



# Saw Palmetto Extract

## An Alternative for Prostatism

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Although herbs have been used for benign prostatic hypertrophy for years in Italy, Germany and Austria, there has recently been a sharp increase of use in North America. One survey showed one-third of men choosing non-surgical treatment for prostatism were using herbs, either alone or in combination with prescription drugs.

### Confusing names

Many physicians and patients find the multiple names of herbs very confusing. Extracts from the fruit or berries of Saw Palmetto or American dwarf palm plant, *Serenoa repens*—which has the botanical name of *Sabal serrulatum*—fit in that category. The most widely studied herb for benign prostatic hypertrophy (BPH) is Permixon, which is a lipid-sterolic extract of *Serenoa repens*.

### What are the possible mechanisms of action?

The mechanism of action of Permixon is still controversial. Possibilities include:

- inhibition of 5-alpha reductase,
- competition with estrogen receptor,
- androgen receptor blockade,
- anti-inflammatory effects or
- decrease in available sex hormone globulin.

### What do the studies show?

#### A Cochrane Review<sup>1</sup>

- Included 3,129 men from 21 randomized trials.
- 18 trials were double-blinded and treatment allocation concealment was adequate in 11 trials.
- Compared to placebo, *Serenoa repens* improved urinary symptom scores, nocturia and flow measures.
- Men taking the herb were nearly twice as likely to report improvement in symptoms than men taking placebo.
- When the herb was compared to finasteride, there were similar responses in urologic symptoms and flow rates, with lower rates of impotence.
- *Serenoa repens* did not seem to decrease prostate size.

#### Boyle *et al.*<sup>2</sup>

- Included 14 randomized, clinical trials and 3 open-label trials, involving a total of 4,280 patients.
- Showed a significant improvement in peak flow rate and reduction in nocturia compared to placebo and a 5-point reduction in the International Prostate Symptom Scores.

#### Debruyne *et al.*<sup>3</sup>

- A randomly assigned, double-blind, controlled trial compared Permixon, 320 mg/day, with tamsulosin, 0.4 mg/day.
- 704 men were studied over 12 months with a placebo run-in phase of 4 weeks.
- Lower urinary tract symptoms, International Prostate Symptom Scores and maximum urinary flow rates improved comparably in the two groups.
- Mean prostate volume decreased by 0.99 cc in the Permixon group compared to an increase of 0.22 cc in the tamsulosin group.
- The overall incidence of side-effects were similar in the two groups, however, ejaculatory disorders were reported in 4.2% of the tamsulosin group as compared to only 0.6% with Permixon.
- No placebo group was included.

### How is Permixon used?

Usually 160 mg of a standardized Saw Palmetto extract is used, taken twice a day with meals. Sometimes, there is no symptom improvement for four to six weeks. Often, Permixon is combined with *Pygeum africanum*, *Hypoxis rooperi*, *Pinus*, *Picea*, *Urtica Dioica* and *Secale cereale*.

Four studies involving a total of 519 men found *Hypoxis rooperi* effective in improving symptom scores and flow measures compared to placebo.

Four studies involving a total of 444 men found modest improvement in overall urologic symptoms with *Secale cereale*.


Although *Pygeum africanum* was found to improve symptoms in 17 studies involving a total of 900 men, there was often inadequate reporting of outcomes, which limits the ability to estimate its safety and efficacy.

### What problems may present?

Adverse events due to phytotherapies were reported to be generally mild and infrequent.

The most common side-effects of Permixon are gastrointestinal complaints, rhinitis, headache and dizziness. The long-term effectiveness, safety and ability to prevent BPH complications

are not known. There is a possibility the herb may cause a false negative PSA result.

Consumer reports have demonstrated a wide variation in the amount of Saw Palmetto contained in each tablet, regardless of the product's labeling. Since the active ingredient is not known, it is possible one product will have better results than another. It is important for patients to use standardized extracts of Saw Palmetto and that there be a DIN number on the package to guarantee that proper manufacturing standards apply. 

#### References

1. Wilt T, Ishani A, Mac Donald R: *Serenoa repens* for benign prostatic hyperplasia. *Cochrane Database Syst Rev* 2000; (2):CD001423.
2. Boyle P, Robertson C, Lowe F, et al: Updated meta-analysis of clinical trials of *Serenoa repens* extract in the treatment of symptomatic benign prostatic hyperplasia. *BJU Int* 2004; 93(6):751-6.
3. Debruyne F, Koch G, Boyle P, et al: Comparison of Permixon with tamsulosin in the treatment of benign prostatic hyperplasia: A one-year randomized international study. *Eur Urol* 2002; 41(5):487-507.

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