

PATIENT INFORMATION LEAFLET

ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS

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 symptoms 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).

In this leaflet:

1. What alfuzosin is and what it is used for
2. What you need to know before you take alfuzosin
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1. WHAT ALFUZOSIN IS AND WHAT IT IS USED FOR

What alfuzosin is

The name of your medicine is Alfuzosin Hydrochloride 2.5mg Tablets (called alfuzosin throughout this leaflet). This belongs to a group of medicines alpha-blockers.

How alfuzosin works

Alfuzosin can be used to treat the symptoms of **Benign Prostatic Hypertrophy**. This is when the prostate gland enlarges (hyperplasia), but the growth is not cancerous (it is benign). It can cause problems in passing water (urine). This happens mainly in older men.

- The prostate gland lies underneath the bladder. It surrounds the urethra. This is the tube that takes your water to the outside of the body.
- If the prostate gets bigger, it presses on the urethra making it smaller. This makes it difficult to pass water.
- Your tablets work by relaxing the prostate gland muscle. This allows the urethra to get bigger and so makes it easier to pass water.

In a few patients with benign prostatic hyperplasia, the prostate gland gets so big that it stops the flow of urine completely. This is called Acute Urinary Retention. This is very painful and you may need a short stay in hospital.

- A thin, flexible tube (catheter) is passed into the bladder. This drains the water and relieves the pain.
- During this time, alfuzosin may be used to help the water to flow again. This has only been shown to help in men aged over 65.

Alfuzosin is used to treat

- Benign Prostatic Hypertrophy

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALFUZOSIN

Do not take alfuzosin and tell your doctor if you:

- are allergic (hypersensitive) to alfuzosin or any of the other ingredients of this medicine (listed in section 6)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- are taking another alpha-blockers (see section below on 'Other medicines and Alfuzosin')
- have something called postural hypotension. This is a drop in blood pressure which usually happens when you stand up. It can make you feel dizzy, light-headed or faint when you stand or sit up quickly
- have severe liver problems

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking alfuzosin.

Take special care and check with your doctor before taking alfuzosin if:

- You have chest pain (angina)

- You have a long term infection in your urinary tract (including your kidneys, bladder and urethra), had difficulty when passing water or had small crystals (stones) forming in the water.
 - 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
 - You are allergic (hypersensitive) to other alpha blockers such as doxazosin, tamsulosin
 - You are taking medicines for high blood pressure. Your doctor should monitor your blood pressure regularly while you are taking this medicine. This is particularly important at the start of your treatment.
 - You have circulatory problems affecting the brain as there is a risk of impaired brain function due to low blood flow
 - You have heart problems, or if your heart suddenly stopped pumping efficiently (acute cardiac failure)
 - You have hereditary problems with the way your heart beats (congenital QTc prolongation)
 - 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.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking alfuzosin.

Other medicines and Alfuzosin

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because alfuzosin can affect the way some other medicines work. Also some medicines can affect the way alfuzosin works.

Do not take this medicine, and tell your doctor, if you are taking:

- Other alpha-blockers such as doxazosin, indoramin, prazosin, terazosin, tamsulosin, or phenoxybenzamine.

Tell your doctor or pharmacist if:

- In the past you have had a large fall in blood pressure while taking an alpha-blocker (this could include previous use of alfuzosin). See paragraph immediately above for examples of other alpha-blockers.

Or if you are taking:

- a medicine for high blood pressure, as you may get dizzy, weak or start sweating within a few hours of taking this medicine. If this happens, lie down until the symptoms have completely gone. Tell your doctor as he or she may decide to change the dose of your medicine.
- medicines such as glyceryl trinitrate for chest pain (angina).
- medicines for fungal infections (such as itraconazole).
- medicines for HIV (such as ritonavir).
- medicines for bacterial infections (such as clarithromycin, telithromycin).
- medicines for treatment of depression (such as nefazodone).
- ketoconazole tablets (used to treat Cushing's syndrome - when the body produces an excess of cortisol).

Operations and tests while taking alfuzosin

- If you are being treated for high blood pressure, your doctor should measure your blood pressure regularly, especially at the start of treatment.
- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking alfuzosin before the operation. Your doctor may decide to stop you having alfuzosin 24 hours before the operation. This is because it can be dangerous as it can lower your blood pressure.

Alfuzosin with food and drink

You may feel dizzy or weak whilst taking alfuzosin. If this happens do not drink any alcohol.

Driving and using machines

You may feel dizzy and weak while taking alfuzosin. If this happens do not drive or operate any tools or machines.

Important information about the ingredients of alfuzosin hydrochloride

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

Alfuzosin 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

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

Taking this medicine

- Swallow the tablets whole
- The first dose should be taken just before bedtime
- The actual dose of alfuzosin depends on your needs and the condition being treated but the usual doses are listed below

How much to take

Adults (under 65 years of age)

- The usual dose is one tablet three times a day
- Your doctor may increase this to a maximum of four tablets each day if needed

Elderly (over 65 years of age), patients with high blood pressure or patients with kidney problems

- The usual dose is one tablet in the morning and one tablet in the evening

Children

- Alfuzosin is not recommended for use in children under 16 years of age

Patients with liver problems

- The usual dose is one tablet per day
- Your doctor may increase this to one tablet in the morning and one tablet in the evening

If you take more alfuzosin than you should

Contact your local hospital Accident and Emergency department straight away. Tell the doctor or nurse how many tablets you have taken. Lie down as much as possible to help stop the side effects. Do not try to drive to the hospital yourself.

If you forget to take alfuzosin

Do not take a double dose to make up for a forgotten tablet. Miss it out and then go on as before.

If you stop taking alfuzosin

Keep taking your tablets, even if your symptoms improve. Only stop if your doctor tells you to. The symptoms are better controlled if you continue taking the same dose of this medicine.

If you have any further questions about this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, alfuzosin can cause side effects, although not everybody gets them.

Stop taking alfuzosin and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to alfuzosin. This side effect is very rare
- You have chest pain (angina). This usually only happens if you have had angina before. This side effect is very rare
- You get a painful erection of the penis, not related to sexual activity, which will not go away. This side effect has only been reported in a very small number of people taking alfuzosin.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet

Common side effects (affects less than 1 in 10 people)

- Feeling dizzy or faint
- Headache
- Feeling sick (nausea)
- Weakness or tiredness
- Diarrhoea
- Stomach pain
- General feeling of being unwell
- Feeling dizzy light-headed or faint when you stand or sit up quickly (postural hypotension)
- Dry mouth
- Being sick (vomiting)

Uncommon side effects (affects less than 1 in 100 people)

- A fast heart beat (tachycardia), pounding in the chest and uneven heartbeat (palpitations)
- Chest pain
- Drowsiness
- Rash and itching
- Hot flushes
- Problems with your vision
- Runny nose, itching, sneezing, stuffy nose and/or burning eyes. These could be symptoms of an allergy
- Water retention (may cause swollen arms or legs)
- Lack of control over passing urine
- Fainting
- Uncomfortable feeling in the stomach and indigestion
- Being sick (vomiting)

Additional side effects (frequency not known) which may occur are:

- Abnormal liver function (liver problem). Signs may include yellowing of your skin or the whites of your eyes
- Occasionally problems have arisen during cataract surgery in patients taking alfuzosin. If you are due to have eye surgery because of cataracts it is important that you tell the specialist before the operation that you are using, or have used, alfuzosin
- You may get more infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia)
- Abnormal heart rhythm
- Impaired brain function due to low blood flow in patients with existing circulatory problems affecting the brain
- 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

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

- Keep this medicine in a safe place where children cannot see or reach it.
- Store this medicine below 30°C. Store in the original packaging.
- Do not use alfuzosin after the expiry date which is stated on the carton.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Alfuzosin Hydrochloride 2.5mg Tablets contain

Each tablet contains 2.5mg of alfuzosin hydrochloride as the active substance.

The other ingredients are, microcrystalline cellulose, lactose, povidone, sodium starch glycollate, magnesium stearate, methylhydroxypropylcellulose, polyethylene glycol 400, titanium dioxide suspension (E171).

What alfuzosin looks like and contents of the pack

Alfuzosin Hydrochloride 2.5mg tablets are white film-coated tablets marked Xatral 2.5 on one side. They are supplied in blister packs of 60 tablets.

Marketing Authorisation Holder:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London EC4A 1JP, United Kingdom

Manufacturer:

Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37000 Tours, France

This leaflet was last revised in: March 2021

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