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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:**	NCT00542165
		Study Code:	L_8819
Generic drug name:	Alfuzosin	**Date:**	10/Oct/2007

Title of the study:	"Multicenter prospective study on the changes of sexual function following treatment with alfuzosin (Xatral XL®) in patients with benign prostatic hypertrophy"
Investigator(s):	Coordinating Investigator: Prof. Tae-Young Ahn Dept. of Urology, Asan Medical Center, Seoul, Korea,
Study center(s):	Multicenter (11 sites) study
Publications (reference):	SIU (abstract no. 388.0) in 2006
Study period: Study Initiation Date: 3-Mar-2004 Study Completion Date: 30-Dec-2004	**Phase of development:** Phase IV
Objectives:	1. Primary : To collect, under daily practice conditions, clinical data on the changes of sexual function when a new formulation of alfuzosin (Xatral XL®) is administered once daily in patients with lower urinary tract symptoms (LUTS) suggestive of prostatic hypertrophy. 2. Secondary : -to investigate the erectile dysfunction frequency among BPH patients -to investigate the change of sexual function according to the change of lower urinary symptoms

Methodology:	This is an open, non-comparative, multicenter, 3-month observational study conducted among urologists in Korea. There was no pre-inclusion or wash-out period. Patients included in the trial received one tablet of alfuzosin at the end of an evening meal for 3 months. 3 visits was done: an inclusion visit (D0), intermediate visit (M1) and final visit (M3). If necessary, visits took place +/- 14 days before or after the theoretical dates, calculated from the D0 visit.
Number of patients/subjects:	A total of 203 subjects from 11 study centers participated in the study, and all of them administered at least one dose of study drug. Subject of 203 patients participating in the study, 166 patients were completed and 37 patients were withdrawn. The reasons for early withdrawal include failure to follow-up with 5.4% (11 patients), others with 4.9% (10 patients), adverse events with 4.4% (9 patients) and lack of efficacy with 1.5% (3 patients). Of those reasons, others include the withdrawal of consent and violation of protocol inclusion/exclusion criteria.

Diagnosis and criteria for inclusion:	Inclusion criteria Patients satisfying the following criteria were included: 1. male patient suffering from LUTS lasting 6 months and over 2. male patient aged 50 years old and over who has a continuous active partner 3. Signed informed consent to participate in the study Exclusion criteria 1. Patients not suitable for participating in the study according to the individual judgment of the investigator such as unstable medical state , mental disorder, drug or alcohol abuse 2. Primary hypogonadism and neuropathy patients 3. History of prostate surgery 4. Patients with prostate cancer 5. History of organ surgery or organ damage in pelvis 6. History of myocardial infarction, stroke, and life threatening arrhythmia within last 6 months 7. Patients with haematuria caused by other reasons except BPH 8. Patients with uncontrolled hypertension in spite of treatment with antihypertensive agents 9. History of a malignant tumor within last 5 years 10. Patients who are currently controlled with other medication for erectile dysfunction 11. Patients who have been administered with androgen or anti-androgen 12. Patients who is treated for psychiatric disorder or depression 13. Combination with other alpha1-blockers 14. Patients previously not improved by an alpha1-blocker treatment 15. Known hypersensitivity to the alfuzosin 16. History of postural hypotension or syncope 17. Hepatic insufficiency 18. Unstable angina pectoris Contraindication of study drug was reflected in exclusion criteria.
Investigational product: Dose:	Alfuzosin 10 mg (XATRAL XL® one tablet) once daily after evening meal

Duration of treatment: 3-month treatment period	**Duration of observation:** 3-month treatment period

Refernce therapy:	NA
Criteria for evaluation:	Safety: • Spontaneously reported adverse events • Blood pressure and heart rate measured in sitting position Efficacy: • IIEF and GEQ (Global Efficacy Question) to be filled by patient • IPSS and Quality of Life Score to be filled by patients • Maximum Flow Rate and Post Voiding Residual Urine
Statistical methods:	No special statistical analysis was planned for this study. However, a descriptive statistical analysis was conducted
Summary:	First patient entered the study on 3 Mar 2004 and the last patient completed the study on 30 Dec 2004. (9month of patients enrolled and 3 month for follow-up of patients) All efficacy assessments, except the assessment of the post void residual urine at Month 3, indicated that there are statistically significant changes between pre-treatment and post-treatment. Most of efficacy assessment parameters including IIEF score, GEQ score, IPSS, QOL score and the maximum flow rate indicated that the symptoms have been improved. There were statistically significant correlation between EF domain and IPSS, however the correlation coefficient was -0.187, suggesting weak correlation. The incidence of adverse drug reaction occurred after the administration of Xatral XL was 5.9%: 3.0% of nervous system disorders, 1.5% of gastrointestinal disorders, 1.0% of vascular disorders, 1.0% of skin and subcutaneous tissue system disorders. In the assessment of vital signs, the changes of systolic/diastolic blood pressure from baseline were statistically significant; however they were not clinically significant. There were no statistically significant changes in heart rate.

Efficacy results:

*IIEF

IIEF Score and 5 Domains - ITT

	Xatral XL (n=186)					
	Erectile Function (1, 2, 3, 4, 5, 15)	Intercourse Satisfaction (6, 7, 8)	Orgasmic Function (9, 10)	Sexual Desire (11, 12)	Overall Satisfaction (13, 14)	Total Scores
Baseline n=186						
Mean(SD)	16.30(±6.43)	6.70(±2.86)	5.98(±2.68)	5.18(±1.74)	5.42(±2.00)	39.59(±13.98)
Range	1 ~ 30	0 ~ 14	0 ~ 10	2 ~ 10	2 ~ 10	7 ~ 69
Month 1 n=183						
Mean(SD)	17.46(±6.93)	7.14(±2.95)	6.10(±2.78)	5.42(±1.72)	5.67(±1.85)	41.80(±14.74)
Range	1 ~ 30	0 ~ 14	0 ~ 10	2 ~ 10	2 ~ 10	5 ~ 68
Month 3 n=186						
Mean(SD)	18.35(±6.70)	7.32(±3.01)	6.24(±2.70)	5.82(±1.69)	5.94(±1.98)	43.73(±14.64)
RANGE	1 ~ 30	0 ~ 15	0 ~ 10	2 ~ 10	2 ~ 10	5 ~ 70
Change From Baseline To Month 1 n=183						
Mean(SD)	1.11(±5.32)	0.39(±2.37)	0.08(±2.25)	0.23(±1.41)	0.21(±1.71)	2.02(±11.08)
Range	-20 ~ 15	-9 ~ 6	-9 ~ 5	-5 ~ 4	-6 ~ 5	-44 ~ 32
P-Value (b)	0.0053	0.0259	0.6221	0.0286	0.1021	0.0145
Change From Baseline To Month 3 n=186						
Mean(SD)	2.05(±6.21)	0.61(±2.89)	0.26(±2.66)	0.64(±1.59)	0.52(±2.05)	4.14(±13.33)
Range	-23 ~ 21	-11 ~ 12	-10 ~ 8	-5 ~ 6	-6 ~ 7	-51 ~ 48
P-Value (b)	<.0001	0.0043	0.1872	<.0001	0.0006	<.0001

(a) This table is based on the last observation carried forward approach

(b) Paired t-test

*GEQ

Global Efficacy Question (GEQ) – ITT

	Xatral XL (n=186)	
	Yes	No
	n (%)	n (%)
Month 1	98 (53.85)	84 (46.15)
Month 3	83 (**49.70)**	84 (50.30)

Global Efficacy Question (GEQ) – PP

	Xatral XL (n=158)	
	Yes	No
	n (%)	n (%)
Month 1	82 (53.25)	72 (46.75)
Month 3	77 (**48.73)**	81 (51.27)

*QoL

Assessment of QOL

	Xatral XL (n=186)				
	Baseline	Month 1	Month 3	Change From Baseline To Month 1	Change From Baseline To Month 3
N	186	181	185	181	184
Mean	3.89	3.05	2.85	-0.83	-1.04
Std Dev	1.08	1.36	7.39	1.28	1.34
Median	4	3	13	-1	-1
Range	0 ~ 6	0 ~ 6	0 ~ 33	-5 ~ 4	-4 ~ 4
P-Value (b)				<.0001	<.0001

(a) This table is based on the last observation carried forward approach

(b) Paired t-test

*IPSS

Assessment of IPSS

	Xatral XL (n=186)				
	Baseline	Month 1	Month 3	Change From Baseline To Month 1	Change From Baseline To Month 3
N	186	182	184	182	185
Mean	18.56	13.93	13.23	-4.68	-5.37
Std Dev	6.88	7.22	1.31	6.20	7.09
Median	18	13.5	3	-4	-4
Range	8 ~ 35	0 ~ 33	0 ~ 6	-31 ~16	-31 ~16
P-Value (b)				<.0001	<.0001

(a) This table is based on the last observation carried forward approach

Assessment of Post Void Residual Urine (ml)

	Xatral XL (n=186)		
	Baseline	Month 3	Change From Baseline To Month 3
N	145	130	110
Mean	46.83	41.88	-3.40
Std Dev	58.05	43.69	68.99
Median	33	24	-4.5
Range	3 ~ 528	3 ~ 177	-455 ~ 162
P-Value (a)			0.6063

(a) Paired t-test

Assessment of Maximum Flow Rate (ml/sec)

	Xatral XL (n=186)		
	Baseline	Month 3	Change From Baseline To Month 3
N	186	168	168
Mean	13.70	14.33	1.08
Std Dev	5.86	5.79	5.65
Median	12.7	13.85	1
Range	2.9 ~ 35.8	1 ~ 34	-19 ~ 26.1
P-Value (a)			0.0145

Safety results:

Adverse Events Summary

Number (%) of Patients	Xatral XL (n=203)	
	n	%
With at least one treatment-emergent adverse event	33	16.26
With Treatment-Emergent ADR	12	5.91
With ADR related to vasodilatation (treatment-emergent)	6	2.96
With unexpected ADR (treatment-emergent)	3	1.48
With Serious Adverse Event (treatment-emergent)	6	2.96
With Serious ADR (treatment-emergent)	1	0.49
Withdrawn Due to Adverse Event	9	4.43
Who Died	0	0.00

Date of report:	25-Aug-2005