

# TAMSUHENZ

Tamsulosin Modified Release 0.4 mg Tablets

# TAMSUHENZ-D

Tamsulosin Prolonged-Release 0.4 mg and  
Dutasteride 0.5 mg Capsules



MOVEMENT

THAT MATTERS

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## Comparison of the Efficacy and Tolerability of Tamsulosin and Finasteride in Patients with LUTS/BPH

- ⦿ A Multicenter, double-blind study
- ⦿ **Duration:** 26 weeks
- ⦿ Patients with LUTS/BPH were randomized with Finasteride 5 mg once daily (n=204) or Tamsulosin 0.4 mg once daily (n=199).
- ⦿ The primary efficacy parameter was the difference in mean change in total Symptom Problem Index (SPI) from baseline to end point at week-26 in the intention-to-treat (ITT) and per protocol (PP) populations.

### Results:

Parameter mean (S.D.)	Assessment	Finasteride (n=204)	Tamsulosin (n=196)	P-Value
Total SPI (points): ITT	N	202	193	0.055
	Baseline	14.0 (4.2)	13.6 (4.4)	
	Change at week 26	-4.5 (5.0)	-5.2 (5.0)	
	% Change at week 26	-31.5%	-37.4%	
Total SPI (points): PP	N	152	130	0.032
	Baseline	14.1 (4.2)	13.6 (4.4)	
	Change at week 26	-4.5 (4.9)	-5.5 (5.0)	
	% Change at week 26	-31.5%	-39.6%	

- ⦿ Tamsulosin induced a greater improvement in total SPI (-5.2 points or -37%) compared to finasteride (-4.5 points or -31%) at week-26 (P=0.055 in ITT and P=0.032 in PP).
- ⦿ With tamsulosin, total SPI was improved very quickly within 1 week of treatment.
- ⦿ Tamsulosin also improved urinary symptoms and flow more quickly than finasteride.

**Conclusion:** Tamsulosin provides greater improvement of the bothersomeness associated with urinary symptoms than finasteride. Tamsulosin has a faster onset of action compared to finasteride.

# Effect of Combination Therapy with Dutasteride and Tamsulosin in Men with Symptomatic Benign Prostatic Hyperplasia



⦿ A Multicenter, randomized, double-blind, parallel-group study

Groups	Tamsulosin Group	Dutasteride Group	Tamsulosin + Dutasteride Combination Group
<b>Dose</b>	Tamsulosin 0.4 mg daily	Dutasteride 0.5 mg daily	Tamsulosin 0.4 mg + Dutasteride 0.5 mg Daily
<b>N</b>	1611	1623	1610
<b>Duration</b>	4 years		

## Results:

Incidence of individual benign prostatic hyperplasia (BPH) clinical progression events, BPH-related surgery and acute urinary retention at 4 years:

Groups	Combination Group		Dutasteride Group		Tamsulosin Group	
	No. of Events	Incidence (95% CI)	No. of Events	Incidence (95% CI)	No. of Events	Incidence (95% CI)
<b>BPH clinical progression events</b>						
Symptom deterioration by IPSS $\geq$ 4 points	139	8.6%	212	13.1%	229	14.2%
BPH-related AUR	26	1.6%	37	2.3%	82	5.1%
BPH-related urinary incontinence	49	3.0%	60	3.7%	65	4.0%
Recurrent BPH related UTI or urosepsis	3	0.2%	5	0.3%	5	0.3%
BPH-related renal insufficiency	1	<0.1%	2	0.1%	7	0.4%
<b>BPH-related surgery</b>	38	2.4%	56	3.5%	126	7.8%
<b>AUR</b>	36	2.2%	44	2.7%	109	6.8%

**Conclusion:** Combination therapy provided significantly greater symptom benefit than either monotherapy at 4 years in men with moderate-to-severe LUTS due to BPH and prostatic enlargement.

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## DESCRIPTION:

- ⊙ **TAMSUHENZ** contains Tamsulosin 0.4 mg Modified Release Tablet which is an alpha-adrenergic antagonist that is used in the treatment of benign prostatic hyperplasia. It helps to relieve symptoms like difficulty in passing urine.
- ⊙ **TAMSUHENZ-D** Capsule is a combination of Tamsulosin (0.4 mg) and Dutasteride (0.5 mg) that work in different ways to treat men with an enlarged prostate gland.

## MECHANISM OF ACTION:

- ⊙ **Tamsulosin** is a blocker of alpha-1A and alpha-1D adrenoceptors. About 70% of the alpha-1 adrenoceptors in the prostate are of the alpha-1A subtype. By blocking these adrenoceptors, smooth muscle in the prostate is relaxed and urinary flow is improved.
- ⊙ **Dutasteride** competitively and specifically binds to isoenzymes 1 and 2 of 5 alpha-reductase, forming stable enzyme complexes and inhibiting the conversion of testosterone to 5 alpha-dihydrotestosterone (DHT); the reduction in DHT activity mitigates or prevents enlargement of the prostate gland.

## INDICATION:

- ⊙ **TAMSUHENZ** is indicated for the treatment of Lower Urinary Tract Symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).
- ⊙ **TAMSUHENZ-D** is indicated for the treatment of symptomatic BPH in men with an enlarged prostate.

## DOSE:

- ⊙ **TAMSUHENZ**: 1 Tablet once a day or as directed by the doctor.
- ⊙ **TAMSUHENZ-D**: 1 Capsule once a day or as directed by the doctor.



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