

Dr. Paul G. Varnas & WholeHealthAmerica.com present

THE BETTER HEALTH NEWS

SEPTEMBER, 2016

BIO-ALLAY®

HAPPY
LABOR DAY

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This is a reprint from a newsletter produced by John Rosenbaum. It does a good job of showing the research behind the herbal constituents of **Bio-Allay®** from Biotics Research

Bio-Allay® is a proprietary blend of 900 mg of *White Willow (Salix alba)* (bark), *Devil's Claw* extract (*Harpagophytum procumbens*) (root) and *Boswellia serrata* extract (gum) with a recommendation of two capsules twice a day. (It is not recommended for pregnant or lactating women.)

Willow bark (Salix spp): Willow bark is a natural COX-2 and cytokine release inhibitor. Aspirin is a COX-1 inhibitor that causes irreversible damage to thrombocytes while willow bark has no such effect. Willow bark is a phyto-anti-inflammatory herb that also has cartilage protective potential. It is useful in any painful osteoarthritis (OA) and rheumatoid arthritis (RA) condition. Actions of willow bark are multifold including antioxidative, anticytokine, along with the cyclooxygenase- and lipoxygenase-inhibiting effects. A non-purified extract of the phytomedicinal is required for full clinical benefit. (see "**Bio-Allay®**, page 2)

PAIN COSTS

Chronic pain is the most costly health problem in America, with an estimated annual cost of about \$90 billion per year. This cost includes lost productivity, legal costs, doctors' visits and medication; 80% of all visits to the doctor are pain related.

An estimated 40 million Americans have arthritis or other rheumatic condition. That number is expected to climb to 59.4 million, or 18.2% of the population, by the year 2020, according to a new report published as a collaborative effort between the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Arthritis Foundation, and the American College of Rheumatology.

Approximately 12% of all Americans suffer from migraine headaches.^{2,3} Nine out of 10 migraine sufferers report they can't "function normally" during days in which a migraine strikes. Three out of 10 migraine sufferers require bed rest when suffering from a migraine.

In 2001, over 13 million people saw a physician for the treatment of back pain. According to the NIH, 65 to 80% of all people have back pain at some time in their life. Half of all working Americans admit to having back pain symptoms each year⁴. Back pain costs an estimated \$50 billion each year.

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BIO ALLAY(FROM PAGE 1)

Except for rare allergy, no adverse effects are known, yet use during pregnancy and with anticoagulant medication is discouraged.

"Treatment of Low Back Pain Exacerbations With Willow Bark Extract: A Randomized Double-Blind Study," Chrubasik S, Eisenberg E, Balan E, et al, *Am J Med*, July 2000;109:9-14. In 70 patients (29 males, mean age of 56 years) with low back pain, subjects received a placebo compared with 70 patients (35 males, mean age of 55 years) who received oral willow bark extract at 120 mg/day (low-dose) and 70 subjects (32 males, mean age of 58 years) who received 240 mg/day of willow bark extract (high-dose) in a 4-week blinded trial. The percentage of pain-free patients in the last week of treatment was 39% in the group receiving the high-dose extract, 21% in the group receiving the low-dose extract and 6% in the placebo group. The response rate in the high-dose group was evident after 1 week of treatment. Significantly more patients in the placebo group required pain medication during each week of the study.

"Treatment of Low Back Pain with a Herbal or Synthetic Anti-Rheumatic: A Randomized Controlled Study. Willow Bark Extract for Low Back Pain." Chrubasik S, Kunzel O, Model A, Conradt C, Black A. *Rheumatology* (Oxford). 2001;40:1388-93. In a head-to-head study of 228 patients comparing willow bark (standardized for 240 mg salicin) with a COX-2 inhibiting drug, treatments were equally effective yet willow bark was safer and 40% less expensive.

"Efficacy and Tolerability of a Standardized Willow Bark Extract in Patients With Osteoarthritis: Randomized, Placebo-Controlled, Double Blind Clinical Trial," Schmid B, Ludtke R, et al, *Z Rheumatol*, 2000;59:314-320. In 39 subjects with osteoarthritis who received willow bark extract at a dose corresponding to 240 mg of salicin/day compared with 39 subjects who received placebo in a double-blind, controlled trial, there was a statistically significant difference in improvement in the WOMAC Osteoarthritis Index pain score, which was reduced 14% from baseline levels on the willow bark treatment compared with an increase of 2% in the placebo group. Patient diaries of symptoms confirmed this result.

"Complementary and Alternative Therapies for Rheumatic Disease," Kolasinski SL, *Hospital Practice*, April 15, 2001:31-39. Herbs used for rheumatic conditions include willow bark, which contains salicin; devil's claw (*Harpagophytum procumbens*) at 2.0 to 2.4 g/day as a powdered extract, which contains 0.3 to 0.7 g of harpagoside, for 1 to 2 months, which resulted in increased mobility.

Devil's Claw (Harpagophytum procumbens) has a long history of use in the alleviation of musculoskeletal pain, and recent clinical trials have substantiated its role as a moderately effective analgesic suitable for clinical utilization. Data suggests that *Harpagophytum* is better than placebo and at least as good as commonly used NSAIDs, suggesting that it should be clinically preferred over NSAIDs due to the lower cost and greater safety. Preparations of Devil's Claw are taken to treat painful arthrosis, tendonitis, gout, lumbago, myalgia, dyspepsia and

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"Comparison of outcome measures during treatment with the proprietary Harpagophytum extract Doloteffin in patients with pain in the lower back, knee or hip." Chrubasik, S., Thanner, J., Kunzel, O., Conradt, C., Black, A. and Pollak, S. (2002). *Phytomedicine* 9(3): 181-194. A recent clinical study (250 patients) assessed the efficacy of Harpagophytum extract in the treatment of non-specific lower back pain as well as osteoarthritic knee or hip pain. Patients were given the equivalent of 60mg harpagoside daily for 8 weeks and benefits (assessed using various disease-specific and generic measures of efficacy) were achieved in 50-70% of cases, with few adverse effects. The conclusion of the investigators was that the preparation was worth considering for all 3 types of pain.

"Efficacy and tolerance of Harpagophytum procumbens versus diacerhein in the treatment of osteoarthritis." Chantre, P., Cappelaere, A. Leban, D. et al. (2000) *Phytomedicine* 7: 177-183. In a recent clinical study involving 122 patients with osteoarthritis of knee and hip, a four-month randomized, double blind trial was undertaken, comparing the effects of a Harpagophytum crude extract (6×435mg capsules/day) with diacerhein 100mg/day. Assessment of pain and functional disability were made according to a visual analogue scale and severity of osteoarthritis evaluated by Lequesne's functional index. A reduction in spontaneous pain, as well as a progressive reduction in the Lequesne index was noted in both groups.

Boswellia (Boswellia serrata): (The ancient Indian herb called frankincense or incense). In clinical trials promising results were observed in patients with rheumatoid arthritis, chronic colitis, ulcerative colitis, Crohn's disease, bronchial asthma and peritumoral brain edema. The target dose is approximately 150 mg of boswellic acids TID; dose and number of capsules/tablets varied depending upon the concentration found in differing products.

"Special Extract of Boswellia serrata (H 15) in the Treatment of Rheumatoid Arthritis," Etzel, R., *Phytomedicine*, 1996;3(1):91-94. This study reviewed the effect of H 15, a special extract of the gum resin of Boswellia serrata, as a treatment for rheumatoid arthritis. In evaluating more than 260 individuals, H 15 was

See Bio-Allay page 6



Biotics Research Corporation, in effort to further the education of Healthcare Professionals and their patients, is pleased to offer several significant and useful practice building tools, all included in a weekly email, the **Biotics Bulletin**.

- **Tuesday Minute** - weekly video clip, full of nutritional education & clinical pearls
- **Weekly Product Feature** - product specific, informational summary
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ENZYMES FOR PAIN AND HEALING

There is some evidence that taking enzymes can reduce pain and inflammation, and improve healing. This is something that has been studied for a long time, with studies dating back to the 1960s and 1970s. Usually enzymes are taken to aid digestion. When they are taken on an empty stomach, they act to clean up the debris left over from the chemical warfare of inflammation. One study, published in the *Journal of Strength and Conditioning Research* (2007 Aug;21(3):661-7), showed that taking enzymes reduced muscle damage loss of strength after exercise. Another study in *Clinical Experimental Rheumatology* (Jan-Feb 2006;24(1):25-30) compared enzyme supplementation to NSAID use in patients with osteoarthritis of the hip. The double-blind, placebo controlled study lasted six weeks and involved 90 subjects and found that enzyme supplementation to be comparable to the drug in relieving pain, joint stiffness and improving function.

A study appearing in the *Journal of Dental Disease* (1964;19(2):73-77) evaluated the plant enzyme bromelain and its effect on pain and healing after dental surgery. One group of 22 patients took 40 mg of a bromelain concentrate four times each day for 2-3 days prior to surgery and continued for 3 days after surgery. In the second phase 33 subjects took 2 tablets 4 times a day on the day of surgery with the first dose being administered prior to surgery. The use of the enzymes produced

a marked reduction in inflammation and the amount of time the inflammation persisted post operatively. There was also a reduction in pain. Another study, appearing in the *Journal of the American Dental Association* (June 1966;72:1420-1425), subjects who underwent dental surgery received a proteolytic enzyme from *Carica papaya* (1 tablet per hour), or a placebo from the time of surgery until the following morning; for the next four days, they were given 1 tablet four times each day. The subjects taking the enzyme experienced less inflammation and pain, and had enhanced wound healing.

Bromelain, or a placebo was given to 160 women following episiotomy in research appearing in the journal *Obstetrics and Gynecology* (February 1967;29(2):275-278). The women were given two tablets, 4x/day for three days beginning within four hours after delivery. One person in the treatment group and four in the placebo group had an episiotomy infection. The amount of medication, especially narcotics, was reduced in these patients taking the bromelain therapy. The incidence of episiotomy infections was also lower in the group treated with the enzymes. Another study on episiotomy patients appearing in *Current Therapeutic Research* (May 1962;4(5):229-237), showed another vegetable enzyme (from papaya) to reduce inflammation and swelling after the surgery. In general, treatment with enzymes has little or no side-effects.

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(*Bio-Allay®* from page 3) found to be effective in the treatment of rheumatoid arthritis. When administering this botanical product, it is noted that: H 15 is normally not used for acute pain therapy; H 15 is a disease-modifying agent and can replace other disease-modifying therapies; early use of H 15 is beneficial; H 15 is well tolerated and shows high levels of safety for early use and long-term therapy; long-term effects of H 15 on the joints and the anatomy are not yet clear; and H 15's efficacy has only been demonstrated scientifically for rheumatoid arthritis. In this study, only 50 to 60% of the patients responded to the H 15 therapy.

"Effects of *Boswellia serrata* Gum Resin in Patients With Bronchial Asthma: Results of a Double-Blind, Placebo-Controlled, 6-Week Clinical Study," Gupta I, Gupta V, et al, *Eur J Med Res*, November 17, 1998;3(11):511-514. In 23 males and 17 females who were between 18 and 75 years of age with a mean duration of bronchial asthma of 9.58 years, 300 mg, 3 times daily, for a period of 6 weeks of *Boswellia serrata* resulted in an improvement in asthma in 70% of patients, as evidenced by disappearance of physical symptoms and signs, such as shortness of breath, rhonchii, number of attacks, an increase in FEV1, FVC and PEFR, as well

as a reduction in the eosinophilic count and ESR. In the control group of 40 patients (16 males and 24 females, age range of 14 to 58 years) who took lactose at 300 mg, 3 times daily, for 6 weeks, only 27% in the control group showed improvement.

"Boswellic Acids Inhibit Glioma Growth: A New Treatment Option?" Winking M, Sarikaya S, Rahmanian A, et al, *J Neuro-Oncol*, 2000;46:97-103. The gum resin of *Boswellia serrata* has been used in India and other countries of the Eastern world for many years to treat inflammatory diseases. In a clinical trial of glioblastoma patients, the extract gum resin was able to reduce the peritumoral edema depending on the dose given. Boswellic acids from gum resin inhibit the 5-lipoxygenase enzyme, which is important in leukotriene synthesis. Reducing these inflammatory leukotrienes can help reduce edema formation.

"Alternative Therapies for Arthritis Treatment," Robert D, *Orthopedic Nursing*, November/December 2003; 22(5):335-342. *Boswellia* has shown benefit in arthritis as a standardized extract at a typical dose of 150 mg, 3 times daily, for 2-3 months. It is generally noted as being safe.