Fuzatal® XL 10mg prolonged release tablets
Alfuzosin hydrochloride

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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. 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 FUZATAL® XL IS AND WHAT IT IS USED FOR

This drug belongs to the group of medicines called alpha-blockers.

It is used to treat functional symptoms of benign prostatic hyperplasia caused by an enlarged prostate gland. Enlarged prostate glands can cause urinary problems such as frequent and difficult urination.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE FUZATAL® XL

Do not take Fuzatal® XL:
- if you are allergic to alfuzosin, other quinazoline (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
- if you are taking other medicines belonging to the group called alpha1-blockers (e.g. tamsulosin).
- if you have severe liver disease.

Warnings and precautions
Before starting treatment with Fuzatal® XL you may be tested by your doctor to rule out the presence of other conditions that may cause the same symptoms as benign prostatic hyperplasia. Before treatment and at regular intervals thereafter, you may undergo a digital rectal examination and, if necessary, a blood test.
Talk to your doctor or pharmacist before taking Fuzatal® XL
- if you have severe kidney problems
- if you have a mild to moderate liver disease, your doctor may prescribe a lower dose.
- if you take other 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 experience a sudden drop in blood pressure when you stand up shown by dizziness, weakness or sweating within a few hours after you have taken Fuzatal® XL. If you experience a drop in blood pressure 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
- if you experienced a marked drop in blood pressure in the past after taking another medicine belonging to the group of 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 acute heart failure
- if you suffer from chest pain (angina) and are treated with a nitrate as this may increase the risk of a drop in blood pressure. You should discuss with your doctor whether to continue or stop your treatment with Fuzatal® XL, especially when the chest pain recurs or worsens
- if you have an abnormal heart rhythm called QTc prolongation (long QT) or you are taking medicines likely to increase the risk of QTc prolongation. Tell your doctor if you suffer from this condition or are taking any other medicines.
- if you are an elderly patient (over 65 years old). This is due to the increased risk of developing low blood pressure (hypotension) and related side effects in elderly patients.
- if 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 Fuzatal® XL. This is because Fuzatal® XL may cause complications during the surgery which can be managed if your specialist is prepared in advance.
- Alfuzosin, like other medicines in the same family, may cause priapism (persistent and painful erection of the penis). If this happens, go to an emergency department immediately so that you can be treated.

Consult your doctor even if any of the above has ever happened to you.

Operations while taking Fuzatal® XL
- if you are going to have surgery, that needs a general anaesthetic, you should tell the anaesthetist before the operation that you are taking Fuzatal® XL (see also section "Other medicines and Fuzatal® XL ").
- if 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 Fuzatal® XL. This is because Fuzatal® XL may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Other medicines and Fuzatal® XL
Tell your doctor or pharmacist if you are taking, ;have recently taken or might take any other medicine, including.

Certain medicines, such as those listed below, may increase the risk of hypotension (lowering of blood pressure) when taken at the same time as Fuzatal® XL:

Medicines that should not be used:
- Medicines that belong to the group of alpha-blockers: you must not take such medicines at the same time as Fuzatal® XL (see "Do not take Fuzatal® XL" above)
- Antihypertensive medicines (medicines that lower blood pressure)
- Nitrates (medicines for the treatment of coronary heart disease)
- Medicines used to treat fungal infections (e.g. itraconazole or ketoconazole)
- Medicine used to treat HIV (AIDS virus) (e.g. ritonavir)
- Medicines to treat bacterial infections (antibiotic drugs like clarithromycin, erythromycin and telithromycin)
- Medicines for the treatmet of depression (e.g. nefazodone)

In addition, the administration of general anaesthetics to patients treated with alfuzosin may cause blood pressure instability, so if you are having surgery, you should warn the anaesthetist about taking Fuzatal® XL.

Fuzatal® XL with food and drink
The tablet should be taken after the same meal each day.

Pregnancy and breast-feeding
Fuzatal® XL is only intended for men.

Driving and using machines
At the beginning, treatment with Fuzatal® XL may make you 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.

Fuzatal® XL contains 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 FUZATAL® XL

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

Posology
Adults
The recommended dose is 1 prolonged-release tablet per day, which is the maximum dose. Take the first tablet at bedtime. Take the tablets after the same meal each day and swallow them whole with a sufficient amount of fluid. Do not crush, chew or divide the tablets.

Elderly patients
The posology does not need to be adjusted for elderly (over 65 years).

Renal insufficiency
In patients with mild to moderate renal impairment, it is recommended to start treatment with a lower dose, which should be increased to 10 mg depending on clinical response.
In patients with severe renal impairment, it is recommended not to use ALFUZOSINE 10 mg as there are no clinical safety data available for this patient group.

Use in children and adolescents
The efficacy of alfuzosin in children and adolescents aged 2 to 16 years has not been demonstrated. Therefore alfuzosin is not indicated for use in this patient group.

If you take more Fuzatal® XL than you should :
If you take large amounts of Fuzatal® XL 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.

If you forget to take Fuzatal® XL, prolonged release tablets:
Do not take a double dose to make up for a forgotten tablet as this may cause a sudden drop in blood pressure, especially if you take blood-pressure lowering medicines. Take the next tablet as directed.

If you stop taking Fuzatal® XL, prolonged release tablets
You should not interrupt or stop taking Fuzatal® XL without speaking to your doctor first. 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.

Common (may affect up to 1 in 10 people):
- Dizziness/faintness, headaches, vertigo
- Orthostatic hypotension (fall in blood pressure when moving from a supine to a standing position (especially when starting treatment with a too high dose and when treatment is resumed) (see section 2 “Warnings and precautions”)
- Digestive disorders such as nausea, abdominal pain, diarrhoea, dry mouth
- Feeling of weakness, malaise.

Uncommon (may affect up to 1 in 100 people):
- Syncope (loss of consciousness);
- Drowsiness, ;
- Visual disturbances
- Faster heartbeat, palpitations (the heart beats more rapidly than normal and it is also noticeable)
- Hot flushes;
- Rhinitis;
- Being sick (vomiting);
- Skin disorders such as skin rash or itching, pruritus;
- Oedema (swelling), chest pain (see section 2 “Warnings and precautions”).

Very rare (may affect up to 1 in 10,000 people):
- Worsening or recurrence of chest pain (angina pectoris) in patients with coronary artery disease (see section 2 “Warnings and precautions”);
- Angiooedema (swelling of the face, lips, tongue and/or throat),
- Skin disorders such as urticaria.

Not known (frequency cannot be estimated from the available data):
- Reduced number of white blood cells (neutropenia), which may lead to more frequent infections than usual;
- Reduced platelet count (thrombocytopenia);
- Stroke in patients who have problems with the blood circulation in the brain;
  - Intraoperative Floppy Iris Syndrome (IFIS) (characterised by pupil constriction and iris deformation);
- Abnormal heart rhythm (atrial fibrillation);
- Liver problems: signs may include yellowing of your skin or the whites of your eyes;
- Abnormal, often painful, persistent erection of the penis unrelated to sexual activity (priapism).

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 FUZATAL® XL

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 carton and blister strips after EXP. The expiry date refers to the last day of that month.
Keep the blister in the outer carton in order to protect from light.
Store below 30°C.

For bottles (HDPE):
The shelf life of the product after first opening is 1 year, but no longer than the expiry date stated on the box or bottle after the letters EXP.

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 PACK AND OTHER INFORMATION

What Fuzatal® contains
The active substance is alfuzosin hydrochloride. Each prolonged release tablet contains 10 mg of alfuzosin hydrochloride.

The other ingredients are lactose monohydrate, hypromellose (E464), povidone K25 and magnesium stearate.

What Fuzatal® XL looks like and contents of the pack
Fuzatal® XL is a round white prolonged release tablet in blister strips (PVC/PVDC/aluminium) of 10, 28, 30, 50, 90 or 100 tablets per pack, or bottles (HDPE) of 100 tablets per pack. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer
Company responsible for manufacture: Merckle GmbH
Ludwig-Merckle Str. 3
89143 Blaubeuren/Germany

Product Licence number:

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TEVA UK LIMITED

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