

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 (*Pinus pinaster* subsp. *atlantica*, Pinaceae) bark extract. It is manufactured by Horphag Research (Geneva, Switzerland). In terms of dollar sales, Pycnogenol was ranked among the 100 top-selling herbal dietary supplements in the United States in mainstream retail outlets (food, drug, and mass-market stores) and top 50 in the natural channel (health food stores) from 2013-2015. In 2017 Pycnogenol ranked 117th in the US mainstream retail channel and 63rd in the natural channel. Pycnogenol is one of the most extensively researched herbal supplement preparations in terms of both clinical studies and its underlying biological activity.

USES

Although there may be many potential uses for Pycnogenol, the most extensively studied use is to treat cardiovascular health, especially chronic venous insufficiency (CVI), a condition defined by poor drainage of blood from veins resulting in swelling or skin problems. Seven 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 on the following potential uses: thrombosis (blood clots), diabetes and its complications, hypertension (high blood pressure) and its complications, coronary artery disease, asthma, attention deficit hyperactivity disorder (ADHD), gynecology (endometriosis [premenstrual pain caused by endometrial tissue outside the uterus], dysmenorrhea [painful menstruation], pregnancy-associated pain, and menopause transition), osteoarthritis (OA), acute and postpartum hemorrhoids, and memory. These indications have 1 to 5 well-designed, published clinical trials that support the findings. All of these studies have shown a benefit, but larger studies are needed to confirm 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), ultraviolet (UV) light-induced erythema (sunburn), skin elasticity and hydration, muscle cramps and pain, postthrombotic syndrome, diabetic microangiopathy, metabolic syndrome, allergic rhinitis, common cold, psoriasis, chemotherapy/radiotherapy side effects, and tinnitus.

DOSAGE AND DURATION OF USE

The following doses were used in the clinical trials reported in Table 2 in the full monograph by the American Botanical Council. It should be noted that some of the doses are based on a single study and/or uncontrolled studies.

- ADHD: 100 mg/day or 1 mg/kg of body weight/day
- Allergic rhinitis: 100 mg/day
- Asthma: 100 mg/day or 1 mg/lb of body weight/day
- Chemotherapy/radiotherapy side effects: 150 mg/day
- Cholesterol/dyslipidemia: 120-150 mg/day
- Cognition: 100-150 mg/day
- Common cold: 100 mg/day
- Coronary artery disease: 200 mg/day
- CVI: 150-360 mg/day
- Diabetes: 50-200 mg/day oral or 100 mg topical Pycnogenol powder
- Dysmenorrhea: 60 mg/day
- Endometriosis: 60 mg/day
- Erectile dysfunction: 120 mg/day
- Gingivitis: 30 mg/day
- Hemorrhoids (acute): 150-300 mg/day oral plus topical 0.5% Pycnogenol cream
- Hemorrhoids (postpartum): 150 mg/day
- Hypertension: 100-200 mg/day
- Melasma: 75 mg/day
- Menopause transition: 60-200 mg/day
- Metabolic syndrome: 150 mg/day
- Muscle cramps: 200 mg/day
- OA: 100-150 mg/day
- Platelet function: 100-200 mg/day
- Pregnancy-associated pain: 30 mg/day
- Psoriasis: 150 mg/day
- Retinopathy: 40-160 mg/day
- Skin elasticity and hydration: 75 mg/day
- Sunburn: 1.10-1.66 mg/kg of body weight/day
- Thrombosis: 100-200 mg/day
- Tinnitus: 150 mg/day

In the clinical trials, the most common duration of use was 2 to 3 months; however, longer-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 by millions of people that might warrant a limitation. Long-term safety studies would be a useful addition to the overall safety profile of Pycnogenol.

MANUFACTURER DOSE RECOMMENDATIONS:

According to the manufacturer, the dosage of Pycnogenol will depend on the nature of the desired health benefits. For example, the dose required for preventative effects may be different from the dose used for improving acute or chronic health problems.

As an antioxidant, Pycnogenol may be effective at any dose. However, the manufacturer states that in order to have measurable physiological 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 hypercoagulation, 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 of venous insufficiency, the daily dosage should be in the range of 100 to 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 levels in patients with diabetes, the manufacturer recommends taking 50 mg once or twice daily.

Anti-inflammatory effects can be achieved with Pycnogenol doses of at least 30 mg/day.

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

For OA, asthma, and ADHD, 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.

Children: As a general precaution, children younger than 6 years old should not use Pycnogenol.

ADVERSE EFFECTS

The safety of Pycnogenol is based on data obtained from 91 human clinical studies with a total of 6845 people, including both healthy participants and patients with a particular dysfunction or pathology. The overall frequency rate of adverse effects (AEs) is very low (2.4%). In healthy participants, the incidence rate is even lower (0.1%). An evaluation of the clinical studies revealed that the occurrence of AEs 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 treatment-related AE. According to the manufacturer, GI effects may be avoided by taking Pycnogenol with food or after a meal. Dizziness, headache, and nausea are the next most frequently reported treatment-related 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.

There have been no reports of serious AEs in any clinical study or from commercial use of Pycnogenol since it was 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 international normalized ratio (INR, a measurement of bleeding tendency) in patients taking aspirin. No drug interaction studies have been performed with Pycnogenol.

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.

