**Alfuzosin hydrochloride**

- **You are taking medicines for chest pain or angina (nitrates).**
- **You are taking a medicine for high blood pressure, as you may get dizzy, weak or start changing.**
- **You are taking medicines for HIV (such as ritonavir).**
- **You are taking medicines for bacterial infections (such as clarithromycin, telithromycin).**
- **You are taking medicines for treatment of depression (such as nefazodone).**

- **If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your doctor or pharmacist.**

- **Take Alfu after a meal.**

- **Driving and using machines.** You may feel dizzy and weak while taking Alfu. Adverse reactions such as dizziness and asthenia may occur especially at the beginning of treatment. If this happens do not drive or operate any tools or machines.

- **You could notice symptoms of an allergic reaction.** 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.

- **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 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**

**Alfu belongs to a group of medicines called alpha-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).

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 can 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.

**What you need to know before you take Alfu**

- **Do not take Alfu:**
  - If you are allergic to alfuzosin or the other ingredients of this medicine (listed in section 6).
  - If you have chest pain (angina).
  - If you have a heart disease.
  - If you are known to have an abnormality of electrocardiogram (ECG), called "QT prolongation".
  - If you are allergic (hypersensitive) to alfuzosin equivalent substances (such as terazosin).
  - 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 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).

- **Tell your doctor or pharmacist if you are taking:**
  - Other alpha-blockers such as doxazosin, indoramin, prazosin, terazosin, tamsulosin or phenoxybenzamine.
  - Medicines for HIV (such as ritonavir).
  - Medicines for bacterial infections (such as clarithromycin, telithromycin).

- **Check with your doctor or pharmacist before taking your medicine if:**
  - You have severe kidney problems.
  - You have a heart disease.
  - You have chest pain (angina).
  - You 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).

- **Do not take Alfu if you are taking:**
  - Other alpha-blockers such as doxazosin, indoramin, prazosin, terazosin, tamsulosin or phenoxybenzamine.
  - Medicines for HIV (such as ritonavir).
  - Medicines for bacterial infections (such as clarithromycin, telithromycin).

Warnings and precautions

- **Talk to your doctor or pharmacist before taking Alfu if:**
  - You have chest pain (angina).
  - You have a heart disease.
  - You 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).

Others medicines and Alfu

- **Tell your doctor or pharmacist if you are taking:**
  - Other medicines for HIV (such as ritonavir).

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.

- **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. Talk to your doctor as the dose of your medicine may be changed.**

- **If you are taking medicines for chest pain or angina (nitrates).**

- **If you are taking medicines for fungal infections (such as ketoconazole, itraconazole).**

- **If you are taking medicines for HIV (such as ritonavir).**

- **If you are taking medicines for bacterial infections (such as doxazosin, telithromycin).**

- **If you are taking medicines for treatment of depression (such as nefazodone).**

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. This is because it can be dangerous as it can lower your 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 Alfu may cause complications during the surgery which can be managed if your specialist is prepared in advance.**

Alfu with food and drink and alcohol

- **Take Alfu after a meal.**

- **Pregnancy, breastfeeding and fertility**
  - **Take Alfu after a meal.**

Driving and using machines

- **You may feel dizzy and weak while taking Alfu. Adverse reactions such as dizziness and asthenia may occur especially at the beginning of treatment. If this happens do not drive or operate any tools or machines.**

Use in children

Alfu is not recommended for children.

Adults:

- **The usual dose is one Alfu 10 mg prolonged release tablet once a day.**

Older patients (> 65 years):

- **The usual dose is one Alfu 10 mg prolonged release tablet once a day.**

Patients with mild to moderate kidney problems

- **First 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 induce vomiting or take charcoal.**

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.

**Possible side effects**

- **Like all medicines, this medicine can cause side effects, although not everybody gets them.**

- **Common (affects less than 1 in 10 people)**
  - Feeling dizzy
  - Headaches
  - Feeling sick (nausea)
  - Stomach pain
  - Weakness or tiredness

- **Uncommon (affects less than 1 in 100 people)**
  - Feeling dizzy, light-headed, or faint when you stand or sit up quickly.
  - Fast heart beat (hypertension)
  - Chest pain
  - Runny nose, itching, sneezing, and stuffy nose.
  - Diarhoea
  - Rashes and itching
  - Water retention (may cause swelling arms or legs)
  - Headache
  - Hot flashes.

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 flaccid during the procedure.**

- **Increase in pulse rate and heart beat.**

- **Decrease in white blood cells.**

- **Side effects not listed in this leaflet.**

**Report any side effects you get while taking Alfu 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.**

**How to store Alfu**

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

This medicinal product 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. This medicinal product does not require any special storage conditions.
**What ATXu 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 anhydrous, carbomer, silica colloidal anhydrous (E551), magnesium stearate (E572).
  - **Film-coating:** Hypromellose (E464), propylene glycol, titanium dioxide (E171).

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

**What ATXu 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.
  - Alfuzosin tablets are available in PA/Aluminium/PVC/Aluminium blister packs and white opaque round HDPE bottles containing silica gel sachets. A cotton coil is used to fill the void in the HDPE bottle.
- **Package size:**
  - Blister pack: 30, 50 and 100 tablets
  - HDPE bottle pack: 30 and 1000 tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
- **Marketing Authorisation Holder:** Milpharm Limited UK, Ares, Odyssey Business Park, West End Road, South Ruislip HA4 6QD, United Kingdom
- **Manufacturer(s):**
  - APL Swift Services (Malta) Limited, HF26, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG 3000, RN 1913, Malta
  - Milpharm Limited, Area Block, Odyssey Business Park, West End Road, Ruislip HA4 6QD, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:
- **Bulgaria:** Алфузосин Ауробиндо 10 mg таблетки судължено освобождаване
- **Cyprus:** Alfuzosin Aurobindo 10 mg δισκία παρατατέταμενης
- **Czech Republic:** Alfuzosin Aurobindo 10 mg tablety s prodloužením uvolňování
- **Germany:** Alfuzosin Aurobindo 10 mg retardtabletten
- **Croatia:** ALFUZOSIN AUROBINDO 10 mg tablete s produljenim oslobađanjem
- **Italy:** Alfuzosina Aurobindo 10 mg compresse a rilascio prolungato
- **Ireland:** Alfu 10 mg Prolonged-release tablets
- **The Netherlands:** Alfuzosine HCl Aurobindo 10 mg, tabletten met verlengde afgifte
- **Romania:** Alfuzosina Aurobindo 10 mg comprimate cu eliberare prolungată
- **Spain:** ALFUZOSINA AUROBINDO 10 mg comprimidos de liberación prolongada EFG
- **The United Kingdom:** RELAPRO XL / PROSTALOC XL 10 mg prolonged-release tablets

This leaflet was last revised in March 2014