

Package Leaflet:  
INFORMATION FOR THE USER

**Xatral 2.5mg**  
**Film-coated Tablets**  
alfuzosin hydrochloride

**Is this leaflet hard to see or read?**  
**Phone 0800 035 2525 for help.**

**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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Xatral is and what it is used for
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**1. What Xatral is and what it is used for**

The name of your tablets is Xatral. This belongs to a group of medicines called alpha-blockers. Xatral can be used to treat the symptoms of **Benign Prostatic Hypertrophy**. This is when the prostate gland enlarges (hyperplasia), but the growth is not cancerous (it is benign). It can cause problems in passing water (urine). This happens mainly in older men.

- The prostate gland lies underneath the bladder. It surrounds the urethra. This is the tube that takes your water to the outside of the body.
- If the prostate gets bigger, it presses on the urethra making it smaller. This makes it difficult to pass water.
- Your tablets work by relaxing the prostate gland muscle. This allows the urethra to get bigger and so makes it easier to pass water.

**2. Before you take Xatral**

Do not take Xatral if:

- × You are allergic (hypersensitive) to alfuzosin or any of the other ingredients of Xatral (see section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, throat, or tongue.
- × You are taking another alpha-blocker. See section below on 'Taking other medicines'.
- × You have something called orthostatic hypotension. This is a drop in blood pressure which usually happens when you stand up. It can make you feel dizzy, light-headed or faint when you stand or sit up quickly.
- × You have serious liver problems.

If you are not sure if any of these apply to you, do not take and talk to your doctor.

**Take special care with Xatral**

Check with your doctor or pharmacist before taking your medicine if:

- ▲ You have chest pain (angina).
- ▲ You have a long-term infection in your urinary tract (including your kidney, bladder and urethra), had difficulty when passing water or had small crystals (stones) forming in the water.
- ▲ You are going to have an operation on the eye because of cataract (cloudiness of the eye), tell your eye specialist you are using or have used Xatral in the past. This is because Xatral may cause complications during your operation. This can be managed if your eye specialist knows before carrying out the operation.
- ▲ You have circulatory problems affecting the brain as there is a risk of impaired brain function due to low blood flow.
- ▲ You have heart problems, or if your heart suddenly stopped pumping efficiently (acute cardiac failure)
- ▲ You have hereditary problems with the way your heart beats (congenital QTc prolongation)
- ▲ You are over 65. This is due to the increased risk of developing hypotension and related adverse reactions in elderly patients.
- ▲ You ever get painful erections of the penis, unrelated to sexual activity that will not go away, before or during treatment.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

This is because Xatral can affect the way some other medicines work. Some medicines can also have an effect on the way that Xatral works.

Do not take Xatral if you are taking:

- Other alpha-blockers such as doxazosin, indoramin, prazosin, terazosin, tamsulosin, or phenoxybenzamine.

Check with your doctor or pharmacist before taking your medicine if:

- In the past, you have had a large fall in blood pressure while taking an alpha-blocker (this could include previous use of alfuzosin. See paragraph immediately above for examples of other alpha-blockers).
- You are taking a medicine for high blood pressure, as you may get dizzy, weak or start sweating within a few hours of taking this medicine. If this happens, lie down until the symptoms have completely gone. Tell your doctor as he or she may decide to change the dose of your medicine.
- You are taking medicines for chest pain (angina)
- You are taking medicines for fungal infections (such as itraconazole).
- You are taking medicines for HIV (such as ritonavir).
- You are taking medicines for bacterial infections (such as clarithromycin, telithromycin).
- You are taking medicines for treatment of depression (such as nefazodone).
- You are taking ketoconazole tablets (used to treat Cushing's syndrome - when the body produces an excess of cortisol).

### **Operations and tests while taking Xatral**

- If you are being treated for high blood pressure, your doctor should measure your blood pressure regularly, especially at the start of treatment.
- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking Xatral before the operation. Your doctor may decide to stop you having Xatral 24 hours before the operation. This is because it can be dangerous as it can lower your blood pressure.

### **Taking Xatral with food and drink**

- You may feel dizzy and weak while taking Xatral. If this happens do not drink any alcohol.

### **Driving and using machines**

You may feel dizzy and weak while taking Xatral. If this happens do not drive or operate any tools or machines.

### **Important information about some of the ingredients of Xatral**

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

### **3. How to take Xatral**

Always take Xatral exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets whole with plenty of water.
- Do not break, crush or chew your tablets. This can affect the release of your medicine into the body.
- Take this medicine after a meal.

**The usual dose is one Xatral tablet three times a day.**

#### **If you are over 65 or are being treated for high blood pressure**

- You should start on one Xatral tablet in the morning and one tablet in the evening.

#### **If you have kidney problems**

- You should start on one Xatral tablet twice a day. This may be changed depending upon how you respond.

#### **If you have liver problems**

- You should start on one Xatral tablet a day. This may be changed to two tablets a day, depending upon how you respond.

#### **If you take more Xatral than you should**

Contact your local hospital Accident and Emergency department straight away. Tell the doctor how many tablets you have taken.

Lie down as much as possible to help stop the side effects. Do not try to drive to the hospital yourself.

#### **If you forget to take Xatral**

Do not take a double dose to make up for a forgotten tablet. Miss it out and then go on as before.

#### **If you stop taking Xatral**

Keep taking your tablets, even if your symptoms improve. Only stop if your doctor tells you to. The symptoms are better controlled if you continue taking the same dose of this medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, Xatral can cause side effects, although not everybody gets them. These side effects are most likely to happen at the start of treatment.

### **Chest pain (angina)**

Normally, this only happens if you have had angina before. **If you get chest pain stop taking your tablets and contact a doctor or go to a hospital immediately.** This happens in less than 1 in 10,000 people.

### **Allergic reactions**

You could notice symptoms of angioedema, such as a red and lumpy skin rash, swelling (on the eyelids face lips, mouth and tongue), difficulty in breathing or swallowing. These are symptoms of an allergic reaction. **If this happens, stop taking your tablets and contact a doctor or go to a hospital immediately.** This happens in less than 1 in 10,000 people.

### **Painful erection of the penis (priapism)**

If you get painful erections of the penis, unrelated to sexual activity, that will not go away **stop taking your tablets and contact a doctor or go to a hospital immediately.** Frequency not known.

### **Other side effects include:**

#### **Common (affects less than 1 in 10 people)**

- Feeling dizzy or faint.
- Headache.
- Feeling sick (nausea).
- Stomach pain.
- Weakness or tiredness.
- General feeling of being unwell.
- Feeling dizzy, lightheaded, or faint when you stand or sit up quickly (postural hypotension).
- Diarrhoea
- Dry mouth.

#### **Uncommon (affects less than 1 in 100 people)**

- Fast heart beat (tachycardia) and palpitations (pounding in the chest and uneven heartbeat).
- Chest pain.
- Drowsiness.
- Rash and itching.
- Flushes.
- Water retention (may cause swollen arms or legs).
- Lack of control over passing water.
- Runny nose, itching, sneezing, and stuffy nose.
- Visual disturbances (changes in your vision or sight).
- Fainting

#### **Very rare side effects (affects less than 1 in 10,000 people)**

- Itchy, lumpy rash also called hives or nettle rash (urticaria).

#### **Other side effects (frequency not known) which may occur are:**

- Liver problems. Signs may include yellowing of your skin or the whites of your eyes.
- Intraoperative Floppy Iris Syndrome (IFIS). If you are having an operation on your eyes because of cataracts (where the lens of the eye is cloudy) and are already taking or have taken Xatral in the past, the pupil may dilate poorly and the iris (the coloured part of the eye) may become floppy during the procedure. This only happens during the operation and it is important for the eye specialist to be aware of this as the operation may need to be

carried out differently (see section 'Take special care with Xatral').

- You may get more infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia).
- Being sick (vomiting).
- Abnormal heart rhythm.
- Impaired brain function due to low blood flow in patients with existing circulatory problems affecting the brain.
- Increased risk of bleeding (including nose bleeds and/or bleeding gums) and bruising. This could be a blood problem called 'thrombocytopenia' which is a reduced number of platelets in the blood.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Xatral**

Keep out of the reach and sight of children.

Do not use Xatral after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store below 30° in a dry place.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Further information**

#### **What Xatral contains**

- The active substance is 2.5 mg alfuzosin hydrochloride.
- The other ingredients are microcrystalline cellulose, lactose, povidone, sodium starch glycollate, magnesium stearate, hypromellose, macrogol, titanium dioxide (E171).

#### **What Xatral looks like and contents of the pack**

White round tablet marked Xatral 2.5 on one side. Your tablets are available in packs of 60 and 90 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

Sanofi

410 Thames Valley Park Drive

Reading

Berkshire

RG6 1PT

Notification 61.3 – Medical Information telephone number change

UK

Tel: 0800 035 2525

Email:

[uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com)

Manufacturer

Sanofi Winthrop Industrie

30 -36 avenue Gustave Eiffel

37000 Tours

France

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

**This leaflet was last revised in 12/2020**

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