

Xatral[®] 2,5 mg

film-coated tablet

Please read all of the leaflet carefully before taking this medicine.

- Keep this leaflet you may need to read it again.
- If you have any other questions or doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed personally for you. Do not give it to anybody else, even if he has identical symptoms since it might cause harm to him.
- 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 leaflet :

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1. WHAT XATRAL 2,5 mg film-coated tablets ARE AND WHAT THEY ARE USED FOR

ALPHA-BLOCKERS.

This medicine belongs to the alpha-blocker class of drugs.

This medicine is recommended in the symptomatic treatment of the functional signs of benign prostatic hypertrophy (increase in volume) of the prostate.

2. BEFORE YOU TAKE Xatral 2.5 mg film-coated tablets

If your doctor has informed you that you have an intolerance to certain sugars, contact him/her before taking this medicine.

Never take Xatral 2.5 mg film-coated 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);
- severely impaired liver function (liver failure);
- severely impaired kidney function;
- in combination with ritonavir.

Take special care with Xatral 2.5 mg film-coated tablets:

Warnings

Some patients may be particularly sensitive to **Xatral 2.5 mg** leading to a drop in blood pressure when standing up. 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 2.5 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 lactose. You should not take it if you are lactose intolerant (rare hereditary disease).

ALWAYS KEEP OUT OF THE REACH OF CHILDREN

Precautions for use

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), ritonavir, or certain antibiotics (clarithromycin, erythromycin), YOU MUST INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER ONGOING TREATMENTS.

Pregnancy and breast-feeding

This medicine is not used in women.

AS A GENERAL RULE, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE IF YOU ARE PREGNANT OR BREASTFEEDING.

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

Lactose monohydrate.

3. HOW TO USE Xatral 2.5 mg film-coated tablets

How many Xatral 2.5 mg film-coated tablets should be taken

The usual dosage is 1 tablet three times daily.

In the elderly or patients taking medication for high blood pressure or with impaired liver function, this dosage may be adjusted.

How Xatral 2.5 mg film-coated tablets should be taken

Oral use. The tablet must be swallowed whole with a glass of water.

When and how often Xatral 2.5 mg film-coated tablets should be taken

According to your doctor's prescription.

How long Xatral 2.5 mg film-coated tablets should be taken

Do not discontinue treatment without first consulting your doctor.

If you take more Xatral 2.5 mg film-coated tablets than you should

Contact your doctor.

If you forget to take Xatral 2.5 mg film-coated tablets

Do not take two or several tablets at the same time, but take your next dose as normal.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Xatral 2.5 mg film-coated tablets** can cause side effects.

Common effects:

- lightheadedness, dizziness, dizzy spells, fainting, drop in blood pressure when standing up, headache;

- digestive disorders such as nausea, stomach pain or diarrhea, dry mouth;
- feeling of fatigue.

Uncommon effects:

- drowsiness;
- vision disorders;
- accelerated heart rate, palpitations, syncope;
- 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 for use");
- 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, or if certain side effects become serious, please inform your doctor or pharmacist.

5. HOW TO STORE Xatral 2.5 mg film-coated tablets

Keep out of the reach and sight of children.

Do not use Xatral 2.5 mg film-coated tablets after the expiry date printed on the box.

Store at a temperature not exceeding 30°C.

Store the heat-formed blister packs in the outer packaging, protected from light and moisture.

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 2.5 mg film-coated tablets contains

The active substance is:

alfuzosin hydrochloride.....2.5 mg

The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate, for one film-coated tablet.

Film coating: hypromellose, macrogol 400, titanium dioxide (E 171).

How are Xatral 2.5 mg film-coated tablets supplied and what are the contents of the outer packaging?

Film-coated tablets (box of 30).

Marketing Authorization Holder and Operating Company

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1-13, boulevard Romain Rolland

75014 Paris, France

Manufacturer

Sanofi Winthrop Industrie

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