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FILE: ■ *Pelargonium sidoides*
■ **Acute Bronchitis**
■ **Respiratory Tract Infections**

HC 050272-346

Date: February 15, 2008

RE: Double Blind Study Finds *Pelargonium sidoides* Effective For Treatment of Acute Bronchitis

Schulz V. Liquid herbal drug preparation from the root of *Pelargonium sidoides* is effective against acute bronchitis: results of a double-blind study with 124 patients. *Phytomed.* 2007;14 Suppl 6:74-75.

This article was a letter to the editor describing a study by Chuchalin et al¹ (2005). (See HC 010261-297.)

Acute bronchitis is one of the most common diagnoses made by primary care physicians. Up to two-thirds of patients with acute bronchitis are treated with antibiotics; however, up to 95% of cases are viral. The use of antibiotics to treat viral infections raises concerns about antibiotic resistance and questionable efficacy.

Extracts from the roots of *Pelargonium sidoides* have been used for years in Germany for the treatment of respiratory tract infections. EPs® 7630, a liquid herbal drug preparation from the roots of *P. sidoides*, is gaining interest in the treatment of acute bronchitis. EPs 7630 possesses antimicrobial and immunomodulatory properties shown to account for the therapeutic effect in respiratory tract infections, as demonstrated in several clinical trials.

This randomized, double-blind, placebo-controlled study, performed over 12 months in Moscow, ascertained whether treatment with EPs 7630 was better than placebo in relieving the symptoms and improving quality-of-life in adult patients with acute bronchitis. The study was designed as a confirmatory study using placebo controls to provide confirmation of the superiority of the active substance.

Patients were instructed to take 30 drops of EPs 7630 (Spitzner Arzneimittel, Ettlingen, Germany) 3 times each day before meals. A 100-ml solution of the active study substance contained 80 g EPs 7630. Patients were assessed for a reduction in the Bronchitis Severity

Score (BSS), calculated as the sum of five symptoms typical of acute bronchitis (cough, sputum, rales/rhonchi, chest pain during coughing, dyspnea).

Of 124 patients enrolled in the study, 64 patients had taken the active substance and 60 patients had taken placebo. At baseline, the mean BSS was 9.0 ± 2.2 points in patients assigned to the EPs 7630 group and 9.1 ± 2.2 points in those allocated to the placebo group. The reduction in BSS up to the final examination (Day 7) was 7.2 ± 3.1 points with active substance and 4.9 ± 2.7 points with placebo. The improvement with EPs 7630 was significantly greater than that with placebo ($P < 0.0001$). Relief of the individual symptoms was also more marked with EPs 7630 than with placebo. Remissions by Day 4 occurred in 69% of the patients receiving active substance treatment, compared with 33% of the patients receiving placebo. Adverse events were reported in 15 of 64 patients with the active substance and in 10 of 60 patients with placebo. None of these events was classified as serious.

Overall, the use of EPs 7630 was well tolerated and effective in the treatment of acute bronchitis. The authors conclude that a prescription of EPs 7630 can minimize the use of antibiotics for respiratory tract infections, thus reducing not only the risks of such therapy, but also the costs of the treatment and any subsequent measures.

—Jennifer Minigh, PhD

Reference

¹Chuchalin AG, Berman B, Lehmacher W. Treatment of acute bronchitis in adults with a *Pelargonium sidoides* preparation (EPs® 7630): A randomized, double-blind, placebo-controlled trial. *Explore*. 2005; 1:437–445.

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