

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Alfuzosin ER Teva 10 mg
Extended release tablets**

Composition:

Each extended release tablet contains:
Alfuzosin Hydrochloride 10 mg

For information about inactive ingredients and allergens, see section 2 under 'Important information about some of this medicine's ingredients', and section 6 - 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This 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 this medicine intended for?

Alfuzosin ER Teva 10 mg is used for treatment of symptoms of benign prostatic hypertrophy, particularly if surgery has to be delayed, and as adjuvant treatment to a catheter in acute urinary retention related to benign prostatic hypertrophy.

Therapeutic group: Alfuzosin ER Teva 10 mg belongs to a class of medicines called alpha blockers and is an α_1 (alpha 1) selective receptor blocker.

2. Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to alfuzosin or to any of the other ingredients in this medicine (see section 6).
- If you have or have had orthostatic hypotension (sudden drop in blood pressure that occurs when you stand up quickly from sitting or lying down).
- In combination with other α_1 blockers.
- If you have a liver function problem.
- Children below 16 years of age.

Special warnings about using this medicine

Before treatment with Alfuzosin ER Teva 10 mg, tell your doctor:

- If you show symptoms of orthostatic hypotension (sudden drop in blood pressure that occurs when you stand up quickly from sitting or lying down). Orthostatic hypotension may occur during the first few hours after taking the medicine. This is especially frequent at the beginning of the treatment, and if you also receive treatment for high blood pressure or if you have arrhythmias. This may be related to the following symptoms: dizziness, fatigue and sweating. In this case, you should lie down until these symptoms, which are temporary, have disappeared completely. Generally speaking, you will be able to continue your treatment. If you have low blood pressure, be careful after taking another medicine of the same class (α_1 blockers). If you are of advanced age, you are at higher risk of low blood pressure.
- If there is a history of sensitivity (allergy) to another medicine in the same class (α_1 blockers).
- If you are elderly.
- If you are treated with medicines to reduce blood pressure, nitrate derivatives or medicines for other cardiovascular (heart and blood vessels) diseases. Your doctor will measure your blood pressure regularly, especially at the beginning of treatment. Your doctor will decide if Alfuzosin ER Teva 10 mg may be used at the same time.
- If you have congestive heart failure or arrhythmias, consult your doctor. They will decide if Alfuzosin ER Teva 10 mg may be used at the same time.
- Persistent and painful erections that are unrelated to sexual activity (priapism) may occur very rarely. If this happens to you, contact your doctor immediately.
- If you need to undergo cataract surgery, you should inform the surgeon that you are taking Alfuzosin ER Teva 10 mg.
- If you have severe renal impairment (creatinine clearance <30 ml/min), do not take Alfuzosin ER Teva 10 mg.
- If you are taking other medicines, read the "Drug interactions" section carefully.

Children and adolescents

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

Tests and follow-up

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

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

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

Other α_1 blockers.

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

- Medicines to reduce blood pressure.
 - Nitrate derivatives - medicines used for angina pectoris (feeling of a cramp or sometimes even a stabbing pain behind the breastbone) and heart disease.
 - Medicines for general anesthesia.
 - Medicines for the treatment of fungal infections (e.g., itraconazole).
 - Medicines for the treatment of HIV (e.g., ritonavir).
 - Medicines for the treatment of bacterial infections (e.g., clarithromycin, telithromycin).
 - Medicines for the treatment of depression (e.g., nefazodone).
 - Ketoconazole tablets (used to treat 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 to treat high blood pressure or benign prostatic hyperplasia may experience dizziness, which may be caused by low blood pressure from sitting or standing up quickly. Some patients experienced these syndromes when taking erectile dysfunction (impotence) medicines and α_1 blockers at the same time. To reduce the risk of these effects, the daily dosage α_1 blockers needs to be fixed before you begin using medicines for erectile dysfunction.
 - Medicines that affect an ECG (QT interval prolongation).
- To prevent interaction with other medicines, you should always report all treatments to your doctor.

Using this medicine and food

Alfuzosin ER Teva 10 mg should be taken immediately following dinner.

Driving and using machines

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

Important information about some of this medicine's ingredients

Each tablet of Alfuzosin ER Teva 10 mg contains: 8 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

For benign prostatic hypertrophy - one tablet once a day.

For adjuvant treatment to a catheter in acute urinary retention due to benign prostatic hypertrophy - one tablet once a day. Treatment begins on the day the catheter is inserted, and treatment ends 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/splitting/chewing:

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

If you have accidentally taken a higher dose of Alfuzosin ER Teva 10 mg or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Lie down as much as possible to help stop the side effects. Do not drive to the hospital yourself.

If you forget to take Alfuzosin ER Teva 10 mg at the scheduled time, do not take a double dose to make up for the forgotten dose. Skip this dose and take your next dose at the usual time.

Adhere to the treatment as recommended by your doctor.

If you stop taking Alfuzosin ER Teva 10 mg

Keep taking Alfuzosin ER Teva 10 mg even if your health improves. Only stop if your doctor tells you to.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Alfuzosin ER Teva 10 mg may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop treatment and contact your doctor immediately if you experience:

Chest pain (angina pectoris) – generally only happens if you have had angina before. This side effect occurs in less than 1 in 10,000 people.

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

Prolonged and painful erection unrelated to sexual activity (priapism) (frequency not known)

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

Very common: affect more than one in ten users

Common: affect 1-10 in 100 users

Uncommon: affect 1-10 in 1,000 users

Rare: affect 1-10 in 10,000 users

Very rare: affect less than one in 10,000 users

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

Nervous system disorders:

Common: vertigo (feeling dizzy), headaches, weakness and dizziness

Uncommon: syncope (temporary loss of consciousness).

Cardiovascular disorders:

Uncommon: hypotension (decrease in blood pressure that occurs, for example, when standing up quickly from sitting or lying down), fast heartbeat and hot flushes

Very rare: angina pectoris (feeling of a cramp or sometimes even a stabbing pain behind the sternum in patients with coronary heart disease)

Unknown frequency: atrial fibrillation (heart rhythm disorders).

Blood and lymphatic system disorders:

Unknown frequency: neutropenia (decrease in the number of white blood cells), thrombocytopenia (decrease in the number of platelets in the blood).

Gastrointestinal disorders:

Common: nausea, abdominal pain

Uncommon: diarrhoea, vomiting.

Skin disorders:

Uncommon: skin rash, itching

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 lining (rhinitis).

General disorders:

Common: general weakness (asthenia)

Uncommon: chest pain, oedema (accumulation of fluid).

Reproductive system disorders:

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

The following side effects were described with a dosage of alfuzosin 5 mg and may not appear in Alfuzosin ER Teva 10 mg

Eye disorders:

Uncommon: abnormal vision.

Cardiovascular disorders:

Uncommon: palpitations (pounding heartbeat).

General disorders:

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

Gastrointestinal disorders:

Common: dry mouth.

Nervous system disorders:

Uncommon: sleepiness.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

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

Storage conditions

- Do not store above 30°C.
- Protect from light and keep in the original package.

6. Additional information

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

Hypromellose, Povidone, Lactose monohydrate, Magnesium stearate

What the medicine looks like and contents of the pack:

White, round, biconvex, uncoated tablet.

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

License holder's name and address:

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv 6944020

Manufacturer's name and address: Unichem Laboratories Ltd., Goa, India.

FoR: Acino Supply AG, Basel, Switzerland.

This leaflet was revised in January 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 142.46.31943