

Xatral PIL

1. What this product is and what it is used for

Xatral contains alfuzosin. This medicine belongs to a group of medicines called alpha-blockers. It has an effect on the bladder, the tube which takes urine outside of the body (the urethra) and the prostate.

Xatral is used when your prostate is enlarged (benign prostatic hypertrophy):

- to make it easier to urinate,
- or in addition to the urine being drained using a catheter in your bladder, when it is impossible to urinate.

This medicine is for use in men only.

2. What you need to know before you use this product

Contraindications

Do not take Xatral:

- if you are allergic to alfuzosin or any of the other ingredients of this medicine listed in section 6,
- If you have orthostatic hypotension (drop in blood pressure when standing up, possibly with dizziness and/or fainting).
- If you have a serious liver disease (liver failure) or a serious kidney disease (severe kidney failure).
- If you are taking certain medicines used to treat hepatitis C (such as ombitasvir and paritaprevir), see section "Other medicines and Xatral".

Warnings and precautions

Talk to your doctor or pharmacist before taking Xatral.

Before beginning treatment, inform your doctor if you have heart disease (particularly if you have angina pectoris, acute heart failure or heart rhythm problems) or if you have ever experienced a significant drop in blood pressure with another medicine from the same group

of medicines as Xatral (alpha-blockers).

During treatment

Orthostatic hypotension (drop in blood pressure when standing up) may develop in the first few hours after taking the medicine and be accompanied by dizziness, tiredness or sweating.

If this occurs, lie down until these symptoms, which are temporary, completely wear off, and contact your doctor.

This effect is seen particularly in elderly patients or patients who are also taking medicine to treat high blood pressure or nitrate derivatives (medicines used for angina pectoris).

This medicine must be used with caution in patients with blood flow problems in the brain, particularly elderly patients.

Contact your doctor immediately if you experience painful prolonged erection.

You should avoid using this medicine in combination with medicines used to treat high blood pressure (antihypertensives such as doxazosin, prazosin and urapidil) (see section "Other medicines and Xatral").

If you are going to have eye surgery (on a cataract) tell your ophthalmologist before the operation if you have recently been or are currently being treated with Xatral. This medicine can have an effect on the pupil (intraoperative floppy iris syndrome) that may lead to complications during surgery.

However, if the surgeon is warned in advance, he or she will take the necessary precautions.

This medicinal product contains castor oil, which can cause gastrointestinal disorders (mild laxative effect, diarrhea).

Other medicines and Xatral

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must not take this medicine in combination with certain medicines used to treat

- hepatitis C (e.g. ombitasvir and paritaprevir) (see section "Do not take Xatral").

You should avoid taking this medicine in combination with certain medicines used to treat

- high blood pressure (antihypertensives such as doxazosin, prazosin and urapidil),
- HIV (e.g. protease inhibitors combined with ritonavir or cobicistat),
- hepatitis C (e.g. telaprevir, boceprevir),
- some fungal infections (e.g. itraconazole, posaconazole),
- Cushing's syndrome (when the body produces too much cortisol), orally-administered ketoconazole,
- some bacterial infections (e.g. clarithromycin, erythromycin, telithromycin)
- depression, such as nefazodone (see section "Warnings and precautions").

Pregnancy, breast-feeding and fertility

This medicine is not intended for use in women.

Driving and using machines

You must take care if you drive a vehicle or use machines.

This medicine can cause a significant drop in blood pressure when standing up, along with dizziness, tiredness or vision disorders, especially at the start of treatment.

3. How to use this product.

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Dosage

The usual dosage is one tablet daily, to be taken immediately after the evening meal.

Your doctor will tell you how long you should take the medicine for.

If you use a urinary catheter, take this medicine from the first day the catheter is inserted.

Method of administration

This medicine must be swallowed whole with a glass of water. These are prolonged-release tablets, i.e. the active ingredient diffuses slowly inside your body.

For the tablets to retain all their properties, you should not crunch, chew, crush or grind them into a powder.

Use in children

Xatral must not be taken by children aged between 2 and 16 years.

If you take more Xatral than you should:

Talk to your doctor or go to the emergency room immediately.

If you forget to take Xatral:

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

4. Possible side effects

Like all medicines, Xatral can cause side effects, although not everybody gets them.

Common:

- Lightheadedness, dizzy spells, fainting, headache,
- Digestive disorders such as nausea, stomach pain,
- Tiredness.

Uncommon:

- Dizziness, drowsiness, syncope (sudden loss of consciousness),
- Drop in blood pressure when standing up from a lying position (see section "Warnings and precautions"),
- Accelerated heart rate, palpitations,

- Diarrhea,
- Vomiting,
- Dry mouth,
- Nasal congestion or runny nose (rhinitis),
- Outbreak of spots on the skin or itching,
- Swelling, chest pain,
- Redness of the face.

Very rare:

- Angina pectoris in patients with a history of coronary artery disorders (see section "Warnings and precautions"),
- Hives, sudden swelling of an organ, the face and/or the neck that can make it difficult to breathe and be life-threatening to the patient (angioedema),

Not known:

- Liver disease (hepatitis), due to biliary tract obstruction,
- Painful, prolonged erection,
- Floppy pupil during cataract surgery (see section "Warnings and precautions"),
- Irregular heartbeat (atrial fibrillation),
- Decreased number of white blood cells (neutropenia),
- Decreased number of platelets (thrombocytopenia),
- Stroke (not enough blood flow to the brain).

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

5. How to store this product

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 box.

Do not store above 30°C.

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. Further information

a. What this product contains

- The active substance is:

Alfuzosin hydrochloride.....

10 mg

For one prolonged-release tablet.

- The other ingredients are: hypromellose, hydrogenated castor oil, ethyl cellulose, yellow iron oxide, colloidal hydrated silica, magnesium stearate, mannitol, povidone, microcrystalline cellulose.

b. What this product looks like and contents of the pack

This medicine is supplied as prolonged-release tablets. Box of 30 tablets.

c. Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

Sanofi-aventis France

82, avenue Raspail

94250 Gentilly

France

Manufacturer

SANOFI WINTHROP INDUSTRIE

30-36, avenue Gustave Eiffel

37100 Tours - France

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