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AMERICAN
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Now in Our
20th Year

FILE: ■ **French Maritime Pine (*Pinus pinaster*)**

■ **Pycnogenol®**

■ **Climacteric Syndrome**

■ **Peri-menopause**

■ **Menopause**

HC-090173-347

Date: February 29, 2008

RE: Efficacy of Pycnogenol® in the Treatment of the Climacteric Syndrome in Peri-menopausal Women

Yang H-M, Liao M-F, Zhu S-Y, Liao M-N, Rohdewald P. A randomised, double-blind, placebo-controlled trial on the effect of Pycnogenol® on the climacteric syndrome in perimenopausal women. *Acta Obstetrica et Gynecologica*. 2007;86:978–985.

The transition from the reproductive to the non-reproductive stage of life, known as the climacteric, adversely affects the quality of life of most women. Some of the most common menopausal symptoms experienced by women are hot flashes, sweating, heart palpitations, fatigue, depression, decreased libido, and cognitive impairment. In recent years there has been a shift from a broad to a more conservative use of hormone replacement therapy (HRT) and further to the use of alternative medicines or lifestyle changes to ameliorate these symptoms. This trend has resulted because of the serious adverse effects associated with the long-term use of estrogens. Pycnogenol®, (Horphag Research Ltd; Geneva, Switzerland) a standardized extract from the bark of *Pinus pinaster*, has been shown in animal and clinical studies to improve cognitive function, improve the elasticity of the skin, stimulate the endothelial production of nitric oxide, alleviate menstrual pain, and reduce hyperactivity. On the basis of these findings, this study was undertaken to evaluate the efficacy of Pycnogenol in treating climacteric symptoms in peri-menopausal women in Taiwan.

Over a 3.5-year period (from January 2002 to July 2005), 200 peri-menopausal women, aged 45-55 years, were allocated to receive 100-mg capsules of Pycnogenol or placebo twice daily (at breakfast and dinner) for 6 months in a double-blind manner. Both capsules were prepared by Wide-Doctor Int., Taiwan. To be eligible for inclusion, the women had to have serum estrogen E2 concentrations <20 pg/mL and follicle-stimulating hormone (FSH) concentrations >30 IU/mL; exclusion criteria included systematic or acute disease, the use of hormones or contraceptives, illiteracy, or a history of oophorectomy or hysterectomy.

The participants were interviewed to determine lifestyle habits and socioeconomic status at the first visit. Blood pressure and body mass index (BMI) were determined and blood was drawn for the measurement of lipid and hormone concentrations at baseline and at 1, 3, and 6 months. Total antioxidant status was also evaluated. The 36-item Women's Health Questionnaire was used to evaluate the climacteric symptoms experienced by subjects throughout the study.

One hundred fifty-five participants (n = 80 in the Pycnogenol group and 75 in the placebo group) completed all of the questionnaires and investigations. Blood pressure decreased in both groups, with no significant difference between groups. High density lipoprotein (HDL) cholesterol increased and low density lipoprotein (LDL) cholesterol decreased significantly from baseline with Pycnogenol treatment. No significant differences in HDL cholesterol were observed between groups; however, the decrease in LDL cholesterol was significantly greater in the Pycnogenol group than in the placebo group. The atherosclerotic index (ratio of HDL to LDL cholesterol) and total antioxidant status were favorably altered by Pycnogenol. All climacteric symptoms evaluated (depression, somatic and vasomotoric symptoms, memory, attractiveness, anxiety, sexual symptoms, sleep, and menstrual symptoms) improved significantly ($P < 0.001$) with Pycnogenol treatment, as early as 1 month after initiation of treatment. Most climacteric symptoms also improved with placebo, but not significantly so. No unwanted side effects were reported.

Pycnogenol treatment resulted in the improvement of all climacteric symptoms evaluated and improved total antioxidant status and the atherosclerotic index. The authors conclude that, "Supplementation with Pycnogenol[®] clearly reduced the frequency as well as the severity of climacteric symptoms." Pycnogenol may offer an alternative to HRT for the amelioration of menopausal symptoms.

—*Brenda Milot, ELS*

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