

PYCNOGENOL[®] Consumer/Patient Information Sheet

(French Maritime Pine Bark Extract) *Pinus pinaster* Aiton subsp. *atlantica* [Fam. Pinaceae]

OVERVIEW

Pycnogenol[®] is a proprietary product made exclusively from French maritime pine bark extract (*Pinus pinaster*). It is manufactured by Horphag Research, Geneva, Switzerland. Pycnogenol was ranked among the 30 top-selling herbal dietary supplements in the United States in mainstream retail outlets (food, drug, and mass market stores) in 2008.

USES

Although there may be many potential uses for Pycnogenol, the most well-studied use is to treat chronic venous insufficiency, a condition defined by poor drainage of blood from veins resulting in swelling or skin problems. Five controlled clinical trials have been published that show improved symptoms. However, larger and more rigorous studies are warranted to confirm these findings. Controlled human clinical trials have been published suggesting the following potential uses: thrombosis (blood clot), diabetes and its complications, hypertension (high blood pressure) and its complications, asthma, attention deficit hyperactivity disorder (ADHD), gynecology (endometriosis [premenstrual pain caused by endometrial tissue in places other than the uterus] and dysmenorrhea [painful menstruation]), and osteoarthritis. These indications only have 1-2 well-designed published clinical trials that support the findings. Preliminary clinical trials have been conducted in the following areas, but more trials are needed to support these potential uses: erectile dysfunction, retinopathy (a diseased condition of the retina in the eye), gingivitis (infection of oral gums), melasma (a dark discoloration of skin), and cramps and muscular pain.

DOSAGE AND DURATION OF USE

The following doses were used in the clinical trials reported in the table of clinical trials in the full monograph by the American Botanical Council. It should be noted that some of the doses are based on single studies and/or uncontrolled studies.

- ADHD: 1 mg/kg (2.2 lbs) of body weight/day
- Asthma: 1 mg/lb of body weight/day
- Cholesterol/dyslipidemia: 120-150 mg/day
- Chronic Venous Insufficiency: 150-360 mg/day
- Diabetes: 50-200 mg/day
- Dysmenorrhea: 30-60 mg/day
- Endometriosis: 60 mg/day
- Erectile dysfunction: 120 mg/day
- Hypertension: 100-200 mg/day
- Melasma: 75 mg/day
- Muscle cramps: 200 mg/day
- Osteoarthritis: 100-150 mg/day
- Perimenopause: 200 mg/day
- Platelet function: 25-200 mg/day
- Retinopathy: 20-160 mg/day

In the clinical trials the most common duration of use was 2-3 months; however, long-term use may be justified. Based on the published chemistry, pharmacology, and toxicology of Pycnogenol, there are no data suggesting a limitation on duration of use and there is no evidence from actual product use over several decades by millions of people that might warrant a limitation.

Manufacturer dose recommendations:

According to the manufacturer, the dosage of Pycnogenol will depend on the nature of the desired health benefit. For example, the dose required for preventative effects is different from the dose aimed at improving acute or chronic health

problems.

As an antioxidant, Pycnogenol may be effective at any dose. The manufacturer states that in order to have measurable physiologic effects related to prevention of oxidative tissue damage, the daily intake should be at least 20 mg.

When used as a preventative measure for cardiovascular health, 25 mg/day is recommended. Higher doses ranging from 50 to 100 mg are recommended for cardiovascular health risks such as hypertension, blood hyper-coagulation, and impaired blood circulation.

When using Pycnogenol for anti-edema (anti-swelling) effects, such as in venous insufficiency, the manufacturer recommends 50 mg/day. For more advanced stages the daily dosage should be higher, in the range of 100-150 mg for a limited period of time such as up to 4 weeks. Once edema and symptoms have improved, a daily maintenance dosage of 50 mg may be considered.

For lowering blood glucose in patients with diabetes the manufacturer recommends taking 50 mg once or twice daily.

Anti-inflammatory effects can be achieved with Pycnogenol doses \geq 30 mg/day.

For dysmenorrhea, 30 mg once or twice daily is recommended.

For osteoarthritis or asthma, 100 mg/day is recommended.

CONTRAINDICATIONS AND PRECAUTIONS

There are no known contraindications for Pycnogenol.

Pregnancy and Lactation: As a general precaution, Pycnogenol should not be taken during the first 3 months of pregnancy.

ADVERSE EFFECTS

The safety of Pycnogenol is based on data obtained from 70 human clinical studies on a total of 5723 people, including both healthy subjects and patients. The overall frequency rate of adverse side effects is very low (2.4%). In healthy subjects, the incidence rate is even lower (0.19%). An evaluation of the clinical studies revealed that the occurrence of adverse effects is unrelated to the level of the dose or duration of use.

From what can be gleaned from the clinical trials, it appears that gastrointestinal (GI) discomfort is the most frequently occurring adverse effect (AE). The GI effects may be avoided by taking Pycnogenol with or after meals. Dizziness, headache, and nausea are the next most frequently reported AEs. Acne, diarrhea, and dysfunctional bleeding are the most frequent AEs in studies of women with premenstrual syndrome or dysmenorrhea. The majority of AEs observed were mild.

Analysis of clinical safety data obtained from 4 clinical studies on a total of 185 people evaluating Pycnogenol's effect on blood pressure and heart rate did not reveal any significant changes on systolic or diastolic blood pressure or heart rate.

There have been no reports of serious AEs in any clinical study or from commercial use since it was initially introduced into the market in Europe around 1970.

DRUG INTERACTIONS

Pycnogenol has been consumed by adult and elderly patients taking conventional pharmaceutical medications at the same time. No information from spontaneous reporting is available on any interactions resulting from simultaneous intake of conventional medicines with Pycnogenol. Other interactions with alcohol consumption or food intake have not been reported. Pycnogenol does not affect INR (bleeding tendency) in patients taking aspirin. No other drug interaction studies have been reported.



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As with all medications and dietary supplements, please inform your healthcare provider of all herbs and medications you are taking. Interactions may occur between medications and herbs or even among different herbs when taken at the same time. Treat your herbal supplement with care by taking it as directed, storing it as advised on the label, and keeping it out of the reach of children and pets. Consult your healthcare provider with any questions. The information contained on this sheet has been excerpted from the full Scientific and Clinical Monograph on Pycnogenol[®]. ABC is an independent member-based educational organization focusing on the medicinal use of herbs. For more information visit the ABC website at www.herbalgram.org.