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:
Alfuzosin Hydrochloride 10 mg.
Inactive ingredients: see section 6 in the leaflet.

Read the 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 to treat you. 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 16 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Alfu-Kal XL is used to treat 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 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 additional ingredients contained in the medicine (see section 6 "Further information").
- You suffer, or have suffered in the past, from a sudden drop in blood pressure when you get up from a sitting or lying position, possibly accompanied by dizziness or fainting (orthostatic hypotension).
- You suffer from a liver function problem.
- You are being treated with other α blockers (e.g., prazosin, trimazosin, urapidil).
- Children under the age of **16**.

Special warnings regarding use of the medicine

Before starting treatment with the medicine, tell the doctor if:

- If you show symptoms of orthostatic hypotension (a sudden drop in blood pressure when changing your position). Orthostatic hypotension may occur within the first few hours after taking the medicine. It is especially common at the beginning of treatment, and also if you are being treated in parallel for hypertension, or if you have heart disturbances. It may be associated with the following symptoms: dizziness, tiredness and sweating. If this happens, lie down until these symptoms, which are transient in nature, completely pass. Generally, you will be able to continue your treatment. Exercise caution if you have low blood pressure after taking another medicine of this type (α1 blockers).
- If you are elderly, you have a higher chance of low blood pressure.
- If you have a history of sensitivity (allergy) to another medicine from this family (α1 blockers).
- If you are elderly.
- You are being treated with medicines to lower blood pressure, nitrate derivatives or medicines for other cardiovascular diseases. Your doctor will measure your blood pressure regularly, especially at the beginning of treatment. Your doctor will decide if Alfu-Kal XL can be used in parallel.
- If you are suffering from heart failure or heart rate disturbance, consult your doctor. He will decide if Alfu-Kal XL can be used in parallel.
- Prolonged and painful erections unrelated to sexual activity (priapism) may occur very infrequently. If this happens, refer to a doctor immediately.
- If you have to undergo cataract surgery, inform the surgeon that you are taking or took Alful-Kal XL.
- If you are suffering from severe renal failure (creatinine clearance below 30 ml/minute), do not take Alfu-Kal XL.
- If you are using other medicines, read the "Drug interactions" section.

Children and adolescents

This medicine is not intended for the treatment of children and adolescents under 16 years of age.

Tests and follow-up

If you are being treated with medicines to lower blood pressure or for other cardiovascular diseases, your doctor will measure your blood pressure regularly, especially at the beginning of the treatment.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Do not take Alfu-Kal XL if you are taking other α1 blockers.

Be especially careful when combining Alfu-Kal XL with the following medicines:

- Medicines to lower blood pressure.
- Nitrate derivatives – medicines used for the treatment of angina (a feeling of tightness or even of stabbing pain, behind the chest bone) and heart disease.
- General anesthesia.
- Medicines to treat fungal infections (e.g., itraconazole).
- Medicines to treat HIV (e.g., ritonavir).
- Medicines to treat bacterial infections (e.g., clarithromycin, telithromycin).
- Medicines to treat depression (e.g., nefazodone).
- Ketoconazole tablets (used to treat Cushing's syndrome – when the body produces excess cortisol).
- Medicines for erection disturbances: some patients being treated with alpha blockers to treat high blood pressure or prostatic hyperplasia may have dizziness, which may be caused by low blood pressure when quickly transitioning from a sitting to standing position. Some patients experienced these symptoms when concomitantly using medicines for erection disturbances (impotence) and alpha blockers. To reduce the chance of such effects, the daily dose of alpha blockers should be constant before starting use of medicines for erection disturbances.
- Medicines that affect the E.C.G. (prolong the QT interval).

In order to avoid interactions with other medicines, always report any treatment to the attending doctor.

Use of Alfu-Kal XL with food

Alfu-Kal XL should be taken immediately after dinner.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult the doctor before taking this medicine.

Driving and operating machinery

Effects such as sleepiness, reduced blood pressure, dizziness and dizzy sensation, weakness, may occur at the beginning of treatment. Keep these effects in mind when driving or operating machinery.

Important information about some of the ingredients in 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 uncertain. Swallow the tablet whole, with plenty of water, after dinner. Do not chew, crush or halve the tablet, as it may affect the absorption of the drug in the body.

The dosage and treatment regimen will be determined by the doctor only.

The usual dose is generally:

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 accidentally swallowed the medicine, proceed 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 regimen 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 <u>each time</u> 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. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to the doctor immediately if you suffer from:

Chest pain (angina pectoris) – usually occurs if you have suffered from angina in the past. This effect occurs in less than 1 in 10,000 users.

Allergic reactions – symptoms of angioedema, such as red rash or lumps on the skin, swelling (of the eyelids, face, lips, mouth and tongue), difficulty breathing and swallowing. This effect occurs in less than 1 in 10,000 users.

Prolonged and painful erection unrelated to sexual activity (priapism) (unknown frequency)

The frequency of side effects is categorized as follows:

Very common: occur in more than 1 in 10 patients
Common: occur in 1 to 10 in 100 patients
Uncommon: occur in 1 to 10 in 1,000 patients
Rare: occur in 1 to 10 in 10,000 patients
Very rare: occur in less than 1 in 10,000 patients
Unknown frequency: frequency can not be estimated from the available data

Nervous system disturbances:
Common: sense of vertigo (lightheadedness), headaches, weakness, tiredness and dizziness.
Uncommon: syncope (temporary loss of consciousness), vertigo.

Cardiovascular disturbances:
Uncommon: hypotension (reduced blood pressure, for example, when rapidly getting up from a sitting or lying position), accelerated heart rate and hot flushes.
Very rare: angina pectoris (feeling of tightness, or sometimes even stabbing pain behind the chest bone, in coronary heart disease patients).
Unknown frequency: atrial fibrillation (heart rate disturbances).

Blood and lymphatic system disturbances:
Unknown frequency: neutropenia (reduced white blood cells), thrombocytopenia (reduced platelet count).

Digestive system disturbances:
Common: nausea, abdominal pains.
Uncommon: diarrhea, vomiting.

Skin disturbances:
Uncommon: skin rash, itching.
Very rare: urticaria, angioedema (swelling of the face, tongue and throat).

Liver disturbances:
Unknown frequency: liver cell damage, cholestatic liver disease (bile clearance disturbance).

Eye disturbances:
Unknown frequency: intraoperative floppy iris syndrome (IFIS).

Respiratory disturbances:
Uncommon: inflammation of the nasal mucosa (rhinitis).

General disturbances:
Common: generalized weakness (asthenia).
Uncommon: chest pains, edema (fluid accumulation).

Reproductive system and breast disturbances:
Unknown frequency: prolonged and often painful erection (priapism).

<u>The following side effects have been described for a dosage of 5 mg and may not occur with Alfu-Kal XL 10 mg</u>:

Eye disturbances:
Uncommon: abnormal vision.

Cardiovascular disturbances:
Uncommon: palpitations (intensified heart beats).

General disturbances:
Common: weakness (general state of discomfort, tiredness or malaise).

Digestive system disturbances:
Common: dry mouth.

Nervous system disturbances:
Uncommon: sleepiness.

If a side effect occurs, if one of the side effects worsens, or if 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://sideeffects.health.gov.il
In addition, you can report to the company via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe 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 package. 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 need. These measures will help to protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  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.
  Product package: The package contains 30 tablets. Each blister contains 10 tablets.
- Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer and address: Rivopharm S.A., Manno, Switzerland.

Revised in April 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14123.31829.