Tamsulosin & Dutasteride combination - superior to monotherapy in moderate to severe BPH

Duodart™
Tamsulosin Hydrochloride 0.4 mg and Dutasteride 0.5 mg Capsule

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Dual action with Power & Safety

Drug Review

Benign prostatic hyperplasia (BPH)

- Benign prostatic hyperplasia is a non-malignant proliferation of both the stromal and epithelial cells of the prostate in the transitional zone surrounding the urethra.[1]
- This is one of the most common diseases in men with an incidence that increases with age. The prevalence of BPH is 20% for men in their 40s, reaches 50% to 60% for men in their 60s & increasing to 80% to 90% of those older than 70 years of age.[2]
- The etiology of BPH is influenced by a wide variety of risk factors, in addition to the direct hormonal effects of testosterone on prostate tissue.[2]
- Testosterones are converted to dihydrotestosterone (DHT) by the catalysis of 5α-reductase (5AR). Excessive expression of DHT triggers the proliferation of prostate epithelial and stromal cells that leads to the development of BPH. This may eventually lead to bladder outlet obstruction and subsequent lower urinary tract symptoms (LUTS) affecting patient's quality of life (QOL).[1,3]
- Hence, the goal of treatment of patient's with BPH is to relieve LUTS and slow the clinical progression of BPH while improving patient QOL.[4]

Tamsulosin-dutasteride combination with dual action in BPH

- Tamsulosin-dutasteride is a combination of two drugs, acts synergistically with dual mechanisms of action to improve symptoms in patients with BPH.[5]
- Tamsulosin is a selective antagonist at α1A and α1B adrenoceptors in the prostate and bladder neck. Blockage of these receptors causes relaxation of smooth muscles in the bladder neck and prostate, and thus decreases urinary outflow resistance.[6]
- Dutasteride is a selective 5α -reductase inhibitor (5-ARI) that inhibits conversion of testosterone to dihydrotestosterone (DHT) – the androgen primarily responsible for hyperplasia of prostatic tissue.[6]

Tamsulosin

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Selectively blocks α1-adrenergic receptor in the prostate

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- Relax the smooth muscles of the prostate
- Expands the prostatic part of the urethra

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Improve LUTS & Reduces the chances of acute urinary retention (AUR)

Dutasteride

↓

Inhibits 5α -reductase enzyme

↓

Prevents the conversion of testosterone to dihydrotestosterone (DHT)

↓

Prevents hyperplasia of prostate cells

- Tamsulosin-dutasteride combination is used for prevention of the progression of BPH, to reduce prostate size, alleviate symptoms, improve urinary flow and reduce the risk of acute urinary retention and the need for BPH-related surgery.

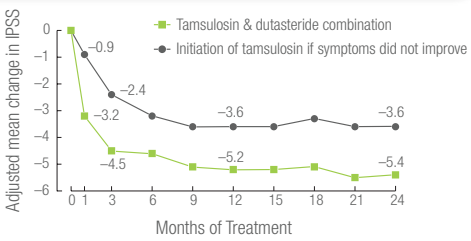
Proven safety & results[7]

- Combination therapy with dutasteride and tamsulosin is a highly efficacious medical treatment in patients with BPH which could be safely tolerated and administrated for ± 4 years.
- In the CombAT trial in men with BPH, moderate to severe LUTS & an increased risk of disease progression, the total International Prostate Symptom Score (IPSS) score improved to a significantly greater extent with dutasteride plus tamsulosin than with dutasteride or tamsulosin alone after 2 and 4 years therapy.

- After 4 years therapy, the time to first acute urinary retention or BPH-related surgery significantly ($p < 0.001$) favored men receiving dutasteride plus tamsulosin versus those receiving tamsulosin alone.
- Mean or median serum PSA levels were reduced from baseline by >55% in men with BPH who received dutasteride plus tamsulosin.
- Mean prostate volume was reduced from baseline by 26–28% in men with BPH who received dutasteride in combination with tamsulosin once daily for 4 years.
- Health-related quality of life and treatment satisfaction were improved to a significantly greater extent with dutasteride plus tamsulosin than with dutasteride or tamsulosin alone.

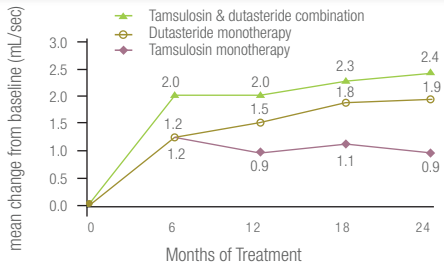
Superior to monotherapies with either tamsulosin or dutasteride

Tamsulosin & dutasteride significantly reduces BPH progression, chance of AUR & BPH related surgery[8]



43.1% relative risk reduction than monotherapy

Tamsulosin & dutasteride is statistically superior to monotherapies in increasing urine flow[9]



Combination treatment with an α1-blocker (Tamsulosin) & a 5α-reductase Inhibitor (Dutasteride) is recommended in men with moderate to severe BPH with an increased risk of disease progression (prostate volume ≥ 30 cc; PSA ≥1.5 ng/ml).[10]

In moderate to severe BPH

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Dual action with Power & Safety

Dosage & Administration

One *Duodart*™ capsule orally after the same meal each day

Recommended by - American Urological Association & European Association of Urology

For full prescribing information

Scan the Code

Reference: 1. Roehrborn CG. Pathology of benign prostatic hyperplasia. Int J Impot Res. 2008 Dec;20 Suppl 3:S11-8. 2. Roehrborn CG. Benign prostatic hyperplasia: an overview. Rev Urol. 2005;7 Suppl 9(Suppl 9):S3-S14. 3. Lepor H. Pathophysiology, epidemiology, and natural history of benign prostatic hyperplasia. Rev Urol.2004;6(suppl 9):S3-S10. 4. McVary KT, Roehrborn CG, Avins AL, et al. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH). Linthicum, MD: American Urological Association; 2010:1-62, Appendix278-285. 5. Dimitropoulos K, Gravas S. Fixed-dose combination therapy with dutasteride and tamsulosin in the management of benign prostatic hyperplasia. Ther Adv Urol. 2016;8(1):19-28. 6. Miller J, Tarter TH. Combination therapy with dutasteride and tamsulosin for the treatment of symptomatic enlarged prostate. Clin Interv Aging. 2009;4:251-8 7. Keating GM. Dutasteride/tamsulosin: in benign prostatic hyperplasia. Drugs Aging. 2012 May 1;29(5):405-19 8. BJU International (2015); 116: 450–459 9. The Journal of Urology (2008); 179, 616-621 10. BMC Urology (2019); 19:17

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