

Raporsin® XL 4mg Prolonged-release Tablets

(doxazosin mesilate)

Your medicine is known by the above name but will be referred to as Raporsin XL through this

Patient Information Leaflet

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.
- The full name of this product is Raporsin XL 4mg Prolonged-release Tablets but within this leaflet it will be referred to as Raporsin XL.

What is in this leaflet

- 1) What Raporsin XL is and what it is used for
- 2) What you need to know before you take Raporsin XL
- 3) How to take Raporsin XL
- 4) Possible side effects
- 5) How to store Raporsin XL
- 6) Contents of the pack and other information

1) What Raporsin XL is and what it is used for

Raporsin XL 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 XL 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 XL is taken to treat poor and/or frequent passing of urine. This is common in patients with an enlarged prostate gland. Raporsin XL 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 XL

Do not take Raporsin XL if you:

- are **allergic** to doxazosin, other types of quinazolines (e.g. prazosin or terazosin) or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash (reddening of the skin), itching, difficulty breathing or swelling of the face, lips, throat or tongue
- are suffering from **benign hyperplasia** (an enlarged prostate gland) and bladder with any of the following: any kind of congestion or blockage in your urinary tract, a long standing infection of the urinary tract or you have bladder stones.
- 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.
- have any form of **obstruction of the digestive tract**
- 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.
- are **breast-feeding**.
- are under 18 years of age.

Warnings and precautions

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

- If you have had a **surgical procedure**
- If you are pregnant or trying to become pregnant
- If you are also taking other medicines
- 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. 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 or kidney problems**
- Persistent painful erections may occur very rarely. If this happens, you should contact a doctor immediately
- 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 the interval required between taking these medicines with doxazosin.
- If you are undergoing eye surgery for **cataracts** (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Raporsin XL. This is because Raporsin XL 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 XL.

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

Children and adolescents

Raporsin XL 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 XL

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 XL. Ask your doctor or pharmacist before use if you are taking any of these medicines as they may change the effect of Raporsin XL.

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. Some patients have experienced these symptoms when taking PDE-5 inhibitors for the treatment of erectile dysfunction (impotence) with alpha-blockers e.g. sildenafil, tadalafil or vardenafil (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 XL may also increase the effects of drugs used to treat high blood pressure (hypertension)
- Anti-inflammatory medicines of the NSAID types (Non Steroidal Anti Inflammatory Drugs) – as they can reduce the effects of Raporsin XL
- 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.
- 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.

Pregnancy, breast-feeding and fertility

Pregnancy

The safety of using Raporsin XL 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. They will decide if this medicine is suitable for you.

Breast-feeding

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

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. They may cause drowsiness and could also make you feel weak or dizzy. If affected, do not drive or operate machinery and contact your doctor immediately.

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 XL

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

Raporsin XL 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.

The usual dose of Raporsin XL 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.

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 XL 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 4mg doxazosin (1 prolonged-release tablet) once a day. If needed, the dosage may be increased to 8mg 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 4mg doxazosin (1 prolonged-release tablet) once a day. If needed, the dosage may be increased to 8mg doxazosin (2 prolonged-release tablets) once a day.
- **Patients with loss of liver function:**
A reduction of the dose may be needed. Always follow your doctor’s recommendations.

If you take more Raporsin XL 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 heartbeat or feeling or being sick.

If you forget to take Raporsin XL

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 XL

Continue taking Raporsin XL for as long as recommended by the doctor and you should not stop taking the Raporsin XL or change the dosage without checking with your doctor. It is important to keep taking your tablets as they help to control your blood pressure.

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 Raporsin XL and call an ambulance immediately if you experience any of the following

- heart attack
- increased, decreased or irregular heartbeat
- weakness of arms, legs or problems speaking which may be symptoms of a stroke
- allergic reactions (hypersensitivity). Symptoms include sudden wheeziness, tightness in chest, difficulty in breathing, swelling of the face, tongue or throat, rash or itching (especially affecting the whole body).

Tell your doctor **immediately** if you experience any of the following symptoms after taking Raporsin XL:

- chest pain (angina), wheezing, shortness of breath, difficulty breathing
- feeling your heartbeat (palpitations)
- fainting

- yellowing of the skin or the eyes (jaundice)
- low number of blood cells or blood platelets, which may result in bruising or easy bleeding.

The following events have been reported in patients being treated with Raporsin XL. If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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

- Respiratory tract infection
- Urinary tract infection, urinary incontinence (inability to control passing urine), inflammation of the bladder (cystitis)
- General weakness and rarely fainting
- Headache
- Drowsiness, sleepiness
- Imbalance when getting upright quickly
- Low blood pressure
- Dizziness, feeling of spinning or rotation of surroundings (vertigo), especially when you stand up abruptly
- Bronchitis (coughing, respiratory tract (nose, throat, lungs) infection)
- Nasal stuffiness, sneezing and/or runny or blocked nose caused by inflammation of the lining of the nose (rhinitis), facial pressure or pain
- Abdominal pain (stomach pain and discomfort), feeling/being sick (nausea)
- Indigestion and heartburn
- Dry mouth
- Itching
- Back pain
- Muscle pain
- Involuntary leakage of urine
- Weakness and loss of strength
- Swelling of the feet, ankles or fingers
- Influenza-like symptoms.

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

- Increased appetite or loss of appetite, weight gain
- Inflammation of the joints (gout), painful joints, general pain
- Sleeplessness, anxiety generalised fear
- Mental state characterised by extreme sadness (depression)
- Reduced or altered sense of touch or sensation of the hands and feet
- Loss of consciousness
- Involuntary shakiness
- Ringing or buzzing in the ears, tremor
- Pain in the centre of the chest (angina pectoris)
- Constipation, wind, inflammation of the stomach and intestines (gastroenteritis) which can cause diarrhoea and vomiting
- Nosebleeds
- Liver enzyme increases which may have an effect on some medical tests
- Stomach flu
- Skin rash
- Pain or discomfort on passing urine, increased frequency in passing urine, blood in urine
- Failure/inability to achieve penile erection.

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

- Blockage of the digestive tract.

Very rare (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
- Excitement or restlessness (agitation)
- Nervousness
- Posture-related dizziness
- Blurred vision
- Slower heartbeat
- Narrowing of the airways e.g. asthma (may cause difficulty breathing, wheezing, or coughing)
- Hepatitis (liver inflammation) or bile disorder
- Hot flushes
- Hives, hair loss, red or purple patches on the skin (purpura), bleeding under the skin, baldness (alopecia)
- Itchy skin rash
- Muscle cramps, muscle weakness
- Tingling, pins and needles or numbness of the hands and feet
- Disorder in passing urine, needing to pass urine at night, increased number of times of passing urine, increased volume of urine passed.
- Persistent painful erections of the penis, seek urgent medical advice
- Discomfort or enlargement of 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 cataracts. Eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye). See section "Warnings and precautions"
- Taste disturbances
- Retrograde ejaculation - occurs when semen is redirected to the urinary bladder instead of normally being 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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Raporsin XL

- **Keep 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 label. The expiry date refers to the last day of the month.
- This medicinal product 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 XL contains:

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

The other ingredients are: polyethylene oxide, microcrystalline cellulose, povidone K 29-32, butylhydroxytoluene (E321), all-rac-alpha-tocopherol,

colloidal anhydrous silica, sodium stearyl fumarate, methacrylic acid-ethyl acrylate copolymer, colloidal hydrated silica, macrogol 1300-1600 and titanium dioxide (E171).

What Raporsin XL looks like and contents of the pack

Raporsin XL 4 mg Prolonged-release Tablets are white, round, biconvex tablets marked with "DL" on one side.

They are available in blister packs containing 30 tablets.

PL 46420/0308 Raporsin XL 4mg Prolonged-release Tablets

POM

Who makes and repackages your medicine?

Your medicine is manufactured by Actavis UK Ltd., Whiddon Valley, Barnstaple, N Devon, EX32 8NS, UK or Actavis Nordic A/S, Ørnegårdsvej 16, DK-2820 Gentofte, Denmark or Actavis Group PTC ehf., Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland or Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN, Baarn, The Netherlands or Generis Farmacêutica, S.A., Rua João de Deus, 19, 2700-487 Amadora, Portugal. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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