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

**The medicine is dispensed with a doctor's prescription only**

# Xatral XL 10 mg

## Prolonged release Tablets

SANOFI

Each prolonged release tablet contains:
ALFUZOSIN HCl 10 mg
Inactive ingredients – see Section 6.

**Read this 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.
If a side effect worsens or if a side effect not mentioned in this leaflet occurs, please refer to the doctor or pharmacist.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

Xatral is used for the treatment of symptoms associated with benign prostate enlargement and as an adjuvant treatment to catheter withdrawal in urinary retention resulting from benign prostatic hypertrophy.

**Therapeutic group:** Xatral 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 to alfuzosin or to any of the ingredients of the medicine (see Section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, throat or tongue.
- You suffer from a sudden drop in blood pressure when you get up, that may be accompanied by dizziness or fainting (orthostatic hypotension).
- You suffer from a problem in liver function.
- You suffer from severe kidney failure (creatinine clearance below 30 ml/min).
- You are being treated with other α (alpha) blockers (such as prazosin, trimazosin and urapidil).
- You are taking medicines to treat HIV (such as protease inhibitors in combination with ritonavir or cobicistat or nelfinavir) or medicines to treat hepatitis C (such as telaprevir or boceprevir) or medicines to treat fungal infections (such as ketoconazole, itraconazole, posaconazole and voriconazole) or medicines to treat bacterial infections (such as clarithromycin, erythromycin, telithromycin). These medicines may increase the blood concentrations of Xatral and cause side effects. See Warnings section.

**Special warnings regarding use of the medicine**
Before treatment with the medicine, tell your doctor if:
- You are being treated with medicines for treatment of hypertension or with nitrate derivatives
- You are suffering from disturbed blood flow to the brain
- You are suffering from heart disease
- You experienced a significant drop in blood pressure after taking another medicine from the α (alpha) blockers group

When taking the medicine, some people may experience a sudden drop in blood pressure when they sit or stand up quickly. This effect may occur within a few hours of taking the medicine and may be accompanied by dizziness, sweating, a feeling of tiredness, or even fainting. The patient must lie down until the symptoms pass and refer to the doctor. It is therefore also recommended to take the first dose before going to sleep.
The risk of developing hypotension and related adverse reactions may be greater in the elderly and in patients taking other medicines for treatment of hypertension or nitrate derivatives (medicines used for angina pectoris).
Use of dapoxetine in combination with Xatral may cause dizziness and fainting.
If you suffer or have suffered from prolonged QT intervals in the ECG or if you are taking medicines that cause prolonged QT intervals in the ECG, you must be monitored before and while taking the medicine.

**❗ 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 if you are taking other α (alpha) blockers.
Do not take Xatral in combination with certain medicines to treat high blood pressure (medicines to lower blood pressure, such as doxazosin, prazosin and urapidil).
Check with the doctor or pharmacist if you are taking: medicines for treatment of impotence (such as sildenafil), antihypertensives, medicines for treatment of angina pectoris (nitrates).
Nitrates for the treatment of chest pains symptoms when taken together with Xatral may cause a drop in blood pressure.
Do not take Xatral if you are taking medicines to treat HIV (such as protease inhibitors in combination with ritonavir or cobicistat or nelfinavir) or medicines to treat hepatitis C (such as telaprevir or boceprevir) or medicines to treat fungal infections (such as ketoconazole, itraconazole, posaconazole and voriconazole) or medicines to treat bacterial infections (such as clarithromycin, erythromycin, telithromycin). See "Before using the medicine" section.
General anesthetics may cause a severe drop in blood pressure.

**❗ Surgery and tests while taking Xatral**
During treatment with Xatral, blood pressure must be monitored, especially at the beginning of treatment with Xatral.
If you are due to undergo surgery under general anesthesia, tell the anesthesiologist that you are taking or have recently taken Xatral. The doctor may decide to stop Xatral treatment 24 hours before the surgery.
If you are due to undergo cataract eye surgery, tell the surgeon that you are taking or that you have taken Xatral, in order to prevent complications during surgery.

**❗ Use of Xatral and food**
Xatral should be taken immediately after dinner.

**❗ Use of Xatral and alcohol consumption**
You may feel dizzy or weak when taking Xatral; if these effects occur, do not drink alcohol.

**❗ Driving and use of machinery**
Use of this medicine may cause dizziness, exhaustion and disturbed vision. If these effects occur, do not drive or operate machinery or dangerous equipment.

**❗ Important information regarding some of the ingredients of the medicine**
Xatral contains hydrogenated castor oil that may cause diarrhea.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure.
Swallow the tablet whole, with plenty of water, after dinner. Do not break, crush or chew the tablet, as it may impact the absorption of the medicine in the body.
The dose and treatment regimen will be determined by the doctor only.
The usual dosage 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 mistakenly took a higher dose of Xatral** or if a child has mistakenly swallowed the medicine, refer immediately to a hospital emergency room and bring the medicine package with you. Remain in a lying position for as long as possible to stop the side effects. Do not drive to the hospital by yourself.
**If you forgot to take Xatral** 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 Xatral**
Continue taking Xatral 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 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 may cause side effects in some users. It is likely that these effects will occur at the start of treatment. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
**Chest pain (angina) -** usually occurs if you have suffered from angina in the past. **If you suffer from chest pain, stop Xatral treatment and refer to the doctor or hospital immediately.** This effect occurs in less than 1 in 10,000 people.
**Allergic reactions -** you may notice signs of angioedema, such as skin redness or rash, swelling (of the eyes, face, lips, mouth and tongue), difficulty breathing and swallowing.

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These are signs of an allergic reaction. If these effects occur, **stop Xatral treatment and refer to the doctor or hospital immediately.** This effect occurs in less than 1 in 10,000 people.

**Additional side effects**

**Occur frequently** (occur in less than 1 in 10 people):
Dizziness, weakness, fainting, headache, nausea, abdominal pain, feeling ill, a drop in blood pressure when switching from a lying position to standing or sitting (orthostatic hypotension).

**Occur infrequently** (occur in less than 1 in 100 people):
Vertigo, drowsiness, syncope, rapid heart rate (tachycardia), palpitations, allergic rhinitis, diarrhea, dryness in the mouth, skin rash, itchiness, edema, chest pain, flushing.

**Occur very rarely** (occur in less than 1 in 10,000 people):
Allergic skin reaction, angioedema.

**Other side effects that may occur** (of unknown frequency):
Cerebral events in patients with disturbed blood flow to the brain, atrial fibrillation, eye problems in patients who are undergoing cataract surgery (see section on Surgery and tests while taking Xatral), vomiting, liver injury, cholestatic liver inflammation, prolonged erection, a decrease in the number of white blood cells and platelets.
If any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

## 5. HOW SHOULD XATRAL BE STORED?

Avoid poisoning! This medicine and all other medicines must be stored in a closed place, out of the reach 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 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 at a temperature below 30°C.

## 6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Hypromellose, Hydrogenated Castor Oil, Ethylcellulose, Magnesium Stearate, Mannitol, Povidone, Microcrystalline Cellulose, Yellow Iron Oxide, Colloidal Hydrated Silica.

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

This leaflet does not contain all the information about your medicine; if you have any questions or are not sure about anything, please ask your doctor.

License holder and address: sanofi-aventis Israel ltd., P.O. Box 8090, Netanya 4250499.

Manufacturer's name and address: Sanofi Winthrop Industrie, France.

This leaflet was checked and approved by the Ministry of Health in 02.2015.

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