Dr.Reddy's

ALFUZOSIN EXERTS CLINICALLY REMARKABLE IMPROVEMENTS THAN TAMSULOSIN IN THE TREATMENT OF SYMPTOMATIC BPH



Alfuzosin exerts clinically remarkable improvements than Tamsulosin in the treatment of symptomatic BPH

Clinical spectrum of benign prostatic hyperplasia

- Benign prostatic hyperplasia (BPH) is a common and progressive clinical disease of ageing men, which may be associated with enlargement of the prostate, bothersome lower urinary tract symptoms (LUTS) and bladder outlet obstruction (BOO).
- · Sexual dysfunction is another common condition in ageing men. Both of these age-dependent conditions have a measurable effect on overall quality-of-life.

Clinical therapy for benign prostatic hyperplasia

- α₁-Adrenoceptor antagonists are considered the first-line treatment for managing LUTS associated with BPH and suggestive of BOO.
- Alfuzosin is selective for α,-adrenoceptors in the prostate and lower urinary tract relative to those in vascular tissues.
- By selectively blocking urinary tract α₁-adrenoceptors, alfuzosin relaxes smooth muscle in the bladder and prostate gland, thereby improving urine flow and LUTS, with minimal effects on blood pressure (BP) values.

Objective

Nordling J, evaluated efficacy and safety of two doses (10 and 15 mg) of alfuzosin once-daily and tamsulosin (0.4 mg) once-daily compared with placebo in men with BPH. The study was designed to compare each of the three active treatments with the placebo group.



Primary outcome measures:

- International prostate symptom score (IPPS)
- Peak urinary flow rate (Q_{max}) at 12 weeks

Results

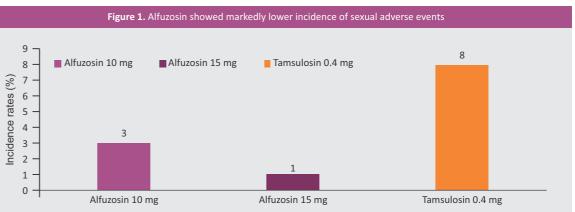
- Alfuzosin 10 mg significantly improved urinary tract symptoms compared with placebo with a mean change from baseline in the IPSS (p=0.007) (Table 1)
- Alfuzosin 10 mg showed significantly better mean changes from baseline in obstructive and irritative subscores of the IPSS vs. placebo
- Both alfuzosin and tamsulosin significantly increased median change from baseline in Q____

Safety

- Alfuzosin 10 mg showed generally mild episodes of dizziness and no case of syncope, hypotension or malaise compared to tamsulosin 0.4 mg
- · Tamsulosin 0.4 mg showed headache, impotence and ejaculation disorder as the most common treatment-emergent adverse events
- alfuzosin 10 mg and tamsulosin 0.4 mg: 1.4% vs. 1.4% and 2.7%)
- Alfuzosin showed markedly lower incidence of sexual adverse events compared to tamsulosin (Figure 1)

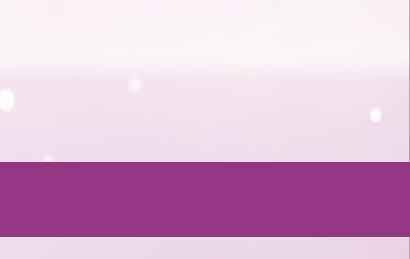
Table 1. Alfuzosin showed clinically significant outcomes compared to other groups (12 weeks)				
Characteristic/variables	Placebo	Alfuzosin (10 mg)	Alfuzosin (15 mg)	Tamsulosin (0.4 mg)
Total IPPS				
Baseline	17.7 (5.0)	18.0 (5.4)	17.4 (4.8)	17.4 (5.6)
Changes from baseline	-4.6 (5.8)	-6.5 (5.2)	-6.0 (5.6)	-6.5 (6.2)
Adjusted p <i>vs.</i> placebo		0.007	0.050	0.014
Q _{max} , mL/s				
Baseline	9	9.2	8.9	9.4
Change from baseline	0.5	1.5	1.4	1.4
Adjusted p vs. placebo		0.02	0.02	0.02

Alfuzosin 10 mg Alfuzosin 15 mg



Reference

Nordling J. Efficacy and safety of two doses (10 and 15 mg) of alfuzosin or tamsulosin (0.4 mg) once daily for treating symptomatic benign prostatic hyperplasia. BJU Int. 2005 May;95(7):1006--1012.



Incidence of orthostatic hypotension was generally low in men who were aged ≥65 years (placebo vs.

Conclusion

Alfuzosin (10 and 15 mg OD) compared with tamsulosin (0.4 mg OD) and placebo in men with symptomatic BPH showed:

- Significantly improved LUTS and peak urinary flow rate
- Both doses of alfuzosin were well-tolerated
- Incidence of sexual function adverse events were markedly lower than tamsulosin group

In Sexually Active Males with LUTS ^RALFOOO[®] Afuzosin Hcl extended release tablets 10 mg

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Dr. Reddy's Laboratories Ltd, Global Generics India, 7-1-27, Ameerpet, Hyderabad-500016, Telangana. www.drreddys.com

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Corporate Office: Boomerang (Kanakia Spaces), Wing-B1, #403, 4th Floor, Chandiwali Farm Road, Chandiwali, Powai, Mumbai - 400 072, Maharashtra, India. Tel: 022-6612 2600, Fax: 022-6612 2626 | Registered Office: Margosa Building,#02,13th Cross Margosa Road, Malleshwaram, Karnataka, India. Tel: 080-4346 4500, Fax: 080-4346 4509 | Regional Office: 709, 7th Floor, Devika Tower, Nehru Place, New Delhi-110019, Board Line: 011 - 4285 4300 Fax: 011 - 4285 4310 | E-mail: enquiry.in@cims.co.in | URL: http://corporate.mims.com