

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Alfuzosin ER Teva 10 mg

Prolonged-release tablets

Composition:

Each prolonged-release tablet contains:

Alfuzosin Hydrochloride 10 mg

For information regarding inactive ingredients and allergens, see section 2, subsection "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for 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 the age of 16 years.

1. WHAT IS THE MEDICINE INTENDED FOR?

Alfuzosin ER Teva 10 mg is used for the treatment of symptoms related to benign prostatic hypertrophy, particularly if there is a delay in performing the surgery, and as adjuvant treatment to a catheter, in acute urinary retention due to benign prostatic hypertrophy.

Therapeutic class: Alfuzosin ER Teva 10 mg belongs to a group of preparations called alpha blockers and is an α_1 (alpha one) selective receptor blocker.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- If you are sensitive (allergic) to alfuzosin or to any of the additional ingredients the medicine contains (see section 6).
- If you suffer or have suffered in the past from orthostatic hypotension (sudden decrease in blood pressure that occurs when you stand up suddenly from sitting or lying down).
- In combination with other α_1 blockers. See below under "Drug interactions".
- If you suffer from a problem in liver function.
- If you are taking ritonavir, alone or in combination with ombitasvir/paritaprevir, lopinavir, nirmatrelvir. See below under "Drug interactions".

Special warnings regarding the use of the medicine

Before treatment with the medicine, tell the doctor:

- If you show symptoms of orthostatic hypotension (sudden decrease in blood pressure upon changing your position). Orthostatic hypotension may occur in the first hours after taking the medicine. It is especially common at the beginning of the treatment, and if in addition you receive treatment for hypertension or if you have arrhythmias. It can be related to the following symptoms: dizziness, tiredness and sweating. If you experience such symptoms, which are temporary, you should lie down until the symptoms completely disappear. In general, you can continue your treatment. Be careful if you have previously experienced low blood pressure after taking an additional medicine from the same class (α_1 blockers).
- If you are of advanced age, there is a higher risk for low blood pressure.
- If you have a history of sensitivity (allergy) to a different medicine from the same class (α_1 blockers).
- If you are elderly.
- If you are being treated with medicines for lowering blood pressure, nitrate derivatives or medicines for other cardiovascular (heart and blood vessels) diseases. The doctor will measure your blood pressure regularly, especially at the beginning of the treatment. The doctor will decide whether you can concomitantly use Alfuzosin ER Teva 10 mg.
- If you suffer from heart failure or from arrhythmias, consult the doctor. He will decide whether you can concomitantly use Alfuzosin ER Teva 10 mg.
- Continuous and painful erections that are unrelated to sexual activity (priapism) may occur very rarely. If this happens, refer to the doctor immediately.
- If you need to undergo a cataract surgery, inform the surgeon that you are taking or have taken Alfuzosin ER Teva 10 mg.
- If you suffer from acute kidney failure (creatinine clearance lower than 30 ml per minute), do not take Alfuzosin ER Teva 10 mg.
- If you are using other medicines, carefully read the "Drug interactions" subsection.

Children and adolescents

Studies in children aged 2-16 years have not proven efficacy of alfuzosin, therefore 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 reduce blood pressure or for the treatment of other cardiovascular diseases, the 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 the pharmacist.

Do not take Alfuzosin ER Teva 10 mg if you are taking:

Other α_1 blockers.

Ritonavir, whether it is taken alone or in combination with lopinavir (usually used for treatment of acquired immunodeficiency syndrome – HIV), or ritonavir in combination with ombitasvir/paritaprevir (usually used for treatment of chronic hepatitis C infection), or ritonavir in combination with nirmatrelvir (usually used for treatment of mild or moderate coronavirus disease (COVID-19)).

Take special care when combining Alfuzosin ER Teva 10 mg with the following medicines:

- Medicines for lowering blood pressure.
- Nitrate derivatives – medicines used in case of angina pectoris (sensation of tightness, or sometimes even a stabbing pain, behind the sternum) and of heart disease.
- Medicines for general anesthesia.
- Medicines for treatment of fungal infections (such as itraconazole).
- Medicines for treatment of bacterial infections (such as clarithromycin, telithromycin).
- Antidepressants (such as nefazodone).
- Ketoconazole tablets (used for the treatment of Cushing's syndrome – when the body produces an excess of cortisol).
- Medicines for the treatment of erectile dysfunction: some patients treated with α_1 blockers for the treatment of hypertension or prostatic hypertrophy, may have dizziness, which may be caused by a decrease in blood pressure during a quick transition from lying down to sitting or standing up. Some patients have experienced such symptoms when concomitantly using medicines for erectile dysfunction (impotence) and alpha blockers. To reduce the risk of these effects, the daily dosage of alpha blockers needs to be fixed before you begin using medicines for erectile dysfunction.
- Medicines that affect the ECG (QT interval prolongation).

To prevent interactions with other medicines, you should always report any treatment to the treating doctor.

Use of the medicine and food

Take Alfuzosin ER Teva 10 mg immediately after dinner.

Driving and operating machinery

Effects such as drowsiness, decrease in blood pressure, dizziness and weakness may occur at the beginning of the treatment. Take these effects into account when driving or operating machinery.

Important information about some of the ingredients of the medicine

Each tablet of Alfuzosin ER Teva 10 mg contains: 8 mg lactose monohydrate.

If you have been told by the doctor that you have an intolerance to certain sugars, contact the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

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

The generally accepted dosage is:

For benign prostatic hypertrophy – one tablet once daily.

For adjuvant treatment to a catheter, in acute urinary retention due to benign prostatic hypertrophy – one tablet once daily. Treatment begins on the day the catheter is inserted, and treatment ends on the day after the catheter is removed (3-4 days in total).

Do not exceed the recommended dose.

Swallow the tablet whole with plenty of water after dinner.

Information about crushing/halving/chewing:

Do not break, crush or chew the tablet as this can affect the absorption of the medicine in the body.

If you accidentally took a higher dosage of the medicine or if a child accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you. Lie down as much as possible to stop the side effects. Do not drive to the hospital yourself.

If you forgot to take the medicine at the scheduled time, do not take a double dose in order to compensate for the forgotten dose. Skip the forgotten dose and take the next dose at the usual time.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine

Keep taking Alfuzosin ER Teva 10 mg even if your health condition improves. Stop the treatment only if the doctor instructs you to do so.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Alfuzosin ER Teva 10 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop the treatment and refer to the doctor immediately if you experience:

Chest pain (angina pectoris) – the risk of this is higher if you have suffered from angina in the past. This effect occurs in less than 1 out of 10,000 patients.

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

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

The frequency of the side effects has been classified as follows:

Very common: occur in more than 1 out of 10 patients.

Common: occur in 1-10 out of 100 patients.

Uncommon: occur in 1-10 out of 1,000 patients.

Rare: occur in 1-10 out of 10,000 patients.

Very rare: occur in less than 1 out of 10,000 patients.

Unknown frequency: the frequency cannot be estimated from the existing data.

Nervous system disorders:

Common: vertigo (spinning sensation), headaches, weakness, tiredness and dizziness.

Uncommon: syncope (temporary loss of consciousness), vertigo.

Cardiovascular disorders:

Uncommon: hypotension (decrease in blood pressure, for example when standing up suddenly from sitting or lying down position), fast heartbeat and hot flashes.

Very rare: chest pain (angina pectoris – sensation of tightness, or sometimes even a stabbing pain, behind the sternum, in patients with coronary heart disease).

Unknown frequency: atrial fibrillation (arrhythmias).

Blood and lymphatic system disorders:

Unknown frequency: neutropenia (decreased white blood cell count), thrombocytopenia (decreased blood platelet count).

Digestive system disorders:

Common: nausea, abdominal pain.

Uncommon: diarrhea, vomiting.

Skin disorders:

Uncommon: skin rash, itch.

Very rare: hives (urticaria), angioedema (swelling of the face, tongue and throat).

Liver disorders:

Unknown frequency: damage to liver cells, cholestatic liver disease (bile drainage disorder).

Eye disorders:

Unknown frequency: intraoperative floppy iris syndrome (IFIS).

Respiratory disorders:

Uncommon: inflammation of the nasal mucosa (rhinitis).

General disorders:

Common: general weakness (asthenia).

Uncommon: chest pain, edema (fluid accumulation).

Reproductive system disorders:

Unknown frequency: prolonged and often painful erection (priapism).

The following side effects have been described with a dosage of alfuzosin 5 mg and their appearance with Alfuzosin ER Teva 10 mg cannot be ruled out:

Eye disorders:

Uncommon: abnormal vision.

Cardiovascular disorders:

Uncommon: palpitations (increased heartbeat).

General disorders:

Common: weakness (general condition of discomfort, tiredness or feeling unwell).

Digestive system disorders:

Common: dry mouth.

Nervous system disorders:

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 this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store at a temperature not exceeding 30°C.
- Protect from light and keep in the original package.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Hypromellose, Povidone, Lactose monohydrate, Magnesium stearate

What does the medicine look like and what are the contents of the package?

White, round, beveled, uncoated tablet.

Each pack contains 28 or 30 tablets. Not all package sizes may be marketed.

Name and address of the marketing authorization holder:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

Name and address of the manufacturer: Unichem Laboratories Ltd.,
Goa, India.

For: Acino Supply AG, Basel, Switzerland.

The leaflet was revised in November 2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 142.46.31943.

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