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Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00575913
		Study Code:	L_8935
Generic drug name:	Alfuzosin	**Date:**	18/Dec/2007

Title of the study:	Alfuzosin XL-Lower Urinary Tract Symptoms Efficacy and Sexuality Study (L_8935)
Investigator(s):	Name: Dr. Apichat Kongkanand Address: Division of Urology, Department of Surgery, Chulalongkorn University, King Chulalongkorn Memorial Hospital, Rama IV Road, Bangkok, Thailand.
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Study center(s):	Number of active centers: 8 Name of the country: Thailand
Publications (reference):	Not applicable

Study period: Date first **patient/subject** enrolled: 01-Sep-2003 Date last **patient/subject** completed: 31-Mar-2005	**Phase of development:** Observational Phase IV

Objectives:	To assess, under daily practice conditions, the safety profile and the efficacy of a new formulation of alfuzosin administered once daily (Xatral XL®) in patients with lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH). To assess the occurrence of acute urinary retention and need for BPH surgery among these patients.

Methodology:	Non comparative, multicentre, observational study conducted among urologists for 6 months		
Number of patients/subjects:	Planned: 120	Enrolled: 118	Treated: 118
Evaluated:	Efficacy: 117	Safety: 118	
Diagnosis and criteria for inclusion:	• Ambulatory patients suffering from LUTS suggestive of BPH • Signed informed consent to participate in the study		
Investigational product: Dose: Administration:	Alfuzosin (Xatral XL®) 10 mg One tablet per day after evening meal		
Duration of treatment: Treatment duration with alfuzosin: 6 months	**Duration of observation:** 4 Visits planned: inclusion visit (D0), 2 intermediated visits (D14, M3), end-point visit (M6)		
Reference therapy: Dose: Administration:	This was open-label, non-comparative study so no reference therapy for this study. Not applicable Not applicable		
Criteria for evaluation:			
Efficacy:	• International Prostate Symptom Score (IPSS) and quality of life index • DAN-PASS sexual function questionnaire • Maximum flow rate • PSA levels measured at baseline		
Safety:	• Spontaneously reported adverse events • Blood pressure and heart rate measured in sitting position • Lab: BUN, Creatinine, SGOT, SGPT in serum and urinalysis		
Statistical methods:	The primary efficacy population is the Intent to Treat (ITT) population composed with all included patients who have at least one study drug intake and at least one evaluation of the primary criterion at D0 and after baseline. The secondary efficacy population is the Per Protocol (PP) population composed with all evaluable patients i.e. those from the ITT population who have no major protocol violations. For the quantitative variables, the descriptive statistics will be the mean, standard deviation, min, max, n and/or, if relevant, median and quartiles. The descriptive statistics used for the qualitative criteria will be n and percentages Safety analysis will be performed on all exposed patients, on adverse events occurring during the study and not present before the administration of the study drug. The number (%) of patients experiencing AUR or undergoing surgery during the study will be provided.		

Summary: Efficacy results:	A total of 118 ambulatory males suffering from LUTS suggestive of BPH were enrolled. There was significant symptomatic improvement on I-PSS scale from 18.25 at D0 to 8.95 at M6 (mean change of -9.3 from baseline, P<0.01) and QOL index score from 4.5 at D0 to 1.54 at M6 (mean change of -2.96 from baseline, P<0.01). Alfuzosin also significantly improved sexual function, as measured by changes in symptom from 3.18 at D0 to 2.46 at M6 (mean change of -0.72 from baseline, P<0.05) as well as bother from 2.23 at D0 to 1.10 at M6 (mean change of -1.13 from baseline, P<0.01) subscores on DAN-PSS sex questionnaire. Approximately 74% patients showed onset of improvement within 2 weeks from start of alfuzosin treatment. The mean flow rate improved from 6.69 mL/sec at D0 to 7.61 mL/sec at M6 (P<0.01). The maximum flow rate also improved, but the change was not significant.
Safety results:	Treatment was well tolerated, with one or more AEs observed in 22% patients. Dizziness (7.6%) was the most common AE. There were 5 (4.23%) serious AEs – one of them treatment-related, and 10 (8.5%) patients discontinued treatment due to AEs. Only one case of AUR and no cases of AUR-related surgery were reported during the 6-month treatment period.
Date of report:	02-Oct-2007