

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed by doctor's prescription only

Xatral XL 10 mg prolonged-release tablets

Each prolonged release tablet contains: alfuzosin HCl 10 mg.

Inactive ingredients and allergens: see Section 6 'Additional information'.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine was prescribed for you. Do not pass it on to others. It can harm them even if it seems to you that their medical condition is similar to yours. The medicine is intended for men.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

Xatral is used to treat symptoms of benign growth of the prostate, particularly if surgery is delayed, and as adjuvant treatment to a catheter in acute urinary retention related to benign prostatic hypertrophy.

Therapeutic group:

Xatral XL belongs to a group of medicines called alpha blockers, and it is a selective blocker of the α_1 (alpha one) receptor.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to alfuzosin or to any of the ingredients of the medicine (see Section 6)
- if you have or have had orthostatic hypotension (sudden drop in blood pressure that occurs when suddenly getting up from a sitting or lying position)
- in combination with other α_1 -blockers
- if you have an impaired liver function

Special warnings relating to use of the medicine

Talk to your doctor before taking this medicine:

- If you show symptoms of orthostatic hypotension (sudden drop in blood pressure when changing position). Orthostatic hypotension may occur in the first few hours after taking this medicine. This is especially common at the beginning of treatment and when you are also being treated for increased blood pressure or have a cardiac disorder. It may be associated with the following symptoms: dizziness, fatigue, and sweating. In this case, you should lie down until the complete disappearance of these symptoms, which are of a transient nature. In general, you will be able to continue your treatment. Be careful if you have low blood pressure after taking another medicine of the same class (α_1 -blockers).
- If you are of advanced age, you are more likely to have low blood pressure.
- If you have a history of hypersensitivity (allergy) to another medicine of the same class (α_1 -blockers).
- If you are elderly.
- If you are taking blood pressure lowering medicines, nitrate derivatives or medicines for other cardiovascular diseases. Your doctor will measure your blood pressure regularly, especially at the beginning of the treatment. Your doctor will decide if the concomitant use of Xatral XL is possible.
- If you suffer from heart failure (cardiac insufficiency) or an arrhythmia, consult your doctor. They will decide if the concomitant use of Xatral XL is possible.
- Persistent, painful erections that are not related to sexual activity (priapism) may occur very rarely. If this happens you should

contact your doctor immediately.

- If you need to undergo a cataract operation, you should inform your surgeon that you are taking or have taken Xatral XL.
- If you have severe kidney failure (creatinine clearance less than 30 ml/min), do not take Xatral XL.
- If you are using other medicines, read the section "Drug interactions" carefully.

Children and adolescents

Studies in children aged 2-16 years have not shown efficacy of Xatral. Therefore, this medicine is not intended for treating children under 16 years old.

Tests and follow up

If you are taking blood pressure lowering medicines or medicines 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 food supplements, tell the doctor or pharmacist.

Do not take Xatral XL if you take:

other α_1 -blockers.

Take special care when combining Xatral XL with the following medicines:

- blood pressure lowering medicines
- nitrate derivatives - medicines used in case of chest tightness (angina) (a constricted feeling or sometimes even a stabbing pain behind the breastbone), and cardiac disease.
- general anaesthesia medicines
- medicines for fungal infections (such as itraconazole)
- medicines for HIV (such as ritonavir)
- medicines for bacterial infections (such as clarithromycin and telithromycin)
- medicines used to treat depression (such as nefazodone)
- ketoconazole tablets (used to treat Cushing's syndrome – when the body makes too much cortisol)
- erectile dysfunction medicines: Some patients receiving alpha-blocker therapy to treat high blood pressure or prostate enlargement may experience dizziness, which may be caused by low blood pressure when sitting or standing up quickly. Some patients have experienced these symptoms when taking medicines for erectile dysfunction (impotence) and alpha blockers at the same time. To reduce the chance of these symptoms occurring, your daily dose of alpha-blocker should be constant before you start taking erectile dysfunction medications.
- medicines that affect the electrocardiogram (prolongation of QT interval)

In order to avoid any interactions with other medicines, always tell your doctor about any treatment.

Use of Xatral XL and food

Take Xatral XL immediately after dinner.

Driving and using machines

Effects such as sleepiness, drop in blood pressure, dizziness and feeling of dizziness, weakness may occur at the start of treatment. Consider these effects when driving or using machines.

Important information regarding some of the ingredients of the medicine

Xatral XL contains hydrogenated castor oil and may cause stomach discomfort and diarrhoea.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure about your dose or about how you should use this medicine.

The dose and treatment regimen will be determined by the doctor only. The usual dosage is:

- Benign prostatic hyperplasia - one tablet once a day
- For adjuvant treatment to a catheter in acute urinary retention

related to benign prostatic hypertrophy – one tablet once a day. Treatment begins on the day the catheter is inserted and 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.

Crushing/splitting/chewing:

Do not break, crush or chew the tablet as this may affect the way the medicine is absorbed in your body.

If you mistakenly took a higher dose of this medicine or if a child has mistakenly swallowed some medicine, go immediately to a hospital emergency room and bring the medicine package with you. Lie down for as long as possible to stop the side effects. Do not drive yourself to hospital.

If you forgot to take the medicine at the required time, do not take a double dose to compensate for the forgotten dose. Skip this dose and take the next one at the usual time.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking this medicine

Even if your health improves, continue taking Xatral XL. Only stop your treatment if your doctor has told you to do so.

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 with the doctor or pharmacist.

4. Side effects

As with any medicine, use of Xatral 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 consult your doctor immediately if you get:

Chest pain (chest tightness - angina pectoris) - usually happens if you have had angina before. This effect occurs in less than 1 in 10,000 patients.

Allergic reactions - signs of angioedema such as red rash or bumpy skin, swelling (of eyelids, face, lips, mouth, and tongue), difficulty breathing and swallowing. This effect occurs in less than 1 in 10,000 patients.

Persistent, painful erection that is not related to sexual activity (priapism) (unknown frequency)

The frequency of side effects is defined as follows:

Very common: occur in more than 1 in 10 patients

Common: occur in 1 to 10 of 100 patients

Uncommon: occurs in 1 to 10 of 1,000 patients

Rare: Occur in 1 to 10 of 10,000 patients

Very rare: Occur in less than 1 to 10,000 patients

Frequency not known: frequency cannot be estimated from the available data

Nervous system disorders:

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

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

Cardiovascular disorders:

Uncommon: hypotension (decrease in blood pressure, for example when suddenly getting up from a sitting or lying position), increased heart rate and hot flushes.

Very rare: angina pectoris (chest tightness - a constricted feeling or sometimes even a stabbing pain behind the breastbone in coronary patients).

Frequency not known: atrial fibrillation (cardiac arrhythmia).

Blood and lymphatic system disorders:

Not known: neutropenia (reduced number of white blood cells), thrombocytopenia (reduced number of platelets).

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).

Hepatobiliary disorders:

Frequency not known: injury to the liver cells, cholestatic liver disease (interruption of the bile drainage).

Eye disorders:

Frequency not known: pupil syndrome (Intraoperative Floppy Iris Syndrome, IFIS).

Respiratory disorders:

Uncommon: inflammation of the nasal mucosa (rhinitis)

General disorders:

Common: overall body weakness (asthenia).

Uncommon: chest pain, oedema (fluid accumulation).

Reproductive system and breast disorders:

Frequency not known: prolonged and often painful erection (priapism).

The following side effects were described with Xatral 5 mg and may not be excluded with Xatral XL 10 mg:

Eye disorders:

Uncommon: abnormal vision.

Cardiovascular disorders:

Uncommon: palpitations (pounding heartbeat)

General disorders:

Common: weakness (general discomfort, fatigue or feeling ill)

Gastrointestinal disorders:

Common: dry mouth.

Nervous system disorders:

Uncommon: sleepiness

If you experience any side effect, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

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 SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and all other medicines must be stored in a closed place, out of the reach and sight of children and/or infants in order to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this medicine after the expiry date that appears on the pack. The expiry date refers to the last day of that month.

Storage conditions

- Store below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains: hypromellose, microcrystalline cellulose, hydrogenated castor oil, mannitol, povidone, ethylcellulose, magnesium stearate, hydrated colloidal silica, yellow iron oxide.

What does the medicine look like and what is included in the pack:

Round, biconvex, three-layer tablet: one white layer between two yellow layers.

There are packs of 10 and 30 tablets (not all pack sizes may be marketed).

Manufacturer and importer's name and address: Sanofi-Aventis Israel Ltd., POB 8090, Netanya.

Revised in April 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 123-01-30140