

Package leaflet: Information for the user

Vasran XL 10 mg prolonged-release tablets Alfuzosin hydrochloride

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 Vasran XL 10 mg prolonged release tablets are and what they are used for
2. What you need to know before you take Vasran XL 10 mg prolonged release tablets
3. How to take Vasran XL 10 mg prolonged release tablets
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1. What Vasran XL 10 mg prolonged release tablets are and what they are used for

Alfuzosin is a medicine in the form of a tablet that must be taken via the mouth.

Alfuzosin belongs to a group of medicines, for prostate diseases, called alpha-1-blockers. It promotes relaxation of the muscle tissue in the prostate and urethra, allowing urine to flow out of the bladder more easily.

Alfuzosin is used to treat the symptoms of Benign Prostate Hyperplasia.

Benign Prostate Hyperplasia

The prostate gland lies underneath the bladder. The urethra goes through the prostate to the outside of the body. In addition to glandular tissue (for the production of prostatic fluid), muscle tissue is also present in the prostate. This muscle tissue is also present in the urethra. In Benign Prostate Hyperplasia, this muscle tissue in the prostate and urethra tenses, causing the urethra to narrow. This makes it more difficult for the urine to flow out of the bladder causing lower urinary tract complaints.

Acute Urinary Retention

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 water and relieves the pain.
- During this time, alfuzosin may be used to help the water to flow again.

2. What you need to know before you take Vasran XL 10 mg prolonged release tablets

Do not take Vasran XL 10 mg prolonged release tablets

- if you are allergic to alfuzosin or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, throat, or tongue.
- if you have had in the past, a drop in blood pressure when sitting or standing up.
- if you are already taking another alpha-1-blocker.
- if you have liver problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vasran XL 10 mg prolonged release tablets:

- You have a condition of the coronary arteries. Any treatment of reduced blood supply to the heart muscle should be continued.
- If symptoms of chest pain (angina pectoris) recur or worsen. The use of Vasran XL 10 mg prolonged release tablets should be discontinued.
- 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).
- If you are elderly, if you have an increased sensitivity to alpha-1 blockers or if you are being treated for high blood pressure.
- If a fall in blood pressure occurs when sitting or standing up in the first hours after taking the tablet. This effect can possibly occur with symptoms such as: dizziness, tiredness or sweating. In such a case you must lie down until the symptoms have completely disappeared. These symptoms are usually transient and may occur at the beginning of treatment. As a rule, treatment can be continued.
- If you have an eye surgery for cataract (cloudiness of the lens) planned, tell your eye specialist before the surgery that you are using or have used Vasran XL 10 mg prolonged release tablets. This is because Vasran XL 10 mg prolonged release tablets may cause complications during your operation which can be managed if your eye specialist is aware of this information before carrying out the operation.
- You continue to have a prolonged erection of the penis without being sexually aroused. This is a serious condition that can lead to permanent impotence if not treated properly.

Consult your doctor if one of the above warnings apply to you, or has done in the past.

Children

Alfuzosin is not to be used in children.

Other medicines and Vasran XL 10 mg prolonged release tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This also applies to medicines that you can obtain without a prescription.

Some medicines may affect each other's actions or may not be used at the same time for other reasons.

Do not use Vasran XL 10 mg prolonged release tablets if:

- You are using other alpha-1-blockers (medicines for prostate problems) at the same time such as doxazosin, indoramin, prazosin, terazosin, tamsulosin, or phenoxybenzamine.

Talk to your doctor before taking your medicine if:

- You are taking medicines for elevated blood pressure. It may be necessary to adjust the dosage of your medicine, due to the possible occurrence of a fall in blood pressure.
- You have to undergo surgery. You must tell your doctor that you are taking Vasran XL 10 mg prolonged release tablets.
- When combined with nitrates (medicines to relieve pain on the chest), it may be necessary to adjust the dosage of your medicine, due to the possible occurrence of a fall in blood pressure.
- You are taking medicines normally used to treat impotence (erectile dysfunction)
- You are taking medicines to treat premature ejaculation (dapoxetine)
- You are taking medicines for hepatitis C (such as telaprevir and boceprevir).
- You are taking medicines for bacterial infections (such as clarithromycin, erythromycin, telithromycin).
- You are taking medicines for treatment of depression (such as nefazodone).
- If you are taking ketoconazole tablets (to treat Cushing's syndrome - when your body produces too much of the hormone cortisol).
- It may be necessary to adjust the dose when used at the same time with medicines that inhibit the CYP3A4 liver enzyme, such as itraconazole, posaconazole, voriconazole, cobicistat, nelfinavir and ritonavir.

Vasran XL 10 mg prolonged release tablets with food and drink

- Take Vasran XL 10 mg prolonged release tablets just after a meal.
- Drinking alcohol may increase the unpleasant effects of alfuzosin. You may feel dizzy and weak while taking Vasran XL 10 mg prolonged release tablets.

If this happens do not drink any alcohol.

Pregnancy and breast-feeding

Not applicable. Vasran XL 10 mg prolonged release tablets is only prescribed for men.

Driving and using machines

No known data are available on the effect on the ability to drive or use machines. Complaints such as dizziness or general weakness may occur. This should be taken into account when driving vehicles or using machines.

Vasran XL 10 mg prolonged release tablets contain lactose.

This medicine contains 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 Vasran XL 10 mg prolonged release tablets

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

For oral use.

Benign Prostate Hyperplasia

The usual dose is one tablet per day.

Acute Urinary Retention

Vasran XL 10 mg prolonged release tablet will be given to you by your doctor on the day you have the catheter inserted.

You should continue taking Vasran XL 10 mg prolonged release tablet once a day.

Take one tablet of Vasran XL 10 mg prolonged release tablet after the evening meal.

Take the tablet with plenty of fluid (for instance a glass of water). The prolonged-release tablet should not be ground, chewed or divided.

Taking the tablet at the same time every day provides the best effect. It also helps you to remember when to take the tablet.

Elderly (over 65 years) and patients with kidney problems

Your dose does not need to be adjusted for mild to moderate kidney problems whereas it is not given by your doctor in case if you have severe kidney problems.

Patients with liver problems

Vasran XL 10 mg prolonged release tablet should not be used in patients with liver problems. However in mild to moderate liver problems other products containing low dose of alfuzosin can be used according to the appropriate dosage regimen. Your doctor will inform you about this.

Use in children and adolescents

The efficacy of Vasran XL 10 mg prolonged release tablet has not been established in children aged 2 to 16 years. Therefore Vasran XL 10 mg prolonged release tablet is not indicated for children and adolescents (2 to 16 years old).

If you take more Vasran XL 10 mg prolonged release tablets than you should

If you take too much Vasran XL 10 mg prolonged release tablets, contact your doctor or pharmacist immediately.

If you forget to take Vasran XL 10 mg prolonged release tablets

You may forget to take a tablet. In that case it is not necessary to take the forgotten tablet. You can continue to take the prescribed dose the next day.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Vasran XL 10 mg prolonged release tablets

You should not interrupt or stop taking Vasran XL 10 mg prolonged release tablets without speaking to your doctor first. Take your tablets as directed and for as long as directed. Do not stop taking them even if you feel better, as otherwise the symptoms may return.

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

4. Possible side effects

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

Serious side effects:

If any of the following happen, stop taking Vasran XL 10 mg prolonged release tablets and tell your doctor immediately or go to your nearest hospital emergency department:

Very rare: (may affect up to 1 in 10,000 people)

- Rapid swelling of the eyelids, face, lips, mouth and tongue, difficulty in breathing or swallowing, rashes, hives and itching. These are symptoms of a very serious allergic reaction (the medical term for these symptoms is **angioedema**).
 - Feeling of tightness, heaviness, discomfort, or crushing pain that is felt behind the breastbone and may spread to the arms, neck and jaw (these may be manifestations of **angina**). Normally, this only happens if you have had angina before.
- Not known (frequency cannot be estimated from the available data):*
- Prolonged and painful erection of the penis, unrelated to sexual activity (these may be due to a medical condition called **priapism**).

Other side effects:

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

- feeling sick (nausea)
- stomach pain
- dryness of mouth
- weakness or tiredness
- feeling unwell (malaise)
- headache
- feeling dizzy or faint
- full body weakness (asthenia)

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

- loose stools (diarrhea)
- problems with your vision
- fast heart beat (tachycardia)
- fast or irregular heart beat (palpitations)
- sudden loss of consciousness (syncope)
- a drop in blood pressure caused, for example, by rising quickly from a sitting or lying position, sometimes accompanied by dizziness (orthostatic hypotension)
- getting warm, blushing (flushing)
- runny or blocked nose, sneezing, facial pressure or pain (rhinitis)
- skin rash
- itching
- water retention (may cause swollen arms or legs)
- chest pain
- drowsiness
- Sensation of spinning or whirling when you are not actually moving (vertigo).

Very rare (may affect up to 1 in 10,000 people):

- damage or injury to the liver caused by a drug or chemical (liver toxicity)
- itchy, lumpy rash also called hives or nettle rash (urticaria).

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

- damage to liver cells
- certain liver diseases caused by narrowing or closure of the bile duct (cholestatic liver disease). Signs may include yellowing of your skin or the whites of your eyes.
- being sick (vomiting)
- 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 Vasran XL 10 mg prolonged release tablet 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 “Warnings and precautions”).
- irregular and often rapid heart rhythm of the atria (atrial fibrillation)
- reduced white blood cell count (neutropenia). You may get more infections than usual.
- 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 or pharmacist. 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 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 Vasran XL 10 mg prolonged release tablets

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

This medicinal product does not require any special storage conditions.

Do not use this medicine 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 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 Vasran XL 10 mg prolonged release tablets contain

- The active substance is alfuzosin hydrochloride.

Each prolonged release tablet contains 10 mg of alfuzosin hydrochloride.

- The other ingredients are: lactose anhydrous, colloidal anhydrous silica (E551), povidone (E1201), talc (E553B), magnesium stearate (E572), hypromellose (E464), hydroxypropyl cellulose (E463).

The tablet has a prolonged effect which means that after taking the active substance is not released immediately but gradually from the tablet and therefore acts longer.

What Vasran XL 10 mg prolonged release tablets look like and contents of the pack

Vasran XL 10 mg prolonged release tablets are white to off-white, round, uncoated, biconvex tablets with flattened edges, marked with ‘RY 10’ on one side.

Vasran XL 10 mg prolonged release tablets are available in boxes of 10, 30 or 90 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:

SUN PHARMA UK LIMITED

6-9 The Square,

Stockley Park,

Uxbridge, UB11 1FW

United Kingdom

Manufacturer:

Sun Pharmaceutical Industries Europe B.V.

Polarisavenue 87

2132 JH Hoofddorp

The Netherlands

Terapia S.A.
Str. Fabricii Nr. 124
Cluj-Napoca 400 632
Romania

Please contact the marketing authorisation holder if you require more information about this medicine.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

France	ALFUZOSINE CRISTERS PHARMA LP 10 mg comprimés à libération prolongée
Italy	Profuzo
Netherlands	Alfuzosine HCl SUN 10 mg tabletten, tabletten met verlengde afgifte
Poland	Alfabax
United Kingdom (Northern Ireland)	Vasran XL 10 mg Prolonged-release Tablets

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