


## Evaluation of the Clinical Benefit of Permixon and Tamsulosin in Severe BPH Patients—PERMAL Study Subset Analysis

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ABSTRACT

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### Abstract

**Objective:** To compare the efficacy of the lipido-sterolic extract of *Serenoa repens*, Permixon, to that of the  $\alpha$ -blocker, tamsulosin, in the treatment of severe low urinary tract symptoms (LUTS) of benign prostatic hyperplasia (BPH).

**Methods:** In a 12-month, double-blind, randomized study that showed equivalent efficacy of Permixon 320mg/day and tamsulosin 0.4mg/day ("PERMAL study"), 685 BPH patients with IPSS  $\geq 10$  had been analyzed for efficacy. Of these, the 124 patients with severe LUTS (IPSS  $> 19$ ) at randomization were retained for this subset analysis. After a 4-week run-in period, 59 and 65 patients had been randomized to tamsulosin and Permixon groups, respectively. Both treatment groups were compared regarding the evolution from baseline of total IPSS and its irritative and obstructive subscores, LUTS-related QoL, prostate volume,  $Q_{\max}$  and MSF-4 (sexual activity questionnaire) at different time points over 1 year. An analysis of variance of changes from baseline to end point was performed for all the parameters. The over-time evolutions of total, irritative and obstructive IPSS were further compared using a variance analysis for repeated measurements.

**Results:** At 12 months, total IPSS decreased by 7.8 with Permixon and 5.8 with tamsulosin ( $P = 0.051$ ); the irritative symptoms improved significantly more ( $P = 0.049$ ) with Permixon ( $-2.9$  versus  $-1.9$  with tamsulosin). The superiority of Permixon in reducing irritative symptoms appeared as soon as month 3 and was maintained up to month 12 ( $P = 0.03$ ).

**Conclusion:** Permixon 320mg/day was shown to be slightly superior to tamsulosin 0.4mg/day in reducing LUTS in severe BPH patients after 3 months and up to 12 months of treatment.

**Keywords:** [Serenoa repens](#), [Permixon](#), [Phytotherapy](#),  [\$\alpha\$ -blockers](#), [Tamsulosin](#), [BPH](#)