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HerbClip™

- **Horse Chestnut (*Aesculus hippocastanum*)**
- **Aesculaforce®**
- **Chronic Venous Insufficiency**
- **Varicose Veins**

HC 060161-307

Date: June 30, 2006

RE: Efficacy of Horse Chestnut Seed Extract in Treating Chronic Venous Insufficiency

Suter A, Bommer S, Rechner J. Treatment of patients with venous insufficiency with fresh plant horse chestnut seed extract: a review of 5 clinical studies. *Adv Ther*. 2006;23(1):179–190.

Chronic venous insufficiency (CVI) afflicts approximately 6–10% of adults in industrialized countries, and its prevalence increases with age. This disease is characterized by venous stasis resulting from valvular incompetence, mainly caused by inflammation or venous occlusion. Early manifestations of CVI include edema (swelling) of the ankles and calf. Horse chestnut (*Aesculus hippocastanum*) seed extract (HCSE) has been used to treat CVI for decades. Published data support its use for alleviating the pain, cramps, itching, and edema associated with this disease.

The active ingredients of HCSE are collectively known as aescin, which comprise a mixture of alkylated triterpene glycosides. The mechanism of action appears to be an inhibitory effect on the catalytic breakdown of proteoglycans in the cell wall. This article is a review of 5 clinical trials on the safety and efficacy of 4 different formulations of HCSE made by the same company (Aesculaforce®; Bioforce AG, Roggwil, Switzerland; marketed in the U.S. as Venaforce®) in patients with CVI and varicose veins. As noted, 4 formulations of Aesculaforce were investigated in the 5 clinical trials: an alcohol tincture containing 39 mg aescin (the DER of the tincture is, 1:2.6, the dosage regimen is equal to 1.5 g of fresh plant), 20-mg aescin tablets, 50-mg aescin tablets, and a 2% aescin gel (external use). All studies were conducted in compliance with Good Clinical Practice. Changes in several symptoms associated with CVI were assessed, including heaviness and tension in the legs, edema, blue discoloration, pain, burning, and itching.

In study 1 (prospective, open, multicenter), 77% of 38 patients had a clinically therapeutic effect after an average of 4 weeks of treatment with the alcohol tincture (25 drops per day), and 60% of the patients rated the efficacy as "good" to "very good" for alleviating leg swelling, pruritus (itching), heaviness and tension in the legs, and cramps. The tincture was well tolerated; 3 adverse events were reported (2 in the placebo group).

In study 2 (randomized, placebo-controlled, double-blind),[1] symptoms improved in the treatment (20 mg aescin per tablet; 2 tablets per day) and placebo groups (n = 52); ankle circumference decreased

significantly more ($P < 0.05$) in the treatment group than in the placebo group. Three reports of gastrointestinal problems were reported (2 in the placebo group and 1 in the treatment group).

In study 3 (open, single-center),[2] mean symptom scores improved in all 78 patients after treatment with 50 mg aescin for 8 weeks, 1 tablet per day. Most of the patients (95%) rated the tolerability of the treatment as "good" or "fairly good," and 51% of the patients rated the overall efficacy as "good" or "very good." Several adverse events were reported; however, only 4 were judged to be related to the study medication.

In study 4 (open, uncontrolled, multicenter),[3] more than 85% of the patients ($n = 64$) and physicians rated the overall efficacy of the aescin gel as "good" or "moderate," and 92% of the patients rated the tolerability to be "good." Ankle circumference and mean individual and total symptom scores all decreased significantly ($P < 0.05$). None of the adverse events reported were judged to be related to the study medication.

In study 5 (open, uncontrolled),[3] 39 patients completed 8 weeks of therapy with a combination of the aescin gel (applied morning and evening) and the 20-mg tablets (1 per day). All symptom scores decreased by the end of treatment, significantly so for heaviness and pain in the legs and blue discoloration. Efficacy and tolerability scores of between 5 and 8 on a 10-point scale were reported.

The review of the abovementioned clinical trials indicates that the Aesculaforce® HCSE products, whether taken orally or applied topically, "provide effective treatment for patients with stage I and II CVI, as assessed by both objective and subjective methods" and their effectiveness is comparable with that of standard compression therapy. The products tested were well tolerated and safe, and the authors conclude that "Aesculaforce represents a real alternative therapy for those with mild to moderate forms of venous insufficiency."

—Brenda Milot, ELS

References

[1]Shah D, Bommmer S, Degenring FH. Aesculaforce bei chronisch venöser insuffizienz. Placebokontrollierte doppelblind-studie zum nacjweis der wirksamkeit und verträglichkeit eines phytotherapeutikums. *Schweiz Z Ganzheitsmed.* 1997;9:86-91.

[2]Dickson S, Gallagher J, McIntyre L, Suter A, Tan J. An open study to assess the safety and efficacy of *Aesculus hippocastanum* tablets (Aescularforce 50 mg) in the treatment of chronic venous insufficiency. *J Herbal Pharmcother.* 2004;4:19-32.

[3]Geissbühler S, Degenring FH. Treatment of chronic venous insufficiency with Aesculaforce vein gel. *Schweiz Z Ganzheitsmed.* 1999;11:82-87.

The American Botanical Council has chosen not to reprint the original article.