**

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