PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only.

Alfu-Kal XL

Prolonged release Tablets:

Each prolonged release tablet contains:
10 mg Alfuzosin Hydrochloride.
Inactive ingredients: see section 6 in the leaflet.

Read this leaflet carefully in its entirety before using the medicine. Keep this leaflet, you may need to read it again. This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar. The medicine is intended for men. This medicine is not intended for treatment of children and adolescents under the age of 16 years. If one of the side effects worsens or if you experience a side effect not mentioned in this leaflet, please refer to the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

Alfu-Kal XL is used for the treatment of symptoms associated with benign prostatic hypertrophy and as an adjuvant treatment to catheter withdrawal in urinary retention resulting from benign prostatic hypertrophy.
Therapeutic group: Alfu-Kal XL belongs to a group of preparations called as alpha blockers and is a selective blocker of the α1 (alpha one) receptor.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- you are **sensitive** (allergic) to the active ingredient alfuzosin or to any of the other ingredients contained in the medicine (see section 6 "Further Information"). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, pharynx or tongue.
- You suffer from a sudden drop in blood pressure when you get up. It may be accompanied by dizziness or fainting (Orthostatic hypotension).
- you suffer from a liver function problem.
- you suffer from severe kidney failure (creatinine clearance below 30 ml/min)
- you are being treated with other α (alpha) blockers (such as: prazosin, trimazosin, urapidil).
- you are taking medicines for treatment of HIV (such as: protease inhibitors together with ritonavir or cobicistat or nelfinavir) or medicines for treatment of hepatitis C (such as telaprevir or boceprevir) or medicines for treatment of fungal infections (such as: ketoconazole, itraconazole, posaconazole, voriconazole) or medicines for treatment of bacterial infections (such as: clarithromycin, erythromycin, telithromycin). These medicines may increase the Alfu-Kal XL blood concentrations and cause side effects. See warnings in the next section.

Special warnings regarding use of the medicine

Before treatment with the medicine, tell the doctor if:
- you are being treated with medicines for treatment of hypertension or with nitrate derivatives.
- you are suffering from disturbed blood flow to the brain.
- you are suffering from a heart disease.
- you experienced a significant drop in blood pressure after taking another medicine from the α (alpha) blockers group.

When taking the medicine, some patients may experience a sudden drop in blood pressure when they sit down or stand up quickly. This effect may occur within a few hours of taking the medicine and may be accompanied by dizziness, sweating, a feeling of tiredness, and even fainting. The patient must lie down until the symptoms pass and refer to the doctor. It is therefore also recommended to take the first dose before going to sleep.
The risk of developing low blood pressure and related side effects may be higher in elderly patients and patients taking other medicines for treatment of hypertension or nitrate derivatives (medicines used for treatment of angina pectoris). Taking dapoxetine in combination with Alfu-Kal XL may cause dizziness and fainting.
If you suffer or have suffered from prolonged QT intervals on the ECG or if you are taking medicines that cause prolonged QT intervals on the ECG, you must be monitored before and while taking the medicine.
Children and adolescents:
This medicine is not intended for treatment of children and adolescents under the age of 16 years.

Drug interaction:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements including herbal medicines, tell the doctor or pharmacist.
- Do not take Alfu-Kal XL if you are taking other α (alpha) blockers.
- Do not take Alfu-Kal XL in combination with certain medicines for treatment of high blood pressure (medicines for reducing blood pressure such as doxazosin, prazosin or urapidil).
- Check with the doctor or pharmacist if you are taking medicines for treatment of impotence (such as sildenafil), medicines for treatment of hypertension, medicines for treatment of angina pectoris (nitrates).
  Taking nitrates for the treatment of symptoms of chest pain in combination with Alfu-Kal XL may cause a drop in blood pressure.
- Do not take Alfu-Kal XL if you are taking medicines for treatment of HIV (such as protease inhibitors in combination with ritonavir or cobicistat or nelfinavir) or medicines for treatment of hepatitis C (such as telaprevir or boceprevir) or medicines for treatment of fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole), or medicines for treatment of bacterial infections (such as clarithromycin, erythromycin, telithromycin). See section 2 "Do not use the medicine if".

Substances for general anesthetics may cause a severe drop in blood pressure.

Surgery and tests while taking Alfu-Kal XL
During treatment with Alfu-Kal XL, blood pressure must be monitored, especially at the beginning of treatment.
If you are about to undergo surgery under general anesthesia, tell the anesthesiologist that you are taking or have recently taken Alfu-Kal XL. The doctor may decide to stop Alfu-Kal XL treatment 24 hours before the surgery.
If you are about to undergo cataract eye surgery, tell the surgeon if you are taking or have taken Alfu-Kal XL, in order to prevent complications during surgery.

Use of Alfu-Kal XL with food
Alfu-Kal XL should be taken immediately after dinner.

Use of Alfu-Kal XL and alcohol consumption
You may feel dizzy or weak when taking Alfu-Kal XL; if these effects occur, do not consume alcohol.

Driving and use of machinery
Use of this medicine may cause dizziness, exhaustion and disturbed vision. If these effects occur, do not drive or operate machinery or dangerous tools.
Important information about some of the ingredients of the medicine
Each tablet contains 0.560 mg propylene glycol.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure.
The tablet should be swallowed whole with plenty of water after dinner. It is forbidden to chew, crush or halve the tablet because it may impact the absorption of the medicine in the body.
The dosage and treatment will be determined only by the doctor.

The usual dosage is:
For benign prostatic hypertrophy - one tablet, once a day.
For adjuvant treatment to catheter withdrawal in urinary retention, resulting from benign prostatic hypertrophy - one tablet, once a day. Treatment is initiated on the day the catheter is inserted and stopped the day after removal of the catheter (a total of 3-4 days).

Do not exceed the recommended dose.
If you accidentally took a higher dosage of Alfu-Kal XL or if someone has accidentally swallowed the medicine, refer immediately to a hospital emergency room and bring the package of the medicine with you. Remain in a lying position as much as possible, to stop the side effects. Do not drive to the hospital by yourself.
If you forgot to take Alfu-Kal XL at the required time, do not take a double dose to compensate for the forgotten dose. Skip this dose and take the next dose at the regular time.
Adhere to the treatment as recommended by the doctor.
If you stop taking Alfu-Kal XL:
Continue taking Alfu-Kal XL even if there has been an improvement in your health. Stop the treatment only if instructed to do so by the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine.
Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Alfu-Kal XL may cause side effects in some users. These symptoms are likely to appear at the beginning of treatment. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Chest pain (angina)- usually occurs if you have suffered from angina in the past. **If you suffer from chest pain stop treatment with Alfu-Kal XL and refer to the doctor or hospital immediately.** This effect occurs in less than 1 in 10,000 users.
Allergic reaction - you can notice signs of angioedema, such as redness or skin rash, swelling (of the eyes, face, lips, mouth and tongue), difficulty in breathing and swallowing. These are signs of an allergic reaction. If these effects occur, **stop treatment with Alfu-Kal XL and refer to the doctor or hospital immediately.** This effect occurs in less than 1 in 10,000 users.
Other side effects
Common side effects (occurs in less than 1 in 10 users): Dizziness, weakness, fainting, headaches, nausea, abdominal pain, feeling ill, a drop in blood pressure when changing position from a lying to a standing or sitting position (orthostatic hypotension).
Uncommon side effects (occurs in less than 1 in 100 users): Vertigo, drowsiness, fainting (syncope), rapid heart rate (tachycardia), palpitations, allergic rhinitis, diarrhea, dryness in the mouth, skin rash, itchiness, edema, chest pain, flushing.
Rare side effects (occurs in less than 1 in 10,000 users): Allergic skin reaction, angioedema.
Other side effects that may possibly occur (of unknown frequency): Cerebral events in patients with disturbed blood flow to the brain, atrial fibrillation, eye problems in patients who are undergoing cataract surgery (see section 2 "Surgeries and tests while taking Alfu-Kal XL"), vomiting, liver injury, cholestatic liver inflammation, prolonged erection, a decrease in the number of white blood cells and platelets.
If a side effect has occurred, if any of the side effects worsen, or when you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il
In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and all other medicines must be kept in a closed place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton and blister packages. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not discard medicines via wastewater or household waste. Ask the pharmacist how to discard medicines you no longer require. These measures will help to protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains the following inactive ingredients:
  Hypromellose, Calcium hydrogen phosphate dehydrate, Hydrogenated vegetable oil, Povidone K30, Colloidal anhydrous silica, Magnesium stearate, Propylene glycol, Titanium dioxide (E-171).
- What the medicine looks like and the contents of the package: A white, round, biconvex tablet. The package contains 30 tablets. 10 tablets in each blister.
- Registration holder and address: Perrigo Israel Agencies Ltd., 1 Rakefet st., Shoham.
- Manufacturer's name and address: Rivopharm S.A., Manno, Switzerland.
- This leaflet was checked and approved by the Ministry of Health in July 2015 and updated in accordance with the provisions of the Ministry of Health in August 2018.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14123.31829