

Pycgnogenol[®]

French Maritime Pine (*Pinus pinaster*)
Muscular Pain
Cramps

HC 080161-312

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RE: Prevention of Cramps and Muscular Pain with Pycnogenol[®] in Healthy Subjects and in Different Patient Groups

Vinciguerra G, Belcaro G, Cesarone MR, et al. Cramps and muscular pain: prevention with Pycnogenol[®] in normal subjects, venous patients, athletes, claudicants and in diabetic microangiopathy. *Angiology*. 2006;57(3):331–339.

Painful muscular cramps are often associated with prolonged muscular stress and dehydration, particularly during sporting activities in warm weather when excessive sweating occurs. Cramps can also occur at rest or during continuous muscle use in a limited range of activities or positions, such as "writer's cramp," which occurs in the thumb and adjacent two fingers. Non-clinical cramps usually disappear in a relatively short period of time without intervention, whereas "clinic cramps" are more serious and can involve circulatory or nerve problems. Muscular cramps and associated pain during or after exercise can impair or decrease the performance and quality of life of both athletes and non-athletes; therefore, therapies for alleviating the pain without side effects are desirable. The objective of this study was to prospectively evaluate the efficacy of Pycnogenol®, the patented special extract of French maritime pine (*Pinus pinaster*) bark (Horphag Research Ltd, UK, a division of Horphag Research, Geneva, Switzerland) in preventing muscular cramps and pain in healthy subjects and different patient groups. The location of the study was the Faculty of Motory Sciences at the University of L'Aquila in Italy.

In the first part of the study, 66 subjects were categorized according to the frequency that they experienced muscular cramps and pain: 22 healthy persons with frequent cramps (at least 4 times weekly), 21 patients with chronic venous insufficiency (CVI) and cramps 4–6 times weekly, and 23 athletes with frequent cramps (at least 8 times weekly) during the night or during the final phase of a training session. The 3 groups of subjects ingested 4 50-mg capsules of Pycnogenol with at least 1.5 L of water daily (total daily dose: 200 mg) for 4 weeks and were followed-up for 1 week after treatment. In the second part of the study, 25 patients with intermittent claudication (a.k.a. peripheral arterial occlusive disease, PAOD, a

condition characterized by pain in leg muscles during walking, thereby limiting distance walked) and 22 patients with diabetic microangiopathy (gradual thickening of capillary basal membranes in diabetes which leads to insufficient tissue supply with oxygen and nutrients) were treated with either Pycnogenol (total daily dose: 200 mg) or placebo for 4 weeks and followed-up for 1 week thereafter. The weekly number of cramps reported during the study and during the 2 weeks preceding the study was compared in both the first and second parts of the study. In addition, the subjects were evaluated according to a visual analogue scale (VAS) in which a possible score of 0 to 10 was recorded for the severity of pain associated with cramps and muscular pain at rest and during exercise and the degree of impairment.

In the first part of the study, the mean number of cramping episodes decreased significantly (P < 0.05) from baseline to 4 weeks in all 3 subjects groups: from 4.8 to 1.3 in the healthy subjects, from 6.3 to 2.6 in the patients with CVI, and from 8.6 to 2.4 in the athletes. The values at 5 weeks remained significantly lower than those at baseline in all 3 subject groups. VAS scores were significantly lower (P < 0.05) at both 4 and 5 weeks than at baseline in all 3 groups.

In the second part of the study, the number of reported cramping episodes and the analogue scores decreased significantly (P < 0.05) in both the PAOD patients and the diabetics after Pycnogenol use. The mean number of cramping episodes decreased from 9.5 at baseline to 3.2 at 4 weeks in the PAOD patients and from 8.9 to 3 in the diabetics. No such decrease was observed in the placebo group.

These results suggest that Pycnogenol use is efficacious in preventing muscular cramps and pain at rest and during exercise in athletes and non-athletes and in patients with diabetes and CVI without negative side effects. The previously well documented antiedamatous (reduces edema), anti-inflammatory, and antithrombotic properties of Pycnogenol are thought to be responsible for these positive effects. (While edema is an abnormal excess accumulation of serous fluid in connective tissue or in a serous cavity, inflammation is defined as a local response to cellular injury that is marked by capillary dilatation, leukocytic infiltration, redness, heat, pain, swelling, and often loss of function and that serves as a mechanism initiating the elimination of noxious agents and of damaged tissue.) The authors recommend that these findings be evaluated further in larger-scale clinical trials.

—Brenda Milot, ELS

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