

PACKAGE LEAFLET: Information for the user

Xatral® 2.5mg Film-coated Tablets

(alfuzosin hydrochloride)

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 get 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 2.5mg Film-coated Tablets is and what it is used for
- 2 Before you take Xatral 2.5mg Film-coated Tablets
- 3 How to take Xatral 2.5mg Film-coated Tablets
- 4 Possible side effects
- 5 How to store Xatral 2.5mg Film-coated Tablets
- 6 Further information

1 What Xatral 2.5mg Film-coated Tablets is and what it is used for

The name of your tablet is Xatral. It contains a medicine called alfuzosin hydrochloride. This belongs to a group of medicines called alpha-blockers. Xatral 2.5mg Film-coated Tablets can be used to treat the symptoms of Benign Prostatic Hypertrophy (BPH). This is when the prostate gland enlarges (hypertrophy) 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 2.5mg Film-coated Tablets

Do not take Xatral 2.5mg Film-coated Tablets if:

- * You are allergic (hypersensitive) to alfuzosin or any of the other ingredients of Xatral (see section 6: Further Information). 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 under 16 years of age. Efficacy of alfuzosin has not been demonstrated in children aged 2 to 16 years. Therefore, alfuzosin is not indicated for use in paediatric population.

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 2.5mg Film-coated Tablets

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 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 low blood pressure (hypotension) and related side effects in elderly patient.
- * In very rare cases, Xatral may cause priapism, a painful erection of the penis which will not go away (See section 4). This is a serious condition and you should contact your doctor.

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. Check with your doctor if you are taking any of the following:
- * Medicines for chest pain (angina)
- * Medicines for fungal infections (such as ketoconazole or itraconazole) and HIV (such as ritonavir).

Operations and tests while taking Xatral 2.5mg Film-coated Tablets:

- * If 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.
- * 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 2.5mg Film-coated Tablets 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 2.5mg Film-coated Tablets

Xatral 2.5mg Film-coated Tablets contain lactose. 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 2.5mg Film-coated Tablets

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. Any other mode of administration, such as crunching, crushing, chewing, grinding or pounding to powder should be prohibited. These actions may lead to inappropriate release and absorption of the drug and therefore possible early adverse reactions. The first dose should be taken just before bedtime.

The usual dose is one tablet three times a day.

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

- * You should start on one Xatral 2.5mg Film-coated Tablets in the morning and one tablet in the evening.

If you have Kidney problems

- * You should start on one Xatral 2.5mg Film-coated Tablets twice a day. This may be changed depending upon how you respond.

If you have liver problems

- * You should start on one Xatral 2.5mg Film-coated Tablets a day. This may be changed to two tablets a day, depending upon how you respond

If you take more Xatral 2.5mg Film-coated Tablets 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 2.5mg Film-coated Tablets

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

PACKAGE LEAFLET: Information for the user (continued)

Xatral® 2.5mg Film-coated Tablets

(alfuzosin hydrochloride)

If you stop taking Xatral 2.5mg Film-coated Tablets

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 2.5mg 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.

Other side effects include:**Common (affects less than 1 in 10 people)**

- * Feeling dizzy or faint
- * Headache.
- * Spinning sensation (vertigo)
- * Feeling sick (nausea).
- * Stomach pain.
- * Weakness or tiredness.
- * General feeling of being unwell
- * Feeling dizzy, light-headed 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).
- * Fainting
- * Chest Pain.
- * Drowsiness.
- * Rash and itching.
- * Flushes.
- * Water retention (may cause swollen arms or legs).
- * Runny nose, itching, sneezing, and stuffy nose.
- * Visual disturbances changes in your vision or sight

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

- * Itchy, lumpy rash also called hives or nettle rash (urticaria).
- * Angina in patients with pre-existing heart disease

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 'Operations and tests while taking Xatral 2.5mg Tablets').
- * Painful erection of the penis, unrelated to sexual activity, that will not go away. The chance of this happening is very small.
- * Abnormal heart rhythm (atrial fibrillation)
- * Getting sick (vomiting)
- * Blood disorder (neutropenia)
- * 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Xatral 2.5mg Film-coated Tablets

Keep this medicine out of the sight and reach of children.

Do not use Xatral 2.5mg Film-coated Tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the tablets in their original package.

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 2.5mg Film-coated Tablets contain**

* Each tablet contains 2.5mg of the active substance alfuzosin hydrochloride.

* The other ingredients are microcrystalline cellulose, lactose, povidone sodium starch glycollate, magnesium stearate, methylhydroxypropylcellulose, polyethylene glycol 400, titanium dioxide suspension (E171)

What Xatral 2.5mg Film-coated Tablets looks like and the contents of the pack

White round, film coated tablet engraved on one side with 'Xatral 2.5'.

Your tablets are available in packs of 60 tablets.

The manufacturer is:

Sanofi Winthorp Industrie, 30-39 Avenue Gustave Eiffel, 3700 Tours, France.

Parallel Product Authorisation Holder:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

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Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.