

Prolonged release tablets

alfuzosin

sanofi aventis

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this package leaflet :

1. WHAT XATRAL XL 10 mg, prolonged-release tablets ARE AND WHAT THEY ARE USED FOR
2. BEFORE YOU USE XATRAL XL 10 mg, prolonged-release tablets
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1. WHAT XATRAL XL 10 mg prolonged-release tablets ARE AND WHAT THEY ARE USED FOR

ALPHA-BLOCKERS

This medicine belongs to the alpha-blocker class of drugs. This medicine is used for the symptomatic treatment of the functional signs of benign hypertrophy (increase in volume) of the prostate.

This medicine is also used as adjunctive treatment for bladder catheterization in acute urinary retention associated with benign hypertrophy of the prostate.

2. BEFORE YOU TAKE XATRAL XL 10 mg prolonged-release tablets

Never take Xatral XL 10 mg prolonged-release tablets in the following cases:

- known allergy to alfuzosin and/or any of the other ingredients of this medicine,
- postural hypotension (feeling of dizziness, usually occurring when moving from the lying to standing position),
- impaired liver function (liver failure),
- severely impaired kidney function,
- in combination with ritonavir.

Take special care with XATRAL XL 10 mg, prolonged-release tablets:

Warnings

Some patients may be particularly sensitive to **XATRAL XL 10 mg**, leading to a drop in blood pressure when moving from the lying to the standing position. This effect may develop in the first few hours after taking the medicine and be accompanied by the following symptoms: dizziness, fatigue, sweating.

Patients must remain lying down until complete disappearance of these symptoms, which are temporary. Caution is recommended, particularly in the elderly and in subjects having experienced a marked drop in blood pressure after taking a medicine from the same class (alpha-blockers).

Intraoperative Floppy Iris Syndrome (IFIS):

If you are going to have cataract surgery (due to an opaque lens) in the near future and if you have been or are currently being treated with **Xatral XL 10 mg**, tell your ophthalmologist before the operation. This medicine can cause a side effect that may lead to complications during surgery. However, if the surgeon is warned in advance, he/she will take the necessary precautions, depending on your treatment, during the operation.

This medicine contains castor oil, which can cause digestive disorders (mild laxative effect, diarrhea).

Precautions when taking Xatral XL 10 mg prolonged-release tablets

Inform your doctor if you have heart disease, in particular if you have coronary artery disease.

Taking or using other medicines

IN ORDER TO AVOID ANY INTERACTION BETWEEN DIFFERENT MEDICINAL PRODUCTS, particularly certain medicines used for blood pressure or certain antifungal agents (ketoconazole, itraconazole) or certain antibiotics (clarithromycin, erythromycin), **YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENTS YOU MAY BE TAKING.**

Pregnancy and breast-feeding

This medicine is not used in women.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

The attention of drivers and machine operators is drawn to the potential risks of postural hypotension (drop in blood pressure when standing up, sometimes accompanied by dizziness), sensations of dizziness, fatigue or visual disturbances, especially at the start of treatment.

Excipient with specific effects: hydrogenated castor oil.

3. HOW TO USE Xatral XL 10 mg prolonged-release tablets

How Xatral XL 10 mg prolonged-release tablets should be taken
Oral use.

How many Xatral XL 10 mg prolonged-release tablets should be taken.

The usual dosage is 1 tablet per day, to be taken immediately after the evening meal.

The tablet must be swallowed whole with a glass of water. The tablets must not be crunched, chewed, crushed or ground into a powder.

In the event of catheterization, the tablet should be taken from the first day of urethral catheterization.

If you have the impression that the effect of **XATRAL XL 10 mg, prolonged-release tablets** is too strong or too weak, talk to your doctor or pharmacist.

If you take more XATRAL XL 10 mg, prolonged-release tablets than you should:

Contact your doctor or your pharmacist immediately.

If you forget to take XATRAL XL 10 mg, prolonged-release tablets:

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Xatral XL 10 mg prolonged-release tablets** can cause side effects.

Common effects:

- lightheadedness, dizziness, fainting, headache,
- digestive disorders such as nausea, stomach pain,
- feeling of fatigue.

Uncommon effects:

- dizzy spells, drowsiness,
- drop in blood pressure when moving from the lying to the standing position,
- accelerated heart rate, palpitations, syncope,
- diarrhea, dry mouth,
- nasal congestion,
- skin reactions, such as rashes or itching,
- redness of the face, oedema, chest pain.

Very rare effects:

- angina pectoris in patients with a history of coronary artery disease (see section "Precautions when taking Xatral XL 10 mg prolonged-release tablets"),
- hives, angioedema.

Effects of unknown frequency:

- hepatitis, particularly due to biliary tract obstruction,
- painful, prolonged erection.

If you notice any side effects not mentioned in this package leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE Xatral XL 10 mg prolonged-release tablets

Keep out of the reach and sight of children.

Do not use Xatral XL 10 mg prolonged-release tablets after the expiry date printed on the box.

Store at a temperature not exceeding 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Xatral XL 10 mg prolonged-release tablets contains?

The active substance is:

alfuzosin hydrochloride 10 mg

The other ingredients are: hypromellose, hydrogenated castor oil, ethylcellulose, yellow iron oxide (E 172), colloidal hydrated silica, magnesium stearate, mannitol, povidone, microcrystalline cellulose, for one prolonged-release tablet.

How are Xatral XL 10 mg prolonged-release tablets supplied and what are the contents of the outer packaging?

Prolonged-release tablets (boxes of 30 or 50).

Marketing Authorization Holder and Operating Company

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This leaflet was last approved on March 2009.