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

The medicine is dispensed by doctor's prescription only

# Xatral SR 5 mg sustained-release tablets

SANOFI

Each Xatral SR 5 mg tablet contains: alfuzosin HCl 5 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 SR is used to treat symptoms of benign growth of the prostate, particularly if surgery is delayed.

**Therapeutic group:**
Xatral belongs to a group of medicines called alpha blockers, and it 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 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 α1-blockers
- if you have reduced 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.
- If you are elderly, you are more likely to have low blood pressure.
- if you have low blood pressure after taking another medicine of the same class (α1-blockers)
- if you are elderly
- if you have a history of hypersensitivity (allergy) to another medicine of the same class (α1-blockers)
- 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 SR is possible.
- if you suffer from heart failure (cardiac insufficiency) or an arrhythmia, consult your doctor. Your doctor will decide if the concomitant use of Xatral SR is possible.
- if you suffer from blood flow disorders in the brain
- 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 eye surgeon that you are taking or have taken Xatral SR.
- If you are using other medicines, read the section "Other medicines and Xatral SR" 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 SR with the following medicines:**
other α1-blockers.

**Take special care when combining Xatral SR 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 SR and food**
Take Xatral SR immediately after a meal.

**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 SR 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.

Take your first dose of Xatral in the evening immediately after your evening meal.

The dose and treatment regimen will be determined by the doctor only. The usual dosage is:
- one tablet twice a day - morning and evening.

- This dose must be adjusted in the elderly and in patients being treated for high blood pressure**.**
- Some patients need a lower dose of Xatral SR, particularly those with liver or kidney failure.

If a lower dose is not possible, the doctor must consider other treatment alternatives for these patients.

**Do not exceed the recommended dose.**

Swallow the tablet whole with a glass of water after a meal.

**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 SR. 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 SR 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: weakening, fatigue, sensation of dizziness, vertigo (spinning), dizziness, headache.
Uncommon: sleepiness, syncope (temporary loss of consciousness).
Frequency not known: bleeding in the brain (cerebral ischaemia).

**Eye disorders:**
Uncommon: abnormal vision.
Frequency not known: pupil syndrome (Intraoperative Floppy Iris Syndrome, IFIS).

**Cardiovascular disorders:**
Common*:* hypotension (decrease in blood pressure, for example when suddenly getting up from a sitting or lying position).
Uncommon: hot flushes, increased heart rate, palpitations (stronger heartbeat).
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).

**Respiratory disorders:**
Uncommon: inflammation of the nasal mucosa (rhinitis)

**Gastrointestinal disorders:**
Common: abdominal pain, nausea, diarrhoea, dry mouth.
Uncommon: 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).

**General disorders:**
Common: overall body weakness (asthenia), nausea.
Uncommon: chest pain, oedema (fluid accumulation).

**Reproductive system and breast disorders:**
Frequency not known: prolonged and often painful erection (priapism).
**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:
calcium hydrogen phosphate dihydrate, microcrystalline cellulose, hydrogenated castor oil, povidone, hypromellose, magnesium stearate, propylene glycol, titanium dioxide, yellow iron oxide, red iron oxide.

**What does the medicine look like and what is included in the pack:**
Xatral SR 5 mg: a round, pale yellow, film-coated sustained-release tablet.
Packs of 28 and 56 tablets (not all pack sizes are 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: 1101629084