

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Alfuzosin hydrochloride Rowex 10 mg Prolonged-Release Tablets**

Alfuzosin hydrochloride

**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. 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 Alfuzosin hydrochloride Rowex is and what it is used for
2. What you need to know before you take Alfuzosin hydrochloride Rowex
3. How to take Alfuzosin hydrochloride Rowex
4. Possible side effects
5. How to store Alfuzosin hydrochloride Rowex
6. Contents of the pack and other information

#### **1. What Alfuzosin hydrochloride Rowex is and what it is used for**

Alfuzosin hydrochloride Rowex belongs to a group of medicines called alpha-adrenoreceptor antagonists or alpha-blockers.

It is used to treat moderate to severe symptoms caused by an enlarged prostate gland, a condition that is also called benign prostatic hyperplasia. Enlarged prostate glands can cause urinary problems such as frequent and difficult urination, especially at night. Alpha-blockers relax the muscles in the prostate and bladder neck. This allows urine to flow out of the bladder more easily.

#### **2. What you need to know before you take Alfuzosin hydrochloride Rowex**

##### **Do not take Alfuzosin hydrochloride Rowex**

- if you are allergic to alfuzosin, other quinazolines (e.g. terazosin, doxazosin, prazosin) or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from conditions that cause a marked drop in blood pressure when standing up.
- if you have liver problems.
- if you take other medicines that belong to the group of alpha-blockers.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Alfuzosin hydrochloride Rowex.

- if you have severe kidney problems, since the safety of Alfuzosin hydrochloride Rowex has not been established in these patients.
- if you take medicines to treat high blood pressure. In this case your doctor will check your blood pressure regularly, especially at the beginning of treatment.

- if you experience a sudden drop in blood pressure when you stand up shown by dizziness, weakness or sweating within a few hours of taking Alfuzosin hydrochloride Rowex. If you experience a drop in blood pressure you should lie down with your legs and feet up in the air until the symptoms have completely disappeared. Usually, these effects last for only a short time and occur at the start of the treatment. Normally, there is no need to stop treatment.
- if you suffer from a cardiac disease.
- if you experienced a marked drop in blood pressure or a hypersensitivity (allergic) reaction in the past after taking another medicine belonging to the group of alpha-blockers. In this case your doctor will start treatment with alfuzosin at low doses and will gradually increase the dose.
- if you suffer from chest pain (angina) and are treated with a nitrate as this may increase the risk of a drop in blood pressure. Your doctor will decide whether to treat your angina with a nitrate medicine or stop treatment with Alfuzosin hydrochloride Rowex, if your angina returns or gets worse.
- 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 Alfuzosin hydrochloride Rowex. This is because Alfuzosin hydrochloride Rowex may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Swallow the tablets whole. Do not crush, powder or chew the tablets as too much of the active substance alfuzosin may reach your body too quickly. This may raise the risk of unwanted effects.

### **Children and adolescents**

Alfuzosin hydrochloride Rowex is not indicated for use in children and adolescent.

### **Other medicines and Alfuzosin hydrochloride Rowex**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Alfuzosin hydrochloride Rowex must not be taken if you take other medicines that belong to the group of alpha-blockers.

Alfuzosin hydrochloride Rowex and some medicines may interfere with each other. These include:

- medicines containing ketoconazole or itraconazole (medicines used to treat fungal infections) or ritonavir (medicine used to treat HIV).
- medicines to lower blood pressure.
- medicines (nitrates) used to treat the symptoms of chest pain (angina). Please note that taking Alfuzosin hydrochloride Rowex together with medicines used to treat high blood pressure and nitrates used e.g. to treat cardiac diseases may lead to low blood pressure.
- medicines you receive before an operation (general anaesthetics). Your blood pressure can drop markedly. If you have to undergo an operation, please tell the doctor that you are taking Alfuzosin hydrochloride Rowex.
- medicines that are known to increase the QT-interval.

### **Alfuzosin hydrochloride Rowex with food and drink**

Alfuzosin hydrochloride Rowex should be taken after a meal.

### **Pregnancy and breast-feeding**

This information is not relevant as Alfuzosin hydrochloride Rowex is only for men.

### **Driving and using machines**

At the beginning of treatment with Alfuzosin hydrochloride Rowex you may feel light-headed, dizzy or weak. Do not drive or operate machinery or perform any hazardous tasks until you know how your body responds to the treatment.

### **Alfuzosin hydrochloride Rowex contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Alfuzosin hydrochloride Rowex**

Always take Alfuzosin hydrochloride Rowex exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults, the elderly (over 65 years) and those with mild or moderate kidney problems is 1 prolonged-release tablet (10 mg alfuzosin) once daily. Take the first tablet at bedtime. Take the tablets immediately after the same meal each day and swallow them whole with a sufficient amount of fluid. Do not crush, chew or divide the tablets.

#### **If you take more Alfuzosin hydrochloride Rowex than you should**

If you take large amounts of Alfuzosin hydrochloride Rowex your blood pressure may suddenly drop and you may feel dizzy or even faint. If you begin to feel dizzy, sit or lie down until you feel better. If the symptoms do not disappear, call your doctor as the drop in blood pressure may have to be treated in hospital.

#### **If you forget to take Alfuzosin hydrochloride Rowex**

Do not take a double dose to make up for a forgotten tablet as this may cause a sudden drop in blood pressure, especially if you take blood-pressure lowering medicines. Take the next tablet as directed.

#### **If you stop taking Alfuzosin hydrochloride Rowex**

You should not interrupt or stop taking Alfuzosin hydrochloride Rowex without speaking to your doctor first. If you want to stop the treatment or have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get chest pain, **stop taking Alfuzosin hydrochloride Rowex and contact a doctor or go to a hospital immediately**. Sign of chest pain (angina) normally happens if you have had angina before. This side effect is very rare and may affect up to 1 in 10,000 people.

If you get symptoms such as red lumpy skin rash, swelling (of the face, tongue or throat), difficulty breathing or swallowing **stop taking Alfuzosin hydrochloride Rowex and contact your doctor immediately**. These are symptoms of angioedema, which is a very rare side effect that may affect up to 1 in 10,000 people.

Other side effects that can occur with Alfuzosin hydrochloride Rowex are:

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

Faintness/dizziness, headache, stomach pain, uncomfortable feeling in the stomach and indigestion (dyspepsia), feeling sick (nausea), feeling of weakness.

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

Feeling drowsy, a spinning sensation in the head (vertigo), loss of consciousness resulting from insufficient blood flow to the brain, faster heartbeat, marked drop in blood pressure when standing up (especially when starting treatment with too high a dose and when treatment is resumed), runny nose, diarrhoea, dry mouth, skin rash, itching, water retention (may cause swollen arms, ankles or legs),, reddening of the face (flushing), chest pain, vomiting.

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

If you must undergo eye surgery because of a cataract and are taking Alfuzosin hydrochloride Rowex or have taken it in the past, difficulties during surgery may occur (see “Warnings and precautions”). Very rapid uncoordinated contractions of the heart, abnormal liver function (signs may include yellowing of your skin or the whites of your eyes), persistent and painful penile erection (priapism), decrease in white blood cells. Low numbers of blood platelets. Signs may include bleeding from your gums and nose, bruising, prolonged bleeding from cuts, rash (pinpoint red spots called petechia).

### **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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Alfuzosin hydrochloride Rowex**

Do not store above 25 °C.

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 that month.

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 Alfuzosin hydrochloride Rowex contains**

The active substance is alfuzosin hydrochloride.

One prolonged-release tablet contains 10 mg alfuzosin hydrochloride.

The other ingredients are: lactose monohydrate, hypromellose (E 464), povidone K25, magnesium stearate (E 470 b).

### **What Alfuzosin hydrochloride Rowex looks like and contents of the pack**

Alfuzosin hydrochloride Rowex are white, round, bevelled-edged, uncoated tablets, approximately 10 mm in diameter.

Alfuzosin hydrochloride Rowex is available in blister packs with 10, 20, 30, 50, 60, 60x1, 90, 100 and 180 prolonged-release tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturers**

##### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

##### **Manufacturers**

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

Austria:	Alfuzosin Hexal 10 mg – Retardtabletten
Belgium:	Alfuzosine Sandoz 10 mg Tabletten met gereguleerde afgifte
Denmark:	Alfuzosin Hexal
Finland:	Alfuzosin Hydrochloride Sandoz 10 mg depottabletti
Hungary:	Alfuzosin Sandoz Uno 10 mg retard tablets
Ireland:	Alfuzosin hydrochloride Rowex 10 mg Prolonged-Release Tablets
Italy:	Alfuzosina Hexal 10 mg compresse a rilascio prolungato
Slovakia:	Alfuzosin Sandoz 10mg tablety s predĺženým uvolňovaním
Spain:	Alfuzosina Bexal 10 mg comprimidos de liberación prolongada
Sweden:	Alufosin Hexal
United Kingdom:	Dazular XL 10 mg Tablets

**This leaflet was last revised in 04/2015.**