**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Alfuzosin Sandoz 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 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.

## 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 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 have severe kidney problems, since the safety of Alfuzosin Sandoz 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 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 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 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 adolescent.

**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 (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 Sandoz 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 should be taken after a meal.

**Pregancy 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 Alfuzosin Sandoz 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 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):*
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 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).

**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

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 Sandoz 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 Sandoz looks like and contents of the pack**
Alfuzosin Sandoz are white, round, bevelled-edged, uncoated tablets approximately 10 mm in diameter.

Alfuzosin Sandoz 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 Manufacturer**
[To be completed nationally]

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

| | |
|---|---|
| Austria: | Alfuzosin Sandoz 10 mg – Retardtabletten |
| Denmark: | Alfuzosin Sandoz |
| Germany: | Alfuzosin-Sandoz 10 mg Retardtabletten |
| Greece: | Zoprost |
| Netherlands: | Alfuzosin HCl Sandoz retard 10 |
| Poland: | Alfuzosin-1A Pharma |
| Spain: | Alfuzosina Sandoz 10 mg comprimidos de liberacion prolongada EFG |
| Sweden: | Alfuzosin Sandoz |
| United Kingdom: | Dazular XL 10 mg Tablets |

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