

Package leaflet: Information for the user

Alfuzosin STADA 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 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, pharmacist or nurse. 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 Alfuzosin STADA is and what it is used for

Alfuzosin STADA 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 STADA

DO NOT take Alfuzosin STADA:

- 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). Symptoms of an allergic reaction include: a rash, swelling of your lips, throat, or tongue, difficulty in swallowing or breathing.
- 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 STADA:

- If you have severe kidney problems, since the safety of Alfuzosin STADA has not been established here.
- If you take other medicines to treat high blood pressure. In this case your doctor will check your blood pressure regularly, especially at the beginning of treatment.
- Especially at the beginning of the treatment with this medicine, blood pressure should be monitored regularly due to the possibility of a pronounced drop in blood pressure. If you experience a sudden drop in blood pressure when you stand up shown by dizziness,

weakness or sweating within a few hours after you have taken Alfuzosin STADA. 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 totally 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 experienced a marked drop in blood pressure 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 your heart is not working well (acute heart failure).
- If you suffer from chest pain (angina) and are treated with a nitrate treatment with alfuzosin may increase the risk of a drop in blood pressure. Your doctor will stop treating you with alfuzosin when the angina recurs or worsens.
- Your doctor will decide whether to continue treatment against chest pain or stop treatment with Alfuzosin STADA, especially when the chest pain recurs or worsens.
- 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 STADA. This is because Alfuzosin STADA may cause complications during the surgery which can be managed if your specialist is prepared in advance.
- If you suffer from a defect in heart rhythm or you are taking medicines which may cause a defect in heart rhythm (the medical term for this defect is QTc prolongation). In this case your doctor should evaluate you before and during the period of administration of Alfuzosin STADA.

Other medicines and Alfuzosin STADA

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

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

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

- ketoconazole and itraconazole (medicines used to treat fungal infections) and ritonavir (medicine used to treat HIV).

If you are taking or have to take any of the following medicines, treatment with Alfuzosin STADA may cause your blood pressure to fall too low:

- medicines used to treat high blood pressure.
- medicines (nitrates) used to treat the symptoms of chest pain (angina).
- 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 STADA.

Alfuzosin STADA with food and drink

Alfuzosin STADA should be taken after a meal.

Pregnancy and breast-feeding

This information is not relevant as Alfuzosin STADA is only for men.

Driving and using machines

At the beginning of treatment with Alfuzosin STADA you may feel lightheaded, 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 STADA 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 STADA

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

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.

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.

Adults:

The usual dose is 1 prolonged-release tablet (10 mg alfuzosin) once daily.

For elderly patients:

The usual dose for elderly patients (over 65 years) is 1 prolonged-release tablet (10 mg alfuzosin) once daily if a lower dose of alfuzosin is well tolerated and a stronger effect is required.

For patients with impaired kidney function:

The usual dose for patients with mild to moderate kidney problems is 1 prolonged-release tablet (10 mg alfuzosin) if a lower dose was not sufficient and depending on how you respond to the treatment.

If you take more Alfuzosin STADA than you should

If you take large amounts of Alfuzosin STADA contact your doctor or nearest hospital casualty department immediately for advice. 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 you forget to take Alfuzosin STADA

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 STADA

You should not interrupt or stop taking Alfuzosin STADA 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.

In very rare cases (may affect up to 1 in 10,000 people), a life-threatening reaction called angioedema has been reported. You should stop taking Alfuzosin STADA and see your doctor immediately if you experience any symptoms of angioedema, such as:

- Swollen face, tongue or throat
- Difficulty in swallowing
- Hives and difficulty breathing

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

Tiredness, faintness/dizziness, headache, a spinning sensation in the head (vertigo), marked drop in blood pressure when standing up (especially when starting treatment with a too high

dose and when treatment is resumed), stomach pain, feeling sick (nausea), indigestion, diarrhoea, dry mouth, general discomfort, feeling weak or ill.

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

Feeling drowsy, problems with your vision, faster heartbeat, fainting (especially at the beginning of treatment), sensation of pounding or racing heartbeat, runny nose, being sick, rash (hives, exanthema), itching, urinary incontinence, swelling of ankles and feet, reddening of the face (flushing), chest pain.

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

Chest pain (angina pectoris), new, worsening or recurrent, liver damage, swelling of skin and mucosa, especially in the face and around the mouth, persistent and painful erection (priapism).

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

Low number of white blood cells (Neutropenia), Intraoperative Floppy Iris Syndrome, IFIS (a complication that may occur during cataract surgery), abnormal heart rhythm, liver problems or liver disease (symptoms may include yellowing of the skin or whites of the eyes), 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 [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alfuzosin STADA

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use Alfuzosin STADA after the expiry date which is stated on the blister and carton.

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 STADA contains:

The active substance is alfuzosin hydrochloride. One prolonged-release tablet contains 10 mg alfuzosin hydrochloride.

The other ingredients are: lactose monohydrate, hypromellose, povidone K25, magnesium stearate.

What Alfuzosin STADA looks like and contents of the pack:

Alfuzosin STADA are white, round, bevelled-edged, uncoated tablets.

Alfuzosin STADA is available in blister packs with 10, 28, 30, 90 and 100 prolonged-release tablets.

Marketing Authorisation Holder and Manufacturer

STADA Arzneimittel AG
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61118 Bad Vilbel
Germany

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

AT: Alfuzosin STADA 10mg - Retardtabletten
CZ: Alfuzostad 10mg tablety s prodlouzenym uvolnovanim
DK: Alfuzosin STADA 10mg
ES: ALFUZOSINA STADA 10 mg comprimidos de liberación prolongada
HU: Alfuzostad 10 mg retard tablette
IT: Alfuzosina EG 10mg Compresse a rilascio prolungato
PL: Alfuzostad 10mg
SE: Alfuzosin Stada 10 mg depottablett

This leaflet was last revised in 2024-03-06