

Package leaflet: Information for the user

Alfu 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alfu is and what it is used for
2. What you need to know before you take Alfu
3. How to take Alfu
4. Possible side effects
5. How to store Alfu
6. Contents of the pack and other information

1. What Alfu is and what it is used for

Alfu belongs to a group of medicines called alpha-1-blockers.

Alfu is used to treat moderate to severe symptoms of Benign Prostate Hyperplasia. This is a condition where the prostate gland enlarges (hyperplasia), but the growth in itself is not cancerous (benign). It occurs most often in older men.

The prostate gland is situated under the bladder surrounding the urethra (the tube that takes your urine to the outside of the body). With age, the prostate gland may grow and press the urethra making it smaller. This may cause problems with urination such as frequent urination and difficulty in passing urine.

Alfu works by relaxing the prostate gland muscle. This reduces the narrowing of the urethra and so makes it easier to pass urine.

In a few patients with benign prostatic hypertrophy, 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, Alfu may be used to help the water to flow again. This has only been shown to help in men aged over 65.

2. What you need to know before you take Alfu

Do not take Alfu

- if you are allergic to alfuzosin 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 are allergic (hypersensitive) to alfuzosin-equivalent substances (such as terazosin, doxazosin).
- If you have, or have had in the past, low blood pressure when standing up from a sitting or lying position (the medical term for this is orthostatic hypotension). It can make you feel dizzy, light-headed or faint when you stand or sit up quickly.
- If you are already taking another alpha-1-blocker (such as terazosin, doxazosin) or dopamine receptor agonists at the same time. See section below on 'Other medicines and Alfu. In case of doubt please ask your pharmacist or doctor.
- If you have liver problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alfu if:

- You have severe kidney problems.
- You have a heart disease.
- You have chest pain (angina).
- You are known to have an abnormality of electrocardiogram (ECG), called "QT prolongation"
- You are over 65. This is due to the increased risk of developing low blood pressure (hypotension) and related side effects in elderly patients.
- Before starting treatment with Alfu, your doctor may do some tests to rule out the presence of other diseases that may cause the same symptoms as benign prostatic hyperplasia. Before treatment and at regular intervals afterwards, a digital rectal examination may be performed and, if necessary, an analysis will be performed.
- You ever get painful erections of the penis, unrelated to sexual activity that will not go away, before or during treatment.

Other medicines and Alfu

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

This is because Alfu can affect the way some other medicines work. Some medicines can also have an effect on the way that Alfu works.

Do not take Alfu if you are taking:

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

Check with your doctor or pharmacist before taking your medicine 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.
- 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 the dose of your medicine may be changed.
- You are taking medicines for chest pain or angina (nitrates).
- You are taking medicines for fungal infections (such as ketoconazole, itraconazole).
- You are taking medicines for HIV (such as ritonavir).
- You are taking certain medicines used to treat Hepatitis C (e.g. ritonavir, ombitasvir and paritaprevir).
- You are taking medicines for bacterial infections (such as clarithromycin, telithromycin).
- You are taking medicines for treatment of depression (such as nefazodone).
- You are taking ketoconazole tablets (used to treat Cushing's syndrome - when the body produces an excess of cortisol).
- You are taking medicines to treat premature ejaculation (e.g. dapoxetine)

Operations while taking Alfu

- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking Alfu before the operation. Your doctor may decide to stop you having Alfu 24 hours before the operation. This is because it can be dangerous as it can lower your blood pressure.
- 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 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 Alfu. This is because Alfu may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Alfu with food, drink and alcohol

- Take Alfu after a meal.
- You may feel dizzy and weak while taking Alfu. If this happens, do not drink any alcohol.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

You may feel dizzy and weak while taking Alfu. Adverse reactions such as significant drop in blood pressure when standing up, along with dizziness, vertigo, visual disturbances and asthenia may occur essentially at the beginning of treatment. If this happens, do not drive or operate any tools or machines.

3. How to take Alfu

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

- Swallow your tablets whole with plenty a fluid (for instance a glass of water).
- Do not break, crush or chew your tablets. This can affect the release of your medicine into the body
- Take this medicine after a meal
- The first dose should be taken at bedtime.

Benign Prostatic Hypertrophy

The usual dose is one Alfu once a day (after a meal).

Acute Urinary Retention

- Alfu will be given to you by your doctor on the day you have the catheter inserted.
- You should continue taking Alfu once a day.
- You should stop taking Alfu the day after the catheter is removed (3-4 days in total).

Use in children and adolescents

Children

Alfu is not recommended for children and adolescents.

Older patients (> 65 years):

The usual dose is one Alfu 10 mg prolonged release tablet once a day. The dose does not need to be adjusted for elderly (over 65 years).

Patients with mild to moderate kidney problems

Your dose does not need to be adjusted for mild to moderate kidney problems.

If you take more Alfu than you should

Contact your doctor or your local hospital Accident and Emergency department straight away. Tell the doctor 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 Alfu

Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet as directed.

If you stop taking Alfu

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 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.

These side effects are most likely to happen at the start of treatment.

Chest pain (angina) (new onset, aggravation or recurrence)

Normally, this only happens if you have had angina before. **If you get chest pain stop taking your tablets and contact a doctor or go to a hospital immediately.** This happens in less than 1 in 10,000 people.

Allergic reactions

You could notice symptoms of angioedema, such as a red and lumpy skin rash, swelling (on the eyelids, face, lips, mouth and tongue), difficulty breathing or swallowing.

These are symptoms of an allergic reaction. **If this happens, stop taking your tablets and contact a doctor or go to a hospital immediately.** This happens in less than 1 in 10,000 people.

Other side effects include:

Common (affects less than 1 in 10 people)

- Feeling dizzy
- Headache
- Feeling sick (nausea)
- Stomach pain
- Weakness or tiredness

Uncommon (affects less than 1 in 100 people)

- Feeling dizzy, lightheaded, or faint when you stand or sit up quickly (postural hypotension).
- Fast heart beat (tachycardia) and pounding in the chest and uneven heartbeat (palpitations).
- Drowsiness
- Runny nose, itching, sneezing, and stuffy nose.
- Diarrhoea
- Dry mouth
- Rashes and itching
- Urinary incontinence
- Water retention (may cause swollen arms or legs)
- Chest pain
- Hot flushes

- General feeling of being unwell.
- Problems with your vision.

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

- Hepatotoxicity
- Itchy, lumpy rash also called hives or nettle rash (urticaria).

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

If you are having an operation on your eyes because of cataracts (where the lens of the eye is cloudy), the pupil may dilate poorly and the iris (the coloured part of the eye) may become floppy during the procedure.

- Irregular and fast heart beat (atrial fibrillation).
- 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 blood 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 Alfu, 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 (see section “**Operations while taking Alfu**”).
- Abnormal, often painful, persistent erection of the penis unrelated to sexual activity (priapism).
- Being sick (vomiting).
- Stroke (not enough blood flow to the brain). This is more likely in patients who have had previous problems with blood flow to the brain.;

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 HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alfu

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label, carton, bottle after EXP. 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 Alfu contains

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

- The other ingredients

Tablet Core: Hypromellose (E464), hydrogenated vegetable oil, povidone (K-30) (E1201), calcium hydrogen phosphate, carbomer, silica colloidal anhydrous (E551), magnesium stearate (E572).

Film-coating: Hypromellose (E464), propylene glycol, titanium dioxide (E 171).

The tablet has a prolonged effect which means that after taking the active substance is not released immediately but gradually from the tablet and therefore acts longer.

What Alfu looks like and contents of the pack

Prolonged-release tablet

White to off-white round, biconvex, film-coated tablets debossed with 'X' on one side and '47' on other side.

Alfu tablets are available in clear PVC/PVdC Aluminium blister packs and white opaque round HDPE bottles containing silica gel.

Pack sizes:

Blister pack: 30, 50, 90 and 100 tablets

HDPE bottle pack: 30, 500 and 1000 tablets

Not all pack sizes may be marketed.

Marketing Authorization Holder

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Manufacturer

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