Alfuzosin Hydrochloride 2.5 mg film-coated tablets

PACKAGE LEAFLET/ INFORMATION FOR THE USER

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.

What is in this leaflet:

1 What Alfuzosin hydrochloride 2.5 mg film-coated tablets are and what they are used for

Alfuzosin belongs to a group of medicines called alpha-blockers, medicines for problems with urination in the case of prostate disorders.

Alfuzosin is indicated for treatment of functional symptoms of benign prostatic hypertrophia Problems with urination in the case of benign prostate enlargement.

2 What you need to know before you take Alfuzosin hydrochloride 2.5 mg film-coated tablets

DO NOT take Alfuzosin if you:

- are allergic to alfuzosin, other quinazolines (e.g. terazosin, doxazosin) or any of the other ingredients of this medicine (listed in section 6)
- suffer (have suffered) from dizziness, particularly when standing up from a sitting or lying position
- are also using other alpha$_1$-blockers such as doxazosin
- are also using dopamine receptor agonists such as ropinirole or pramipexole;
- have serious liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alfuzosin:

- if you have a condition which affects the coronary arteries (any treatment of a reduction in the supply of blood to the cardiac muscle should be continued); if symptoms of pain in the chest (angina pectoris) recur or become worse, the use of alfuzosin should be stopped
- if you belong to one of the following patient groups:
  - older patients
  - patients with an increased sensitivity to alpha$_1$-blockers
- patients who are treated for high blood pressure
- in some patients, a drop in blood pressure can occur on standing or sitting up within the first few hours of taking the tablet, particularly when sitting or standing up from a lying position. In this case, you should lie down until the symptoms have completely disappeared. This symptom usually occurs at the start of the treatment and is usually of a temporary nature. It is usually possible to continue with the treatment
- the risk of a pronounced drop in blood pressure is greater in older patients who have heart problems, or are being treated with medicines for high blood pressure.
- 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. This is because Alfuzosin may cause complications during the surgery which can be managed if your specialist is prepared in advance
- if you are incontinent.

Consult your doctor if one of the above warnings applies to you or has applied to you in the past.

Children and adolescents (aged 2 to 16 years)

Efficacy of alfuzosin has not been demonstrated in children aged 2 to 16 years. Therefore, alfuzosin is not indicated for use in children and adolescents (aged 2 to 16 years).

Other medicines and Alfuzosin

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

Note: the following comments can also apply to the use of medicines some time ago or in the near future.
The medicines mentioned in this section might be known to you by another name, often the tradename.
In this section, only the name of the active substance or the category of active substances of the medicine is mentioned and not the trade name! For this reason, you should always take a good look at the packaging or the package insert to see what is the active substance of the medicine you are using.

Interaction means that medicines will have a bearing on each other's effect and/or side effects when used together. Interaction can occur when these tablets are used with:

- other alpha$_1$-blockers (concomitant use - is contraindicated);
- antihypertensives (it might be necessary to adjust the dose of these because of the possibility of a drop in blood pressure);
- nitrates (anti-anginal medicines) (it might be necessary to adjust the dose of these because of the possibility of a drop in blood pressure).
- products such as ketoconazole and itraconazole which treat fungal infections, clarithromycine and erythromycine which treat bacterial infections or ritonavir which is used for HIV. These products affect the way that alfuzosin works.
- general anaesthetics. If you are to undergo an operation which requires a general anaesthetic you should tell the anaesthesist, as your blood pressure could fall too law.

Pregnancy and breast-feeding

As Alfuzosin is not used in women, this section does not apply.

Driving and using machines:

The use of Alfuzosin can sometimes result in dizziness or general weakness (see "possible side effects"). If you suffer from these side effects, do not drive any vehicle and/or operate any machinery which requires you to be alert.

Alfuzosin hydrochloride 2.5 mg film-coated tablets contains lactose

This medicine 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.

Alfuzosin hydrochloride 2.5 mg film-coated tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3 How to take Alfuzosin hydrochloride 2.5 mg film-coated tablets

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

The recommended dose is one 2.5 mg tablets three times a day. Your doctor may increase this to four times a day if needed.

In patients with poor kidney function: The usual dose is two 2.5 mg tablets daily. Take the first tablet in the evening.

In patients with liver problems: The usual dose is one 2.5 mg tablet daily. Your doctor may increase this to one 2.5 mg tablet twice a day (in the morning and evening).

Adults over 65, patients taking other medicines for high blood pressure, or patients with poor kidney function: The initial dose is one 2.5 mg tablet twice a day (morning and evening).

If you are starting the treatment, it is best if you take the first tablet before you go to bed.

If you notice that Alfuzosin has too strong or too weak an effect, consult your doctor or pharmacist.

How long will the treatment last
Your doctor or pharmacist will tell you how long you should use Alfuzosin.
Alfuzosin is prescribed for a fairly long period of time.

If you take more Alfuzosin than you should
If you (or someone else) have taken too much Alfuzosin, or you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. If you have taken too much Alfuzosin, you might suffer from low blood pressure. Lie down as much as possible, as this will help minimise the side effects.

If you forget to take Alfuzosin
If you forget to take a tablet, 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 your next dose at the usual time.

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.

You should see your doctor immediately if you experience the following symptoms:
Swollen face, tongue or throat; difficulty in swallowing; difficulty in breathing and hives (these symptoms occur in less than 1 in 10,000 persons treated).

The following side effects have been reported at the approximate frequencies shown:

Common (may affect up to 1 in 10 people):
- nausea, abdominal pain, diarrhoea and dry mouth
- weakness, dizziness (vertigo), malaise and headache
- low blood pressure (orthostatic hypotension)
- asthenia (general weakness of the body).

Uncommon (may affect up to 1 in 100 people):
- rapid heartbeat (tachycardia), palpitations and fainting episodes;
- drowsiness;
- disturbances of vision;
- blocked nose, sneezing and nasal discharge (rhinitis);
- skin rash and itching;
- incontinence
- accumulation of fluid (oedema), flushes and chest pain.

Very rare (may affect up to 1 in 10,000 people):
- people with pre-existing disease of the blood vessels of the heart may either experience heart pain (angina pectoris) for the first time or aggravate existing angina
- hives
- liver damage

Not known (frequency cannot be estimated from the available data):
- decrease in the number of white blood cells (neutropenia)
- Intraoperative Floppy Iris Syndrome (IFIS) - 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, as your pupil may dilate poorly and the iris (coloured part of the eye) may become floppy during the operation.
- abnormal heart rhythm (atrial fibrillation)
- vomiting
- problems with your liver
- persistent and painful penile erection (priapism)

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5 How to store Alfuzosin hydrochloride 2.5 mg film-coated tablets

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 cartonafter EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

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 contains:
- The active substance is alfuzosin hydrochloride. Each tablet contains 2.5 mg of alfuzosin hydrochloride
- The other ingredients are: Tablet core: lactose monohydrate, povidone, sodium starch glycolate, microcrystalline cellulose, magnesium stearate. Tablet coat: hypromellose, titanium dioxide (E171), lactose monohydrate, macrogol, glycerol triacetate.

What Alfuzosin Hydrochloride 2.5 mg film-coated tablets look like and contents of the pack:
Alfuzosin are white, round, film-coated tablets, debossed "LFN" on one side and "2.5" on the other.
The tablets are available in blister packs of 30, 50, 60, 90, 100 tablets and 50 tablets in unit-dose blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer:
Teva Pharmaceuticals Works Private Limited Company, Pallagi Ut 13, 4042 Debrecen, Hungary

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