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FILE: · *Pygeum (Prunus africana, Pygeum africanum)*  
· Benign Prostatic Hyperplasia (BPH)

DATE: May 15, 2000

HC 021305

## RE: *Pygeum* Extract Equally Effective in Once Daily and Twice Daily Doses in Treating BPH

Chatelain, C., W. Autet and F. Brackman, Comparison of once and twice daily dosage forms of *Pygeum africanum* extract in patients with benign prostatic hyperplasia: A randomized, double-blind study, with long-term open label extension. *Urology*, 1999, Vol. 54, No. 3, pp.473–478.

Phytotherapeutic drugs are widely used to treat benign prostatic hyperplasia (BPH). Several randomized, double-blind, placebo-controlled and open trials have found *Pygeum africanum* to be an effective treatment.

The current study was designed to investigate the safety and effectiveness of *Pygeum africanum* in 209 patients age 50 and older, with clinical symptoms of BPH and reduced urinary flow. The study featured three phases: After a one-month run-in phase without treatment, patients meeting all selection criteria were randomized into a 2-month double-blind, double-placebo, parallel-group phase and received 100 milligrams of *P. africanum* extract (Tadenan<sup>®</sup>, Laboratoires Fournier, Chenove, France) either once daily (one 100-mg capsule in the evening) or twice daily (one 50-mg capsule morning and evening).

The efficacy of the treatment was assessed using the International Prostate Symptom Score (IPSS), quality of life and maximum urinary flow rate. The researchers found that after two months, *P. africanum* extract in both groups proved equally effective and safe. After a two-month treatment period, 174 patients continued receiving 100 milligrams daily for an additional ten months. Further improvements in efficacy with continued safety were observed after 12 months. There were no significant changes either in PSA levels or in sexual function of the patients studied.

The researchers pointed out that the absence of a placebo arm in the 10-month extension of the study limited the evaluation of the net effect of the product, and that the observed effects must be considered as a combination of the herb and placebo effects. They concluded, however, that *P. africanum* extract offers an alternative for the treatment of patients with mild to moderate symptoms of BPH and that the effects of once daily administration of 100 milligrams are similar to those of the currently recommended dosage regimen of 50 milligrams twice daily. —Densie Webb, Ph.D.

Enclosure: Reprinted from *Urology* Chatelain, C., W. Autet and F. Brackman.

Comparison of once and twice daily dosage forms of *Pygeum africanum* extract in patients with benign prostatic hyperplasia: A randomized, double-blind study, with long-term open label extension. 1999, with permission from Elsevier Science.

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