



AMERICAN
BOTANICAL
COUNCIL

Post Office Box 144345
Austin, Texas 78714-4345
Phone 512/926-4900
Fax 512/926-2345
Email: abc@herbalgram.org
www.herbalgram.org

Mark Blumenthal
Editor

Wayne Silverman, PhD
Underwriting Coordinator

Leela Devi, MSN, RN
Marian Garner-Wizard
Betsy Levy
Heather S. Oliff, PhD
Risa Schulman, PhD
Densie Webb, PhD
Ginger Webb
Summary Writers

Karen Newton
Database Manager

Karen Robin
Susan McFarland
Coordinators

Dawnelle Malone
Research Assistant

The American Botanical Council provides this summary and the enclosed article as an educational service. By providing this article, ABC does not warrant that the data is accurate and correct, nor does distribution of the enclosed article constitute any endorsement of the information contained or of the views of the authors.

ABC does not authorize the copying or use of the original articles. Reproduction of the summaries is allowed on a limited basis for students, colleagues, employees and/or customers. Other uses and distribution require prior approval.

HERBCLIPTM

FILE: · *Pygeum (Pygeum africanum); syn. (Prunus africana)*
· BPH (Benign Prostatic Hyperplasia)

DATE: January 30, 2000

HC 061191

RE: *Pygeum* Extract Demonstrates Beneficial Prostate Effects for One Month After Use is Discontinued – Clinical Study

Breza, J., O. Dzurny, A. Borowka, T. Hanus, R. Petrik, G. Blaine and H. Chadha-Boreham. Efficacy and Acceptability of Tadenan® (*Pygeum africanum* Extract) in the Treatment of Benign Prostatic Hyperplasia (BPH): A Multicentre Trial in Central Europe. *Current Medical Research and Opinion*. 14(3): 127-139. 1998.

Benign prostatic hyperplasia (BPH) is a common condition among older men, with 50% of men aged 60 showing histological evidence of the disease. Symptoms include frequent and difficult urination, a weak urinary stream and sensations of incomplete emptying of the bladder. This paper presents the results of an open, uncontrolled, multicenter clinical trial of Tadenan® (Debat Laboratories, France), a commercial preparation of *Pygeum africanum* bark extract (African plum tree) successfully used in Europe to treat BPH.

BPH is customarily treated using hormone suppressing drugs. Though beneficial in treating symptoms, these drugs have sexual side effects and can take 6-12 months to take effect. *Pygeum africanum* acts by inhibiting fibroblast proliferation, which is thought to contribute to the development of BPH.

The study was designed with a detailed set of inclusion criteria. Subjects had to be in good physical condition, aged 50-75 years and score within certain cut-off points for measures of urination frequency and flow rate, voiding volume, residual urinary volume, prostate volume, serum creatinine and serum prostate specific antigen (PSA). In addition they had to score 12 or more on the International Prostate Symptom Score (IPSS, scale 0-35) and 3 or more on the Quality of Life scale (QoL). Patients were excluded if they had had or required surgical intervention or had taken *P. africanum* or conventional drugs for BPH within the previous three months.

Suitable subjects were prescribed pygeum extract 50 mg twice daily for two months. Subjects returned after one and two months and were reassessed one month after treatment was discontinued. Biochemical and hematological safety was assessed, and oral reports of unexpected events were recorded at each visit.

Eighty-five men were recruited evenly between three centers in Bratislava, Prague and Warsaw. In Bratislava, three men dropped out before beginning the study for personal reasons. The average IPSS score was similar in all three centers. The QoL score followed the same pattern, as did the average frequency of urination.

After treatment with pygeum, IPSS dropped 31% after one month and 40% after two months. This value may be compared to a 24% reduction in IPSS for placebo reported by Hansen (1996). QoL scores also dropped 31%, and the frequency of nocturnal urination fell 32% after two months. The following urinary parameters also improved: maximum urinary flow (19%), average urinary flow (17%) and urinary volume (21%). All these effects persisted for a month after treatment was discontinued. Urination time, prostatic volume and sexual function were not significantly affected. No adverse effects or clinically relevant changes in biochemical and hematological safety parameters were observed.

The study concludes that treatment of BPH with 50 mg of *Pygeum africanum* bark extract as Tadenan® twice a day compares favorably with other medical treatments, is safe, and does not cause unpleasant side effects. —*Risa N. Schulman, Ph.D.*

Enclosure: Copyright © 1998, Reprinted with permission from *Current Medical Research and Opinion*.

Bin #169