



Package leaflet: Information for the user

BESAVAR XL 10MG 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 Besavar XL is and what it is used for
2. What you need to know before you take Besavar XL
3. How to take Besavar XL
4. Possible side effects
5. How to store Besavar XL
6. Contents of the pack and other information

1. What Besavar XL is and what it is used for

The name of your medicine is Besavar XL 10mg Tablets (called Besavar XL throughout this leaflet). Besavar XL contains a medicine called alfuzosin hydrochloride. This belongs to a group of medicines called alpha-blockers.

Besavar XL can be used to treat the symptoms of **Benign Prostatic Hyperplasia**. 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.

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, Besavar XL may be used to help the water to flow again. This has only been shown to help in men aged over 65.

2. What you need to know before you take Besavar XL

Do not take Besavar XL and tell your doctor if you:

- are allergic (hypersensitive) to alfuzosin hydrochloride 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, face, throat or tongue
- are taking another alpha-blocker. See section below on 'Other Medicines and Besavar XL'
- 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
- have liver problems
- You are taking Ritonavir alone or in combination with ombitasvir/paritaprevir, lopinavir, nirmatrelvir. See section "Other medicines and Besavar XL".
- If you are not sure if any of these apply to you do not take Besavar XL and talk to your doctor.

Take special care and check with your doctor or pharmacist before taking Besavar XL 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 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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Besavar XL.

Other medicines and Besavar XL

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Besavar XL and some other medicines can affect the way each other work.

Do not take this medicine, and tell your doctor, if you are taking:

- Other alpha-blockers such as doxazosin, indoramin, prazosin, terazosin, tamsulosin, or phenoxybenzamine.
- Ritonavir by itself, or in combination with ombitasvir/paritaprevir, or lopinavir and nirmatrelvir. Using these medicines together can make the amount of alfuzosin in your blood too high because your liver won't be able to clear it properly.

Tell 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 such as glyceryl trinitrate 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 Besavar XL

- 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 on the eye because of cataract (cloudiness of the eye), tell your eye specialist you are using or have used Besavar XL in the past. This is because Besavar XL may cause complications during your operation. This can be managed if your eye specialist knows before carrying out the operation.
- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking Besavar XL before the operation. Your doctor may decide to stop you having Besavar XL 24 hours before the operation. This is because it can be dangerous as it can lower your blood pressure.

Besavar XL with food and drink

- Take Besavar XL after a meal.
- You may feel dizzy and weak while taking Besavar XL. If this happens do not drink any alcohol.

Driving and using machines

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

Besavar XL contains hydrogenated castor oil. This can cause stomach upset and diarrhoea.

3. How to take Besavar XL

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

Taking this medicine

- Swallow the 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.

How much to take

Benign Prostatic Hyperplasia

- The usual dose is one Besavar XL tablet once a day.

Acute Urinary Retention

- Besavar XL will be given to you by your doctor on the day you have the catheter inserted.



- You should continue taking Besavar XL once a day.
- You should stop taking Besavar XL the day after the catheter is removed (3-4 days in total).

Children

- Alfuzosin is not recommended for use in children under 16 years of age.

If you take more Besavar XL than you should

Contact your local hospital Accident and Emergency department straight away. Tell the doctor or nurse 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 Besavar XL

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

If you stop taking Besavar XL

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Besavar XL 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 pains 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 erection of the penis, unrelated to sexual activity, which 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

Uncommon (affects less than 1 in 100 people)

- Feeling dizzy light-headed or faint when you stand or sit up quickly (postural hypotension)
- A fast heart beat (tachycardia) and pounding in the chest and uneven heartbeat (palpitations)
- 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 (affects less than 1 in 10,000 people)

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

Other (frequency not known) which may occur are:

- Abnormal liver function (liver problem). Signs may include yellowing of your skin or the whites of your eyes.
- 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 Besavar XL 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 Besavar XL"). 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).

- Increased risk of bleeding (including nose bleeds and/or bleeding gums) and bruising. This could be a 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 Besavar XL

- Keep this medicine out of the sight and reach of children.
- Store in the original packaging.
- Do not use this medicine after the expiry date which is stated on the carton and foil 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 any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Besavar XL 10mg Tablets contain

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

What Besavar XL looks like and contents of the pack

Besavar XL 10mg Tablets are round, biconvex, three layer tablets: one white layer between two yellow layers. They are supplied in blister packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

Manufacturer:

Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37000 Tours, France

or

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