

Package leaflet: Information for the patient

Xatger 10 mg, prolonged-release tablets

alfuzosin hydrochloride

For male adults

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Xatger is and what it is used for
2. What you need to know before you take Xatger
3. How to take Xatger
4. Possible side effects
5. How to store Xatger
6. Contents of the pack and other information

1. What Xatger is and what it is used for

Xatger contains the active ingredient alfuzosin, which belongs to a group of medicines called alpha-adrenoreceptor antagonists or alpha-blockers.

It is used to treat moderate to severe symptoms caused by an enlarged prostate gland, a condition that is also called **benign** (non-cancerous) **prostatic hyperplasia**. The prostate gland lies underneath the bladder. It surrounds the urethra, the tube that takes your urine to the outside of the body. If the prostate gets bigger, it presses on the urethra making it smaller. Enlarged prostate glands can cause urinary problems such as frequent and difficult urination, especially at night.

Alpha-blockers relax the muscles in the prostate and bladder neck. This allows urine to flow out of the bladder more easily.

In a few patients with benign prostatic hyperplasia, 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 urine and relieves the pain. Xatger may be used to help the urine flow again

2. What you need to know before you take Xatger

Do not take Xatger:

- if you are allergic to alfuzosin, other quinazoline medicines (e.g. terazosin, doxazosin) or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from conditions that cause a marked drop in blood pressure when standing up (your doctor may have told you this is called ‘postural’ or ‘orthostatic’ hypotension). This can make you feel dizzy.
- if you have liver problems.
- if you take other medicines that belong to the group known as alpha-blockers (see below section on ‘Other medicines and Xatger’).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Xatger.

Warnings and precautions

Talk to your doctor or pharmacist before taking Xatger:

- If you have severe kidney problems
 - if you take medicines to treat high blood pressure. In this case your doctor will check your blood pressure regularly, especially at the beginning of treatment.
 - if you have experienced a marked drop in blood pressure in the past after taking another medicine belonging to the group known as alpha-blockers. In this case your doctor will start treatment with alfuzosin at low doses and will gradually increase the dose.
 - if you suffer from heart failure (a weakness of the heart muscle), or other heart problems.
 - if you have, or have had, problems with decreased blood flow to parts of the brain (cerebral circulatory disturbances).
- if you suffer from chest pain (angina) and are treated with a nitrate. Use of nitrates and alfuzosin at the same time may increase the risk of decreasing blood pressure. Your doctor may stop treating you with alfuzosin if your angina comes back or worsens.
- if you were born with, or have had any condition associated with an abnormal heart rhythm (which may be seen on ECG test which looks at the electrical activity of the heart) or you take medicines known to affect the heart rhythm.

When taking this medicine, you may experience a sudden drop in blood pressure when you stand up (you may feel dizzy, tired, weak or sweaty), particularly in the first few hours after taking. If this happens, you should lie down with your legs and feet up in the air until the symptoms have disappeared. Usually, these effects last for only a short time and occur at the start of the treatment. Normally, there is no need to stop treatment. Let your doctor know as he may decide to adjust your dose.

In case of an erection (often painful), unrelated to sexual activity, that persists longer than 4 hours you should contact a doctor or go to a hospital immediately because you may need treatment. See the section below “possible side effects”.

If you need to have eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are taking or have previously taken alfuzosin. This is because alfuzosin may cause complications during the surgery, which can be managed if your specialist is prepared in advance.

Children and adolescents

Xatger is not recommended for use in children and adolescents (patients below 16 years of age).

Other medicines and Xatger

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not take alfuzosin if you are taking other medicines that belong to the group known as alpha-blockers, such as doxazosin, indoramin, terazosin, prazosin or tamsulosin.

Xatger and some medicines may interfere with each other. Talk to your doctor or pharmacist if you are taking any of the following:

- medicines for fungal infections (such as ketoconazole, itraconazole)
- medicines used to treat HIV (such as ritonavir)
- medicines for bacterial infections (such as clarithromycin, telithromycin)
- medicines for treatment of depression (such as nefazodone)
- medicines to lower blood pressure
- medicines for chest pain (angina)
- medicines normally used to treat impotence (erectile dysfunction).
 - The use of alfuzosin at the same time as medicines used to treat high blood pressure, or nitrates used to treat heart problems such as chest pain (angina) or to treat impotence may lead to low blood pressure. If this happens, lie down until the symptoms have completely gone. Tell your doctor as the dose of your medicine may be changed.

If you are going to have an operation that needs a general anaesthetic, tell your doctor or hospital staff that you are taking this medicine. Your doctor may recommend that you stop taking this medicine 24 hours before the operation, to help prevent the risk of blood pressure changes.

Pregnancy and breast-feeding

Xatger is only indicated for use in male.

Xatger with food and drink

Take alfuzosin after a meal.

Driving and using machines

Especially at the beginning of treatment with Xatger, you may feel light-headed, dizzy or weak. Do not drive or operate machinery or perform any hazardous tasks until you know how your body responds to the treatment.

Xatger contains lactose

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

3. How to take Xatger

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

Benign Prostatic Hyperplasia

- The recommended dose is one tablet (10 mg xatger) once daily.
- Take the tablet after an evening meal.

Acute Urinary Retention

- Xatger will be given to you by your doctor on the day you have the catheter inserted.
- You should continue taking Xatger once a day after a meal. Follow the advice on your doctor's prescription.

Swallow the tablets whole with a sufficient amount of fluid. Do not crush, powder, divide or chew the tablets as too much of the active substance alfuzosin may reach your body too quickly. This may increase the risk of unwanted side effects.

If you have kidney problems

If you have mild to moderate kidney problems, your doctor may recommend that you start on a lower dose of alfuzosin first. If a lower dose does not work for you, then they may recommend that you take one tablet (10 mg xatger) once daily. Take the tablet after an evening meal.

If you take more Xatger than you should

If you take large amounts of alfuzosin your blood pressure may suddenly drop and you may feel dizzy or even faint. If you begin to feel dizzy, sit or lie down until you feel better. If the symptoms do not disappear, call your doctor as the drop in blood pressure may have to be treated in hospital. **Do not try to drive to the hospital yourself.**

If you forget to take Xatger

Do not take a double dose to make up for a forgotten tablet as this may cause a sudden drop in blood pressure. Take the next tablet as directed.

If you stop taking Xatger

You should not interrupt or stop taking Xatger without speaking to your doctor first.

If you want to stop the treatment or have any further questions on the use of this medicine, ask your doctor or pharmacist.

Use in children

Xatger is not indicated for use in children.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:

- worsening of, or new onset of, **chest pain (angina)**. Normally, this only happens if you have had angina before.
- red and lumpy skin rash (hives), swelling of the eyelids, face, lips, mouth or tongue, difficulty in breathing or swallowing. These are symptoms of **serious allergic reactions**.
- an increase in the number of **infections** (e.g. sore throat, mouth ulcers etc. and fever) that you may get. This may be a sign of a reduction in the number of white blood cells.
- an unusual or abnormal heart rhythm – you may notice a **very fast or irregular heartbeat**, which may make you feel short of breath, dizzy or faint.
- **liver problems**, which may be due to a blockage in the bile duct. You may feel sick, notice a loss of appetite, pale stools, dark urine or yellowing of the skin and whites of the eyes.
- **sudden collapse**, numbness or weakness in the arms or leg, dizziness and confusion, disturbances in vision, difficulty swallowing, slurred or loss of speech (these may be signs of a **stroke**, or mini stroke caused by changes in blood supply to parts of the brain). These are more likely in patients who have had previous problems with blood flow to the brain.
- **persistent erection** (priapism) - Priapism is an abnormal, often painful, persistent erection of the penis unrelated to sexual activity. If you would get an erection such as the one described here that would persist longer than 4 hours, contact a doctor or go to a hospital immediately because you may need treatment. This condition can lead to permanent impotence if not properly treated.

Other possible side effects

Common (may affect up to 1 in 10 people):

Tiredness, dizziness, headache, faintness, stomach pain, feeling sick (nausea), indigestion, feeling of general weakness, generally feeling unwell.

Uncommon (may affect up to 1 in 100 people):

Feeling drowsy, vision/eye problems, faster heartbeat, fainting (especially when starting treatment with too high a dose or when treatment is resumed), sensation of pounding or racing heartbeat, dry mouth, runny nose, skin rash, itching, urinary incontinence, water retention (e.g. swelling of ankles and feet), reddening of the face or body (flushing/hot flushes), sweating, a spinning sensation in the head (vertigo), being sick (vomiting), diarrhoea, marked drop in blood pressure when standing up (especially when starting treatment with too high a dose or when treatment is resumed).

Not known (frequency cannot be estimated from the available data):

Painful or prolonged erection (priapism), unexplained bruising or bleeding (this may be a sign of reduced number of platelets in the blood, which help the blood to clot).

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 alfuzosin 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 ‘Warnings and precautions’).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xatger

Do not store above 30°C

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

Do not use this medicine after the expiry date, which is stated on the blister and carton after ‘EXP’. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xatger contains:

The active substance is alfuzosin hydrochloride. One prolonged-release tablet contains 10 mg alfuzosin hydrochloride.

The other ingredients are: lactose monohydrate, hypromellose, povidone, magnesium stearate.

What Xatger looks like and contents of the pack

Xatger 10 mg, are white, round, bevelled-edged, uncoated tablets.

They are available in blister packs of 10, 20, 30, 30 x 1, 50, 60, 60 x 1, 90, 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder

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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic:	Alfuzosin Mylan 10 mg
Denmark:	Lafunomyl 10 mg
Ireland:	Xatger 10 mg prolonged-release tablets
Italy:	Alfuzosina Mylan 10 mg
The Netherlands:	Alfuzosine HCl Retard Mylan 10 mg, tabletten met gereguleerde afgifte
Poland:	Alugen 10 mg
Portugal:	Alfuzosina Mylan 10 mg
Slovakia:	Alfuzosin Mylan 10mg
Spain:	Alfuzosina Mylan 10 mg comprimidos de liberación prolongada
Sweden:	Lafunomyl 10 mg
United Kingdom (Northern Ireland):	Taurazil SR 10 mg Tablets

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