

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

<sup>Pr</sup>**APO-ALFUZOSIN**  
**Alfuzosin Hydrochloride Prolonged-Release**  
**Tablets, 10 mg**

This leaflet is part III of a three-part “Product Monograph” published when APO-ALFUZOSIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-ALFUZOSIN. 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 APO-ALFUZOSIN 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:

APO-ALFUZOSIN 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, APO-ALFUZOSIN 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 APO-ALFUZOSIN (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<sup>®</sup>; Norvir<sup>®</sup>) or itraconazole (Sporanox<sup>®</sup>).

Sporanox<sup>®</sup> is manufactured by Janssen-Ortho Inc. Kaletra<sup>®</sup> and Norvir<sup>®</sup> are manufactured by Abbott Laboratories Ltd.

##### What the medicinal ingredient is:

alfuzosin

##### What the important nonmedicinal ingredients are:

hydroxypropyl methylcellulose, polyvinyl acetate phthalate, dibasic calcium phosphate dihydrate magnesium stearate, and yellow ferric oxide.

##### What dosage forms it comes in:

Prolonged-release tablets. Each tablet contains 10 mg alfuzosin hydrochloride.

#### WARNINGS AND PRECAUTIONS

APO-ALFUZOSIN is not indicated as a treatment to lower blood pressure.

APO-ALFUZOSIN is not indicated nor recommended for use in women and children.

Prostate cancer and BPH cause many of the same symptoms. Prior to starting APO-ALFUZOSIN, 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. 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 APO-ALFUZOSIN.

### **INTERACTIONS WITH THIS MEDICATION**

APO-ALFUZOSIN 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 APO-ALFUZOSIN include:

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

Sporanox<sup>®</sup> is manufactured by Janssen-Ortho Inc. Kaletra<sup>®</sup> and Norvir<sup>®</sup> are manufactured by Abbott Laboratories Ltd. Viagra<sup>™</sup> and Revatio<sup>™</sup> are manufactured by Pfizer Canada Inc.

### **PROPER USE OF THIS MEDICATION**

#### **Usual dose:**

Follow your doctor's instructions very carefully about how to take APO-ALFUZOSIN.

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 APO-ALFUZOSIN MAY OCCUR.**

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

#### **Overdose:**

In the event of overdosage, contact your doctor, hospital emergency department or regional Poison Control Centre.

If you have taken too much APO-ALFUZOSIN, immediately see your doctor or go to your nearest hospital emergency department. 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.

### **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all prescription drugs, APO-ALFUZOSIN may cause side effects. Most side effects are mild. Side effects due to APO-ALFUZOSIN may include dizziness and headache. In some cases, side effects may decrease or disappear while the patient continues to take APO-ALFUZOSIN.

You may experience dizziness or fainting caused by a decrease in blood pressure after taking APO-ALFUZOSIN. 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 alfuzosin hydrochloride. 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, generalized itching or abdominal pain.

### 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		* *	

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

### HOW TO STORE IT

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

Keep APO-ALFUZOSIN out of reach of children.

### REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax 866-678-6789

Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:

Canada Vigilance National Office

Marketed Health Products Safety and Effectiveness Information Bureau

Marketed Health Products Directorate

Health Products and Food Branch

Health Canada

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

*NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.*

### MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at:

<http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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