

## PATIENT INFORMATION LEAFLET

# 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 symptoms 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 Hypertrophy**. 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-blockers (see section below on 'Other Medicines and Besavar XL')
- have something called postural 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 severe liver problems

### 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 kidney problems
- You are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Besavar XL. This is because Besavar XL may cause complications during the surgery which can be managed if your specialist is prepared in advance
- You are allergic (hypersensitive) to other alpha blockers such as doxazosin, tamsulosin
- You are taking medicines for high blood pressure. Your doctor should monitor your blood pressure regularly while you are taking this medicine. This is particularly important at the start of your treatment.
- 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.

#### **Tell your doctor or pharmacist 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.

Or if 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.
- medicines such as glyceryl trinitrate for chest pain (angina)
- medicines for fungal infections (such as itraconazole).
- medicines for HIV (such as ritonavir).
- medicines for bacterial infections (such as clarithromycin, telithromycin).
- medicines for treatment of depression (such as nefazodone).
- 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 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 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. Miss it out and then go on as before.

**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 about 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.

**Stop taking Besavar XL and see a doctor or go to a hospital straight away if:**

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Besavar XL tablets.
- You have chest pain (angina). This usually only happens if you have had angina before. This side effect is very rare.
- You have a painful erection of the penis, not related to sexual activity, which will not go away. This side effect has only been reported in a very small number of people taking Besavar XL.

**Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet****Common side effects (affects less than 1 in 10 people)**

- Feeling dizzy or faint
- Headache
- Feeling sick (nausea)
- Stomach pain
- Weakness or tiredness

**Uncommon side effects (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)
- General feeling of being unwell

**Additional side effects (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.
- Occasionally problems have arisen during cataract surgery in patients taking alfuzosin. If you are due to have eye surgery because of cataracts it is important that you tell the specialist before the operation that you are using, or have used, 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](http://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 in a safe place where children cannot see or reach it.
- Store in the original packaging.
- Do not use Besavar XL after the expiry date which is stated on the carton.
- 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. 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:**

Zentiva Pharma UK Limited,  
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**This leaflet was last revised in:** December 2019

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