



# HerbClip™

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**FILE: ■Hyben Vital® (Litozin®)  
■Rose Hip (*Rosa canina*)  
■Anti-inflammatory  
■Analgesic**

**HC 020452-283**

**Date: June 30, 2005**

**RE: Hyben Vital® (Litozin®) Special Standardized Rose Hip Preparation Lowers Osteoarthritis Pain in Clinical Trial**

Rein E, Kharazmi A, Winther K. A herbal remedy, Hyben Vital (stand. powder of a subspecies of *Rosa canina* fruits), reduces pain and improves general wellbeing in patients with osteoarthritis--a double-blind, placebo-controlled, randomized trial. *Phytomed.* July 2004;11(5):383-391.

Osteoarthritis is a degenerative joint disease that affects an estimated 20.7 million Americans. It is characterized by the breakdown of the joint's cartilage, thus allowing bones to rub against each other, causing pain and loss of movement. Treatment of osteoarthritis involves the alleviation of symptoms such as pain and stiffness, and the reduction of inflammation. Hyben Vital® (Hyben Vital International, Langeland, Denmark; imported in the U.S. as Litozin®, EuroPharma, Green Bay, WI), a patented phytomedicinal preparation made from a rose hip subspecies of a special type of dog rose (*Rosa canina*), has been shown in recent *in vitro* and *in vivo* pharmacological studies, as well as several clinical trials, to have anti-inflammatory properties. The purpose of this randomized double-blind, placebo-controlled crossover study was to determine the safety and efficacy of Hyben Vital as a treatment for osteoarthritis.

Caucasian patients ( $n = 112$ ) were enrolled into the study through advertisements in local Denmark newspapers. Patients were diagnosed to be suffering osteoarthritis by a physician and were reported to have an X-ray verified diagnosis and symptoms of primary osteoarthritis in the hip, knee, hand, shoulder or neck, or some combination of these, for at least the last 12 months. The study consisted of 3 phases. The first phase was a 14-day run-in period in which baseline values were obtained. The second and third phases were treatment periods of 3 months each. Patients were randomly assigned to 2 groups. One group would receive Hyben Vital in the first treatment period and the other group would receive placebo. After 3 months, the groups switched immediately to the alternative treatment for the second treatment period.

Hyben Vital was supplied as capsules containing a biologically standardized rose hip powder. The daily dosage was 5 capsules containing 0.5 g each in the morning and evening. During the run-in phase and at the end of each treatment period, patients recorded the incidence of joint

stiffness and pain. In addition, the patients made a daily subjective assessment of the severity of joint pain, stiffness, and the state of wellbeing, sleep, energy, and mood. Compliance was measured at the end of the study by counting the number of capsules remaining and was calculated to be greater than 90% in all groups.

The results in the two arms of the crossover differed markedly. Group A (placebo first) showed significantly more improvement from Hyben Vital than from placebo for pain ( $P < 0.0078$ ) and for stiffness ( $P < 0.0025$ ). However Group B (Hyben Vital first) revealed a positive effect of equal magnitude for Hyben Vital in Group A, not only from the active phytomedicine, but also from placebo. A pattern very much like that described for pain occurred in the consumption of "rescue" medication as well. (Rescue medication refers to the conventional pharmaceutical analgesic drugs used by patients before the trial and during the trial to assist them in coping with daily activities.) Group A (placebo first) had a significant 44% decline ( $P < 0.0024$ ) in consumption of "rescue" medication during the Hyben Vital treatment. Group B (Hyben Vital first) had a consumption similar to that of Group A during Hyben Vital treatment. In addition, the consumption continued to decrease during the placebo treatment period, possibly due to the lasting or "carryover" effect of the components in the special rose hip preparation. This same pattern was observed when the diary records were evaluated for wellbeing. Furthermore, in a comparison of Groups A and B, patients significantly favored Hyben Vital as treatment ( $p < 0.0040$ ). No major side effects occurred in either group.

The data indicated that Hyben Vital reduces the symptoms of osteoarthritis. The authors interpreted the marked differences in the responses of the two groups as indicating a strong "carryover" effect of Hyben Vital. However, they caution that alternatively, the data may reflect the possibility of a slow onset of the active phytomedicine. Overall, the authors reported the herbal remedy Hyben Vital has a moderate alleviating effect on joint pain and improves general wellbeing, sleep quality, and mood in patients with osteoarthritis, without producing any adverse side effects. They suggested that the results warrant a large-scale double-blind, long-term, placebo-controlled, parallel study of Hyben Vital.

Considering the current public interest in natural, low-risk alternatives to the COX-2 pharmacological drugs, particularly since the voluntary recall of Vioxx (Merck) in September 2004, it is reasonable to predict that products like Hyben Vital/Litozin will receive considerable attention in the market and that larger, long-term studies will be welcomed.

—Heather S. Oliff, PhD

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