

Date submitted: 8.02.2010 (with CCDSv06-PIL not affected but generated for safety update)
Based on Alfuwin PIL approved 6.07.2009 CCC recommendation: 31.08.2010
1st response (this submission): 11.10.2010
2nd CCC recommendation: 05.04.2011
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PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking XATRAL XL 10 mg

Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.
- XATRAL XL 10 mg 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

XATRAL XL 10 mg (Tablets)

WHAT XATRAL XL 10 mg CONTAINS:

The active substance is alfuzosin hydrochloride. This belongs to a group of medicines called alpha-blockers.

The other ingredients are:

Hypromellose, castor oil, ethylcellulose, ferric oxide yellow, colloidal hydrated silica, magnesium stearate, mannitol, povidone, microcrystalline cellulose.

WHAT XATRAL XL 10 mg IS USED FOR:

XATRAL XL 10 mg 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 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 (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 water and relieves the pain.
- During this time, XATRAL XL 10 mg may be used to help the water to flow again. This has only been shown to help in men aged over 65.

BEFORE YOU TAKE XATRAL XL 10 mg:

Do not take XATRAL XL 10 mg and tell your doctor if:

- You are allergic (hypersensitive) to alfuzosin hydrochloride or any of the other ingredients of XATRAL XL 10 mg. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

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- You are taking other alpha-blockers to treat benign prostatic hyperplasia or if you are taking other medicine to treat your blood pressure (see section on TAKING XATRAL XL 10 mg WITH OTHER MEDICINES).

- 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.

Take special care and check with your doctor before taking XATRAL XL 10 mg if:

- You have chest pain (angina).

- You have a condition where your kidneys are not functioning properly.

- If 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 XATRAL XL 10 mg. This is because XATRAL XL 10 mg 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 and 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.

If you are not sure of any of the above, please talk to your doctor or pharmacist before taking XATRAL XL 10 mg.

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Taking XATRAL XL 10 mg with food and drink:

- Take XATRAL XL 10 mg after a meal.
- You may feel dizzy and weak while taking XATRAL XL 10 mg.

Driving and using machinery:

You may feel dizzy and weak while taking XATRAL XL 10 mg. If this happens, do not drive or operate any tools or machines.

Important information about some of the ingredients of XATRAL XL 10 mg:

- Castor oil: This may cause stomach upset and diarrhoea.

Taking other medicines with XATRAL XL 10 mg:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of XATRAL XL 10 mg with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Do not take XATRAL XL 10 mg and tell your doctor if you are taking:

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

Tell your doctor if you are taking any of the following:

- You are taking any medicine for high blood pressure, as you may get dizzy, weak or start sweating within a few hours of taking XATRAL XL 10 mg. 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.

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- Medicines such as glyceryl trinitrate for chest pain (angina).
- Medicines for fungal infections (such as ketoconazole and itraconazole) and HIV (ritonavir).

Operations and tests while taking XATRAL XL 10 mg:

- 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 XATRAL XL 10 mg before the operation. Your doctor may ask you to stop taking XATRAL XL 10 mg 24 hours before the operation. This is because it can be dangerous as it can lower your blood pressure.

HOW TO TAKE XATRAL XL 10 mg:

Always take XATRAL XL 10 mg exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is as follows:

For benign prostate hyperplasia:

One XATRAL XL 10 mg tablet once a day.

For acute urinary retention:

- XATRAL XL 10 mg will be given to you by your doctor on the day you have the catheter inserted.
- You should continue taking XATRAL XL 10 mg once a day.

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

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If you take more XATRAL XL 10 mg 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.

If you forget to take XATRAL XL 10 mg:

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

Effects when treatment with XATRAL XL 10 mg is stopped:

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.

POSSIBLE SIDE EFFECTS:

XATRAL XL 10 mg can have side effects.

Stop taking XATRAL XL 10 mg 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 XATRAL XL 10 mg.
- You have chest pain (angina).
- You have a painful erection of the penis not related to sexual activity, which will not go away.

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.

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Frequent side effects:

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

Less frequent side effects:

- 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.

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- 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 XATRAL XL 10 mg.

Not all side effects reported for XATRAL XL 10 mg are included in this leaflet. Should your general health worsen while taking XATRAL XL 10 mg please consult your doctor, pharmacist or healthcare professional for advice.

STORAGE AND DISPOSAL OF XATRAL XL 10 mg:

Store below 25 °C. Protect from moisture.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not take this medicine after the month shown on the pack. Store in the original container.

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

PRESENTATION:

Blister pack of 30 tablets.

IDENTIFICATION OF XATRAL XL 10 mg:

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

REGISTRATION NUMBER OF XATRAL XL 10 mg:

35/5.2/0074

NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

sanofi-aventis south africa (pty) ltd.

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2 Bond Street

Midrand

1685

South Africa

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