



### Film-coated, prolonged-release tablets

**Read all of this leaflet carefully before you start taking this medicine.**

- . Keep this leaflet. You may need to read it again.
- . If you have any questions or are unsure of anything, ask your doctor or pharmacist for more information.
- . This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same.
- . If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this package leaflet :**

1. WHAT XATRAL SR 5 mg, film-coated, prolonged-release tablets ARE AND WHAT THEY ARE USED FOR
2. BEFORE YOU USE XATRAL SR 5 mg, film-coated, prolonged-release tablets
3. HOW TO USE XATRAL SR 5 mg, film-coated, prolonged-release tablets
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE XATRAL SR 5 mg, film-coated, prolonged-release tablets
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#### **1. WHAT XATRAL SR 5 MG, film-coated prolonged-release tablets ARE AND WHAT THEY ARE USED FOR**

##### **ALPHA-BLOCKERS.**

This medicine belongs to the alpha-blocker class of drugs. This medicine is used for the symptomatic treatment of the functional signs of benign hypertrophy (increase in volume) of the prostate.

#### **2. BEFORE YOU TAKE XATRAL SR 5 mg, film-coated prolonged-release tablets**

**Never take Xatral SR 5 mg, film-coated prolonged-release tablets in the following cases :**

- allergy to alfuzosin and/or any of the other ingredients of this medicine;
- postural hypotension (feeling of dizziness, usually occurring when moving from the lying to standing position);
- severely impaired liver function (liver failure);
- severely impaired kidney function;
- in combination with ritonavir.

#### **Take special care with Xatral SR 5 mg, film-coated prolonged-release tablets :**

##### **Special warnings**

Some patients may be particularly sensitive to **XATRAL SR 5 mg**, leading to a drop in blood pressure when moving from the lying to the standing position. This effect may develop in the first few hours after taking the medicine and be accompanied by the following symptoms: dizziness, fatigue, sweating. Patients must remain lying down until complete disappearance of these symptoms, which are temporary.

Caution is recommended, particularly in the elderly and in subjects having experienced a marked drop in blood pressure after taking a medicine from the same class (alpha-blockers).

##### **Intraoperative Floppy Iris Syndrome (IFIS):**

If you are going to have cataract surgery (due to an opaque lens) in the near future and if you have been or are currently

being treated with **Xatral SR 5 mg**, tell your ophthalmologist before the operation. This medicine can cause a side effect that may lead to complications during surgery. However, if the surgeon is warned in advance, he/she will take the necessary precautions, depending on your treatment, during the operation.

This medicine contains castor oil, which can cause digestive disorders (mild laxative effect, diarrhoea).

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

### **Precautions when taking Xatral SR 5 mg, film-coated prolonged-release tablets**

Inform your doctor if you have had heart disease, in particular if you have coronary artery disease.

### **Taking or using other medicines**

IN ORDER TO AVOID ANY INTERACTION BETWEEN DIFFERENT MEDICINAL PRODUCTS, particularly certain medicines used for blood pressure or certain antifungal agents (ketoconazole, itraconazole), or certain antibiotics (clarithromycin, erythromycin), YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER ONGOING TREATMENTS.

### **Pregnancy and breast-feeding**

This medicine is not used in women.

*AS A GENERAL RULE, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE IF YOU ARE PREGNANT OR BREASTFEEDING.*

### **Driving and using machines**

The attention of drivers and machine operators is drawn to the potential risks of postural hypotension (drop in blood pressure when moving to the standing position, sometimes accompanied by dizziness), sensations of dizziness, fatigue or visual disturbances, especially at the start of treatment.

### **Expicient with specific effects**

Hydrogenated castor oil.

## **3. HOW TO USE XATRAL SR 5 MG, film-coated prolonged-release tablets**

How many Xatral SR 5 mg, film-coated prolonged-release tablets should be taken

The usual dosage is 1 tablet morning and evening.

In the elderly or patients taking medication for high blood pressure or with liver failure, this dosage may be adjusted.

How Xatral SR 5 mg, film-coated prolonged-release tablets are taken

Oral use.

The tablet must be swallowed whole with a glass of water. The tablets must not be crunched, chewed, crushed or ground into a powder.

### **When and how often Xatral SR 5 mg, film-coated prolonged-release tablets should be taken**

According to your doctor's prescription.

### **How long Xatral SR 5 mg, film-coated prolonged-release tablets should be taken**

Do not discontinue treatment without first consulting your doctor.

### **If you take more Xatral SR 5 mg, film-coated prolonged-release tablets than you should**

Contact your doctor.

### **If you forget to take Xatral SR 5 mg, film-coated prolonged-release tablets**

Do not take two or several tablets at the same time, but take your next dose as usual.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, **Xatral SR 5 mg, film-coated prolonged-release tablets can cause side-effects.**

Common effects:

- lightheadedness, dizziness, dizzy spells, fainting, drop in blood pressure when moving from the lying to the standing position, headache;
- digestive disorders such as nausea, stomach pain or diarrhoea, dry mouth;
- feeling of fatigue.

Uncommon effects:

- drowsiness;
- vision disorders;
- accelerated heart rate, palpitations, syncope;
- nasal congestion;
- skin reactions, such as rashes or itching;
- redness of the face, oedema, chest pain.

Very rare effects:

- angina pectoris in patients with a history of coronary artery disease (see section "Precautions when taking **Xatral SR 5 mg** film-coated, prolonged-release tablets");
- hives, angioedema.

Effects of unknown frequency:

- hepatitis, particularly due to biliary tract obstruction;
- painful, prolonged erection.

If you notice any side effects not mentioned in this package leaflet, or if certain side effects become serious, please inform your doctor or pharmacist.

## **5. HOW TO STORE XATRAL SR 5 MG, film-coated prolonged-release tablets**

Keep out of the reach and sight of children.

Do not use **Xatral SR 5 mg** film-coated, prolonged-release tablets after the expiry date printed on the box.

Store at a temperature not exceeding 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Xatral SR 5 mg, film-coated prolonged-release tablets contain**

The active substance is:

alfuzosin hydrochloride.....5 mg

The other ingredients are: microcrystalline cellulose, polyidone k 29/32, calcium dihydrate hydrogen phosphate, magnesium stearate, hydrogenated castor oil, hypromellose, propylene glycol, titanium dioxide, yellow and red iron oxides, for one sustained-release, film-coated tablet.

### **How are Xatral SR 5 mg, film-coated prolonged-release tablets supplied and what are the contents of the outer packaging?**

Sustained-release coated tablets (boxes of 56).

### **Marketing Authorization Holder and Operating Company**

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1-13, boulevard Romain Rolland - 75014 Paris, France

### **Manufacturers**

#### **Sanofi Winthrop Industrie**

30 - 36, avenue Gustave Eiffel - 37100 Tours, France

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