PATIENT MEDICATION INFORMATION

PrXATRAL®
Alfuzosin Hydrochloride
Prolonged-release tablet

This leaflet is part III of a three-part "Product Monograph" published when XATRAL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XATRAL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Your doctor has prescribed XATRAL because you have a medical condition called benign prostatic hyperplasia (BPH) or acute urinary retention (AUR) related to BPH. This occurs in men.

What it does:
XATRAL relaxes muscles in the prostate, bladder neck and base. This results in improved urine flow, and reduced BPH symptoms.

When taken during catheterization for sudden acute urinary retention, XATRAL may help you pass urine after catheter removal. Urinary catheters are flexible tubes placed in the bladder to drain urine.

When it should not be used:

- If you have ever had an allergic reaction to alfuzosin hydrochloride or to any ingredient in XATRAL (see below "**What the important nonmedicinal ingredients are** :").
- If you have a moderate to severe decrease in liver function.
- If you take other alpha1-blockers for high blood pressure or prostate problems.
- If you take ketoconazole, ritonavir (Kaletra®; Norvir®) or itraconazole (Sporanox®).

What the medicinal ingredient is:
alfuzosin

What the important nonmedicinal ingredients are:
colloidal hydrated silica, ethylcellulose, hydrogenated castor oil, hydroxypropyl methylcellulose, magnesium stearate, mannitol, microcrystalline cellulose, povidone, yellow ferric oxide.

What dosage forms it comes in:
Prolonged-release tablets. Each tablet contains 10 mg alfuzosin hydrochloride.

WARNINGS AND PRECAUTIONS

XATRAL is not indicated as a treatment to lower blood pressure.

XATRAL is not indicated nor recommended for use in women and children.

Prostate cancer and BPH cause many of the same symptoms. Prior to starting XATRAL, your doctor will examine you to rule out the presence of prostate cancer.

You (in particular, if you are receiving drugs to lower blood pressure) may experience low blood pressure and feel dizzy at the start of treatment, especially when getting up from a lying or sitting position or if you are elderly. In such cases, lie down until the symptoms have completely disappeared.

Tell your doctor or pharmacist, before using the medication, if:

- you suffer liver or kidneys problems
- you suffer from heart problems
- you have ever had a reaction to the ingredients of this medication
- you have had low blood pressure or signs of low blood pressure [fainting, dizziness] after taking another medicine
- you or any family members have a condition known as congenital prolongation of the QT interval
- you have suffered from QT prolongation following the administration of any drug
- you have a family history of sudden death at an age < 50 years
- you have suffered from electrolytes disturbances

If you will have eye surgery, you must inform your eye surgeon that you are currently using XATRAL.

INTERACTIONS WITH THIS MEDICATION

XATRAL is metabolized by specific enzymes in the liver. It is not known how combined use of any drugs, herbal products metabolized by the same enzymes or grapefruit juice may influence the efficacy or unwanted side effects of these drugs or herbal medicines.

Before using any prescription, over-the-counter medicines or herbal products, check with your doctor or your pharmacist.

Drugs that interact with XATRAL include:

- Alpha1-blockers for high blood pressure or prostate problems
- Anti-infection drugs: ketoconazole, itraconazole (Sporanox®) and ritonavir (Kaletra®; Norvir ®)
- Drugs for high blood pressure
- Drugs for heart problems (nitrates)
- Sildenafil (Viagra®, Revatio®)

PROPER USE OF THIS MEDICATION

Usual dose:

Follow your doctor's instructions very carefully about how to take XATRAL.

The recommended dosage is one tablet (10 mg) daily to be taken right after the same meal each day or from the first day of catheterization. The tablet should be swallowed whole.

DO NOT CHEW, CRUSH, POUND, GRIND OR CRUNCH THE TABLET AS HIGH BLOOD LEVELS OF XATRAL MAY OCCUR.

If you interrupt your treatment for several days or more, resume treatment after consulting with your doctor.

Overdose:

If you have taken too much XATRAL, immediately see your doctor or go to your nearest hospital emergency department or contact poison control centre. Show the doctor your bottle of tablets. Do this even if there are no signs of discomfort or poisoning. Overdose of alfuzosin may lead to low blood pressure.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all prescription drugs, XATRAL may cause side effects. Most side effects are mild.

Side effects due to XATRAL may include dizziness and headache. In some cases, side effects may decrease or disappear while the patient continues to take XATRAL.

You may experience dizziness or fainting caused by a decrease in blood pressure after taking XATRAL. However, these effects are usually transient, occur at the beginning of treatment and do not usually prevent the continuation of treatment. In such cases, lie down until the symptoms have completely disappeared. Although these symptoms are unlikely, do not drive, operate machinery or perform hazardous tasks for 12 hours after the initial dose.

Cases of liver disorder have been observed in patients taking XATRAL. You should inform your doctor if you experience symptoms such as nausea, fatigue, jaundice (yellow colour to the skin and/or eyes), dark urine, light-coloured stools, generalised itching or abdominal pain.

Cases of priapism (painful erection greater than 6 hours) have been rarely reported with the use of XATRAL®. If you experience painful erection lasting more than 4 hours, you should contact your doctor immediately. If priapism is not immediately treated, penile tissue damage and erectile dysfunction could result.

Cases of atrial fibrillation (irregular heart beat) have been reported with the use of XATRAL®.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	**Headache**	√		
	Dizziness	√		
Uncommon	**Fainting**		√	
	Liver disease		√	
	Priapism/erection lasting longer than 4 hours			√
	Irregular heart beat			√
	Low Blood Pressure: dizziness, fainting, lightheadedness	√		
	Stroke: blurred vision, difficulty speaking, weakness on one side of your face or body.			√

This is not a complete list of side effects. For any unexpected effects while taking XATRAL, contact your doctor or pharmacist.

HOW TO STORE IT

XATRAL tablets should be stored at room temperature (15-30°C).

Keep XATRAL out of reach and sight of children.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
- Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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Sporanox® is manufactured by Janssen Inc.
Kaletra® and Norvir® are manufactured by AbbVie Corporation
Viagra® and Revatio® are manufactured by Pfizer Canada Inc.