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UROXATRAL® (ALFUZOSIN HCL) EXTENDED-RELEASE TABLETS FASTEST-GROWING BPH TREATMENT PRESCRIBED BY UROLOGISTS

Delivers Powerful Efficacy with a Proven Safety Profile

More than 50 percent of all men over the age of 60 have benign prostatic hyperplasia (BPH), and that number increases to 90 percent of men over age 70 (*1*). In addition to coping with urinary symptoms such as frequent urination, incomplete emptying of the bladder, nocturia, and urgency, men with BPH are at risk for compromised sexual function (*2,3*). In fact, urinary symptoms associated with BPH are linked to sexual problems and may make sexual function worse (*3*). **Uroxatral**® (alfuzosin HCl), manufactured by Sanofi-Aventis, is a once-daily, clinically uroselective alpha$_1$-blocker that provides effective symptom relief with a proven safety profile in patients with BPH.

According to Steven Kaplan, MD, Professor of Urology, Vice Chairman of the College of Physicians and Surgeons at Columbia University, "while urinary symptoms associated with BPH are linked to sexual problems or could make them worse, there are clinical studies to show that patients taking Uroxatral experience overall symptom relief."

Managing BPH can be a challenge for both physicians and patients. While some clinicians consider the sexual side effects secondary to the effective treatment of BPH, one large study—The Multinational Survey of the Aging Male—found that the majority of older men surveyed consider an active sex life to be important. Researchers surveyed 14,000 men between 50 and 80 years of age in seven countries including the US, and found that 59 percent of the respondents were bothered by Ejaculatory Dysfunction (EjD) and 78 percent were bothered by Erectile Dysfunction (ED)(*4*).

A recent change in labeling in the popular erectile dysfunction drug, Cialis® (tadalafil) has removed a contraindication for use with alpha-blockers, which allows that Uroxatral can now be administered in combination with Cialis when used with appropriate caution.

Since its introduction into the US marketplace in 2003, Uroxatral has become the fastest-growing medical treatment with urologists for BPH (*5*). Studies have demonstrated that Uroxatral provides rapid relief and that patients taking Uroxatral have not only shown improvement in peak urine flow rate within eight hours of the first dose (*6*), but have also experienced significant overall improvements in BPH symptoms (*7*). Uroxatral shown consistent improvement in both irritative and

obstructive BPH symptoms as measured by the International Prostate Symptom Score (IPSS), indicating a reduction of symptom severity (*6*).

Results of a randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of Uroxatral 10 mg once daily vs. placebo in 625 men with symptomatic BPH showed that 81 percent of patients reported overall symptom relief (*7*). A pooled analysis of three double-blind, placebo-controlled studies found that Uroxatral resulted in a statistically significant reduction in nocturia at 12 weeks ($p = .04$ vs. placebo), significant improvement in quality of life at 12 weeks (27.8 percent improvement in IPSS Bother Score, $p < .001$ vs. placebo), and significant improvement in peak urine flow at day 84 ($p < .001$) (*7*). Uroxatral allows patients to sleep with fewer interruptions at night and to feel more in control of their symptoms.

Uroxatral is associated with a low incidence of vasodilatory side effects; there were no significant changes in the blood pressure among elderly or hypertensive patients. Approximately 20-30 percent of patients in the clinical trial were on antihypertensive medications (*6*).

Important safety information

Uroxatral is contraindicated in patients with moderate or severe hepatic insufficiency and therefore should not be used in these patients. Uroxatral should not be administered with potent CYP3A4 inhibitors and therefore should not be used in combination with drugs such as ketoconazole, itraconazole, or ritonavir.

Postural hypotension with or without symptoms (e.g., dizziness) may develop within a few hours following administration of Uroxatral. As with all alpha-blockers, there is a potential for syncope. Patients should be warned of the possible occurrence of such events and should avoid situations where injury could result should syncope occur.

Uroxatral (alfuzosin HCl) should be used with caution in patients with severe renal insufficiency, and should not be prescribed to patients with a known history of QT prolongation or to patients who are taking medication known to prolong QT.

The most common side effects are dizziness, upper respiratory tract infection, headache, and fatigue.

For more information concerning **Sanofi-Synthelabo** (New York, NY), call 1-212-551-4000, or for full prescribing information, visit the company's Web site at www.uroxatral.com.

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