**PACKAGE LEAFLET: INFORMATION FOR THE USER**
Alfuzosin Sandoz 5 mg, prolonged-release tablets

Alfuzosin hydrochloride

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**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.

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**What is in this leaflet:**

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

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**1. What Alfuzosin Sandoz is and what it is used for**

Alfuzosin Sandoz 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.

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**2. What you need to know before you take Alfuzosin Sandoz**

**Do not take Alfuzosin Sandoz**

- 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 severe 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 Sandoz

- 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 Sandoz. 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 have had a stroke or short-lasting symptoms similar to stroke, there is a risk of decreased blood flow to parts of the brain.
- 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 continue to treat your angina with a nitrate medicine or stop treatment with Alfuzosin Sandoz, 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 Sandoz. This is because Alfuzosin Sandoz 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 Sandoz is not indicated for use in children and adolescents.

**Other medicines and Alfuzosin Sandoz**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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

- medicines containing ketoconazole or itraconazole (medicines used to treat fungal infections) or ritonavir (medicines 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 Sandoz 5 mg 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 Sandoz.
- medicines that are known to increase the QT-interval.

**Alfuzosin Sandoz with food and drink**
Alfuzosin Sandoz could be taken with or without food.

**Pregnancy and breast-feeding**
This information is not relevant as Alfuzosin Sandoz is only for men.

**Driving and using machines**
At the beginning of treatment with Alfuzosin Sandoz 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 Sandoz 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 Sandoz**

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

The recommended dose is 1 prolonged-release tablet (5 mg alfuzosin) twice daily. Take the first tablet at bedtime. Swallow the tablets whole with a sufficient amount of fluid. Do not crush, chew or divide the tablets.

The usual dose for elderly patients (over 65 years) is 1 prolonged-release tablet (5 mg alfuzosin) once daily. Take the first tablet at bedtime. Your doctor may increase the dose to two times a day if needed.

The usual dose for patients with mild to moderate kidney problems is 1 prolonged-release tablet (5 mg alfuzosin once daily). Take the first tablet at bedtime.

**If you take more Alfuzosin Sandoz than you should**

If you take large amounts of Alfuzosin Sandoz 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 Sandoz**

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 Sandoz**

You should not interrupt or stop taking Alfuzosin Sandoz 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 Sandoz 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 Sandoz 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 Sandoz are:

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

Fainting/dizziness, headache, a spinning sensation in the head (vertigo), marked drop in blood pressure
when standing up (especially when starting treatment with too high a dose and when treatment is resumed), stomach pain, feeling sick (nausea), diarrhoea, dry mouth, feeling of weakness, malaise.

*Uncommon (may affect up to 1 in 100 people):*
Feeling drowsy, loss of consciousness resulting from insufficient blood flow to the brain, eye problems, faster heartbeat, sensation of pounding or racing heartbeat, runny nose, skin rash, itching, water retention (may cause swollen arms, ankles or legs), reddening of the face (flushing), chest pain, uncomfortable feeling in the stomach and indigestion (dyspepsia), being sick (vomiting), lack of control over passing urine.

*Not known (frequency cannot be estimated from the available data):*
If you must undergo eye surgery because of a cataract and are taking Alfuzosin Sandoz 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). Decreased blood flow to parts of the brain in patients known to have vascular disturbances in the brain.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Alfuzosin Sandoz**
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 store above 25°C.

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 Sandoz contains**
The active substance is alfuzosin hydrochloride.

One prolonged-release tablet contains 5 mg alfuzosin hydrochloride.

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

**What Alfuzosin Sandoz looks like and contents of the pack**
Alfuzosin Sandoz are white, round, bevelled-edged, uncoated tablets.
Alfuzosin Sandoz is available in blister packs with 20, 28, 30, 50, 56, 60, 60x1, 100 and 180 prolonged-release tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
[To be completed nationally]

**This medicinal product is authorised in the Member States of the EEA under the following names:**
- Austria: Alfuzosin Sandoz 5 mg – Retardtabletten
- Greece: Zoprost
- Netherlands: Alfuzosin HCl Sandoz retard 5
- Spain: Alfuzosina Sandoz 5 mg comprimidos de liberacion prolongada EFG
- Sweden: Alfuzosin Sandoz

**This leaflet was last revised in 2016-11-25**