PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ALFUWIN XL (prolonged-release tablets)

Alfuzosin hydrochloride

Contains sugar alcohol: 10 mg mannitol.

Read all of this leaflet carefully before you start taking ALFUWIN XL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ALFUWIN XL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. WHAT ALFUWIN XL IS AND WHAT IT IS USED FOR

ALFUWIN XL belongs to a group of medicines called alpha-blockers.

ALFUWIN XL can be used to treat the symptoms of **benign prostatic hyperplasia (BPH)**. 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 urine 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 widen 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 (AUR)**. 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.
- During this time, ALFUWIN XL may be used to help the urine to flow again. This has only been shown to help in men aged over 65.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALFUWIN XL

Do not take ALFUWIN XL and tell your doctor if:

- You are allergic (hypersensitive) to alfuzosin hydrochloride or any of the other ingredients of ALFUWIN XL (listed in section 6). Signs of an allergic reaction include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You are taking other alpha-blockers to treat BPH or to treat your blood pressure (see Other medicines and ALFUWIN XL).

- You have or have ever had something called orthostatic hypotension. This is a drop in blood pressure which usually happens when you stand up quickly. It can make you feel dizzy, light-headed or faint when you stand or sit up quickly.
- You have liver problems.
- You have serious kidney problems (see Warnings and precautions).
- You are 18 years old or younger.
- You are taking medicines known as potent CYP3A4 inhibitors such as itraconazole, ketoconazole, protease inhibitors, clarithromycin, telithromycin and nefazodone, since it can increase the blood levels of ALFUWIN XL (see Other medicines and ALFUWIN XL).

Warnings and precautions:

Talk to your doctor or pharmacist before taking your medicine if:

- You have chest pain (angina) or are taking medicine for angina.
- You are taking medicines for high blood pressure. Your doctor should monitor your blood pressure regularly while you are taking this medicine. Some patients, with pre-existing risk factors (such as cardiac disease and/or who are taking medicine for high blood pressure or medicines for chest pain) may experience dizziness, weakness or sweating within a few hours of taking a dose. If this happens, you should lie down until the symptoms have completely disappeared. Let your doctor know as he may decide to adjust your dose. This is particularly important at the start of your treatment as the symptoms may get less severe with continued treatment. The risk of developing these side effects may be greater in elderly patients.
- You have a known problem with the way your heart beats (QT prolongation).
- You are undergoing eye surgery because of cataracts (cloudiness of the lens). Please inform your eye specialist before the operation that you are using or have previously used

ALFUWIN XL. This is because ALFUWIN XL may cause complications during the surgery which can be managed if your specialist is prepared in advance.

- In the past, you have had a large fall in blood pressure while taking an alpha-blocker such as doxazosin and tamsulosin. This could include previous use of ALFUWIN XL (see Other medicines and ALFUWIN XL).

In case of an erection (often painful), unrelated to sexual activity, that persists longer than 4 hours you should contact your doctor or go to a hospital immediately because you may need treatment (see POSSIBLE SIDE EFFECTS).

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

Other medicines and ALFUWIN XL:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take ALFUWIN XL and tell your doctor if you are taking:

- Other alpha-blockers such as doxazosin, prazosin, terazosin or tamsulosin.
- 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).

Tell your doctor or health care provider before taking your medicine if (see Warnings and precautions):

- You are taking any medicine for high blood pressure, as you may get dizzy, weak or start sweating within a few hours of taking ALFUWIN XL. 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).

Operations and tests while taking ALFUWIN 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 ALFUWIN XL before the operation. Your doctor may ask you to stop taking ALFUWIN XL 24 hours before the operation. This is because it can be dangerous as it can lower your blood pressure.
- If you are undergoing eye surgery, please refer to Warnings and precautions section.

ALFUWIN XL with food, drink and alcohol:

Please refer to section 3.

Pregnancy and breastfeeding:

ALFUWIN XL tablets are used only in male patients; hence this section is not applicable.

Driving and using machinery:

You may feel dizzy and weak while taking ALFUWIN XL. If this happens, do not drive or operate any tools or machines (see POSSIBLE SIDE EFFECTS).

ALFUWIN XL contains hydrogenated castor oil. This may cause stomach upset and diarrhoea.

3. HOW TO TAKE ALFUWIN XL

Do not share medicines prescribed for you with any other person.

Always take ALFUWIN XL exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is as follows:

For **benign prostatic hyperplasia:**

- One ALFUWIN XL tablet once a day.

For **acute urinary retention:**

- ALFUWIN XL will be given to you by your doctor on the day you have the catheter inserted.
- You should continue taking ALFUWIN XL once a day.

Swallow the tablets whole with plenty of water. Do not break, crush or chew the prolonged-release tablets – this can affect the release of the medicine into your body.

Take the tablet after a meal.

If you take more ALFUWIN XL tablets than you should:

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre, straight away. Tell the doctor 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 (see section 4 – POSSIBLE SIDE EFFECTS).

If you forget to take ALFUWIN XL:

Do not take a double dose to make up for the forgotten individual doses.

If you stop taking ALFUWIN 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.

4. POSSIBLE SIDE EFFECTS

ALFUWIN XL can have side effects.

Stop taking ALFUWIN 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 that you have an allergic reaction to ALFUWIN XL.
- You have chest pain (angina).
- You have an abnormal, often painful, erection of the penis not related to sexual activity, lasting for longer than 4 hours. This condition can lead to permanent impotence if not properly treated.

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days. Also, tell them if you notice any side effects not listed in this leaflet (see Reporting of side effects).

Frequent side effects:

- feeling dizzy or faint
- headache

- feeling sick (nausea)
- stomach pain
- weakness or tiredness (asthenia).

Less frequent side effects:

- feeling dizzy, light-headed or faint when you stand or sit up quickly (postural hypotension)
- a fast heartbeat (tachycardia) and pounding in the chest and uneven heartbeat (palpitations)
- runny, itchy, stuffy nose and sneezing (rhinitis)
- chest pain (angina)
- drowsiness
- diarrhoea and being sick (vomiting)
- dry mouth
- rash and itching
- flushing
- water retention (may cause swollen arms or legs)
- general feeling of being unwell (malaise)
- abnormal vision.

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 ALFUWIN XL. 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 ALFUWIN XL (see Warnings and precautions).

- Low numbers of blood platelets. Signs may include bleeding from your gums and nose, bruising, prolonged bleeding from cuts, rash (pinpoint red spots called petechia).

Not all side effects reported for ALFUWIN XL are included in this leaflet. Should your general health worsen or if you experience any untoward effect while taking ALFUWIN XL please consult your healthcare provider for advice.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report side effects directly to Sanofi's Pharmacovigilance Unit at Email: za.drugsafety@sanofi.com or Tel: 011 256 3700.

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ALFUWIN XL.

5. HOW TO STORE ALFUWIN XL

Store at or below 25 °C.

Protect from moisture.

Keep tablets in the blister strips until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not take this medicine after the month shown on the pack.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ALFUWIN XL contains:

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

The other ingredients are ethylcellulose, hydrogenated castor oil, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, povidone, hydrated colloidal silica and yellow ferric oxide (E172).

What ALFUWIN XL looks like and contents of the pack:

Round, biconvex, three-layer tablets, with one white layer between two yellow layers.

ALFUWIN XL tablets are packed in printed aluminium foil and clear, colourless, rigid polyvinyl chloride (PVC) film blister strips, inserted into a printed outer cardboard carton containing 30 tablets (3 blister strips of 10 tablets each).

Holder of Certificate of Registration

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