Package leaflet:
Information for the user

Alfuzosin HCl 2.5 mg film-coated tablets

alfuzosin hydrochloride

Read all of this leaflet carefully before you start using 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 of the 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 HCl is and what it is used for
2. What you need to know before you use Alfuzosin HCl
3. How to use Alfuzosin HCl
4. Possible side effects
5. How to store Alfuzosin HCl
6. Contents of the pack and other information

1. What Alfuzosin HCl is and what it is used for

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

Use for:
- Alfuzosin HCl is indicated for treatment of functional symptoms of benign prostatic hyperplasia.
- Problems with urination in the case of benign prostate enlargement.

2. What you need to know before you use Alfuzosin HCl

Do not use Alfuzosin HCl
- If you are allergic (hypersensitive) 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 alpha1-blockers such as doxazosin and / or other dopamine receptor agonists such as ropinirole.
- have serious liver disease.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before using Alfuzosin HCl

- 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 are known to have an abnormality of electrocardiogram (ECG), called “QT prolongation”
- if you belong to one of the following patient groups:
  - elderly patients
  - patients with an increased sensitivity to alpha1-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
- 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 HCl . This is because Alfuzosin HCl may cause complications during the surgery which can be managed if your specialist is prepared in advance
- if you are incontinent (unable to hold urine).
- You are over 65. This is due to the increased risk of developing hypotension and related adverse reactions in elderly patients.
- You ever get painful erections of the penis, unrelated to sexual activity that will not go away, before or during treatment.

Other medicines and Alfuzosin HCl
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 trade name. 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 alpha1-blockers (concomitant use should be avoided)
- 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 or ritonavir which is used for HIV. These products affect the way that alfuzosin works
- medicines for bacterial infections (such as clarithromycin, telithromycin).
- medicines for treatment of depression (such as nefazodone).
- general anaesthetics. If you are to undergo an operation which requires a general anaesthetic you should tell the anaesthetist, as your blood pressure could fall too low.

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

Pregnancy and breast-feeding
As Alfuzosin HCl is not used in women, this section does not apply.

Driving and using machines
The use of Alfuzosin HCl 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 HCl contains lactose:
This medicinal product 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 HCl Aurobindo contains sodium:
This medicine contains less than 1 mmol (23 mg) of sodium per tablet, that is to say essentially ‘sodium-free.’

3. How to use Alfuzosin HCl

Always use Alfuzosin HCl exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Use in children
Alfuzosin HCl is not recommended for children.

Dosage and method of use
The recommended dose is one 2.5 mg tablet 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.

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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 HCl 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 HCl. Alfuzosin HCl is prescribed for a fairly long period of time.

If you use more Alfuzosin HCl than you should
If you (or someone else) have taken too much Alfuzosin HCl, 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 HCl, 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 use Alfuzosin HCl
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 tablet. Take your next dose at the usual time.

If you stop using Alfuzosin HCl
If you 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.

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
- 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
- hepatotoxicity

Additional side effects (Not known: frequency cannot be estimated from the available data) which may occur are:
- decrease in white blood cells (neutropenia). Signs may include more frequent infections, sore throat or mouth ulcers.
- increased risk of bleeding (including nose bleeds and/or bleeding gums) and bruising. This could be a problem called 'thrombocytopenia' which is a reduced number of platelets in the blood
- abnormal liver function (liver problem). Signs may include yellowing of your skin or the whites of your eyes.
- if you are undergoing eye surgery because of cataract (cloudiness of the lens) and are using or have previously used Alfuzosin HCl, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure. This only occurs during the operation and it is important for the eye specialist to be aware of this possibility as the operation may need to be performed differently.
- abnormal heart rhythm (Atrial fibrillation)
- abnormal, often painful, persistent erection of the penis unrelated to sexual activity (priapism).
- being sick (vomiting)

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: 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 HCl

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

Do not use Alfuzosin HCl after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of the month.

This medicine does not require any special storage conditions

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 HCl contains
- The active ingredient of Alfuzosin HCl 2.5 mg is alfuzosin hydrochloride.
- The other ingredients (excipients) are *Tablet core:* Sodium starch glycolate (Type A), cellulose microcrystalline, lactose monohydrate, povidone, magnesium stearate.
  Coating: Hypromellose, macrogol 400, titanium dioxide (E 171).

What Alfuzosin HCl looks like and contents of the pack
Film-coated tablet

White to off-white round, biconvex, film-coated tablets debossed with 'X' on one side and '31' on other side.

Alfuzosin HCl is packed in PVC / PVdC-Aluminium foil blister packs or (HDPE) bottle packs.

Pack sizes:
Blister pack: 15, 30, 50, 60, 90 and 100 film-coated tablets
Bottle pack: 100, 250 and 1000 film-coated tablets

Not all pack sizes may be marketed.

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