

PACKAGE LEAFLET: Information for the user

Xatral® 10mg Prolonged-Release 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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- 1 What Xatral 10mg Prolonged Release Tablets is and what it is used for
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1 What Xatral 10mg Prolonged Release 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 10mg Prolonged Release 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.

In a few patients with benign prostatic hypertrophy, the prostate gland gets so big that it stops the flow of urine completely.

This is called Acute Urinary Retention.

- * This is very painful and you may need a short stay in hospital
- * A thin, flexible tube (catheter) is passed into the bladder. This drains the water and relieves the pain.
- * During this time, Xatral 10mg Prolonged Release Tablets may be used to help the water to flow again. This has only been shown to help in men aged over 65.

2 Before you take Xatral 10mg Prolonged Release Tablets**Do not take Xatral 10mg Prolonged Release 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 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 10mg Prolonged Release Tablets

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

- * You have chest pain (angina).
- * You have a condition where your kidneys are hardly working at all.
- * 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 patients.

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 10mg Prolonged Release Tablets 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 high blood pressure (hypertension)
- * 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 10mg Prolonged Release 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 10mg Prolonged Release tablets in the past. This is because Xatral 10mg Prolonged Release Tablets 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 10mg Prolonged Release Tablets with food and drink

- * Take Xatral 10mg Prolonged Release Tablets after a meal.
- * 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 10mg Prolonged Release Tablets

Xatral 10mg Prolonged Release Tablets contain hydrogenated castor oil. This can cause stomach upset and diarrhoea.

3 How to take Xatral 10mg Prolonged Release 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.
- * 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.

Benign Prostatic Hypertrophy

The usual dose is one Xatral 10mg Prolonged Release Tablet once a day (after a meal).

Acute Urinary Retention

- * Xatral 10mg Prolonged Release Tablets will be given to you by your doctor on the day you have the catheter inserted.
- * You should continue taking Xatral 10mg Prolonged Release Tablets once a day.
- * You should stop taking Xatral 10mg Prolonged Release Tablets the day after the catheter is removed (3-4 days in total).

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If you take more Xatral 10mg Prolonged Release 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 10mg Prolonged Release Tablets

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

If you stop taking Xatral 10mg Prolonged Release 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 10mg Prolonged Release Tablets 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.
- * Feeling sick (nausea).
- * Stomach pain.
- * Weakness or tiredness.

Uncommon (affects less than 1 in 100 people)

- * Feeling dizzy, lightheaded, or faint when you stand or sit up quickly (postural hypotension).
- * Fast Heart beat (tachycardia) and palpitations (pounding in the chest and uneven heartbeat).
- * Chest Pain.
- * Drowsiness.
- * Diarrhoea.
- * Dry mouth.
- * Rash and itching.
- * Flushes.
- * Water retention (may cause swollen arms or legs).
- * Runny nose, itching, sneezing, and stuffy nose.
- * General feeling of being unwell.
- * Problems with your vision.

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 10mg Prolonged Release 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)
- * 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 10mg Prolonged Release Tablets

Keep this medicine out of the sight and reach of children. Do not use Xatral 10mg Prolonged Release 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 10mg Prolonged Release Tablets contain

- * Each tablet contains 10mg of the active substance alfuzosin hydrochloride.
- * The other ingredients are ethyl cellulose, hydrogenated castor oil, hypromellose, yellow ferric oxide (E172), magnesium stearate, microcrystalline cellulose, povidone, colloidal hydrated silica, mannitol

What Xatral 10mg Prolonged Release Tablets looks like and the contents of the pack

Round biconvex three layer prolonged release tablet: one white layer between two yellow layers. Your tablets are available in packs 30 tablets.

The Parallel Product Authorisation Holder is:

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

Repackaged by:

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

The manufacturer is:

Sanofi Winthrop Industrie, 30-36 Avenue Gustava 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.

Xatral is a registered trademark of Sanofi-Aventis.

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