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HerbClip™

File: ■ *Pelargonium sidoides*
■ EPs 7630
■ Acute Bronchitis
■ Children and Adolescents

HC 041236-450

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RE: An Extract of *Pelargonium sidoides* Root (EPs 7630) Is Safe and Effective in Children and Adolescents with Acute Bronchitis

Kamin W, Ilyenko LI, Malek FA, Kieser M. Treatment of acute bronchitis with EPs 7630: Randomized, controlled trial in children and adolescents. *Pediatr Int*. 2012 Apr;54(2):219-226.

Acute bronchitis is a common childhood illness. Although 95% of the cases are caused by viruses, about one-third of patients are prescribed antibiotics. Studies have shown that antibiotic therapy is mostly ineffective in acute bronchitis, unless the pathogen is of bacterial origin and known by lab test. A therapeutic alternative in the first-line treatment of acute bronchitis is EPs 7630 (the active ingredient of the product Umckaloabo®; ISO Arzneimittel; Ettlingen, Germany), which has been approved in Germany for use in adults and in children aged 1 year and older. EPs 7630 is an herbal drug preparation derived from the roots of *Pelargonium sidoides* (1:8-10); extraction solvent: ethanol, 11% (w/w). These authors conducted a randomized, double-blind, placebo-controlled clinical trial to demonstrate the efficacy and tolerability of EPs 7630 in children and adolescents suffering from acute bronchitis.

The pharmacological activities of EPs 7630 and its components, which include antibacterial potencies and immunomodulatory capabilities, have been demonstrated in vitro. The immunomodulatory activities are mainly mediated by the release of tumor necrosis factor-α and nitric oxides, the stimulation of interferon-β, and the increase in natural killer cell activity.[1-4]

This study was conducted between March 2006 and May 2006 in 11 Russian centers. Patients meeting the inclusion criteria were randomly allocated to 1 of 2 treatment groups. Following a baseline examination and subjective evaluations, the patients were scheduled for follow-up examinations on days 3-5 (visit 2) and day 7 (visit 3).

To be included, the patients had to be aged 1-18 years; suffering from acute bronchitis with symptoms starting ≤48 hours before inclusion in the study; and have a total score of bronchitis-specific symptoms (BSS) ≥5 points at the time of screening.

A total of 220 patients were randomized to receive EPs 7630 (n=111) or placebo (n=109) as follows: 10 drops 3 times daily for patients aged 1-6 years; 20 drops 3 times daily for patients aged >6 to 12 years; or 30 drops 3 times daily for patients aged >12 to 18 years for 7 consecutive days.

No significant differences were noted at baseline between the groups for demographic and anthropometric data. Concomitant medication was taken by 6.3% of patients in the EPs 7630 group and 10.1% in the placebo group. Acetaminophen use was allowed and did not differ between groups. Antibiotics were taken by 5 patients in the EPs 7630 group and 3 patients in the placebo group.

The primary efficacy variable was the change in the BSS total score from day 0 to day 7. The BSS total score comprised the 3 items "coughing," "pulmonary rales at auscultation" (also known as "crackles"; the clicking, rattling, or crackling noises that may be made by one or both lungs), and "dyspnea" (difficult breathing; shortness of breath). At each visit, those symptoms were scored according to a 5-point verbal rating scale from 0 ("not present") to 4 ("very severe").

From baseline to day 7, the mean BSS total score decreased by 4.4 ± 1.6 points in the EPs 7630 group compared with 2.9 ± 1.4 points in the placebo group.

A continuous decrease in the mean BSS total score between baseline and day 7 was observed in both groups, but scores were significantly better with EPs 7630 than placebo after 3-5 days and 7 days: EPs 7630 vs. placebo — day 0: 6.0 ± 1.6 vs. 5.8 ± 1.3; days 3-5: 3.6 ± 1.4 vs. 4.3 ± 1.4; day 7: 1.6 ± 1.4 vs. 2.9 ± 1.4 ($P<0.0001$ for days 3-5 and day 7, respectively).

For the individual symptoms "coughing" and "pulmonary rales at auscultation," the mean decrease in BSS between day 0 and day 7 was more pronounced in the EPs 7630 group compared with the placebo group ($P<0.0001$). "Dyspnea" showed a nonsignificant advantage for EPs 7630.

Regarding general symptoms, "lack of appetite" was significantly improved in the EPs 7630 group at day 7 ($P=0.0003$).

Amongst other secondary efficacy variables were the response rates defined as a BSS total score of <3 points at day 7 (criterion 1); a decrease in the BSS total score by at least 4 points from day 0 to day 7 (criterion 2); and a BSS total score <3 at day 7 combined with a decrease in the BSS total score by at least 4 points from day 0 to day 7 (criterion 3).

Response rates at day 7 were considerably higher in the EPs 7630 group compared with the placebo group. For all 3 response criteria, a statistically significant difference was observed for the EPs 7630 group ($P<0.0001$ for each).

The treatment effect occurred significantly earlier in the EPs 7630 group compared with the placebo group ($P<0.0001$).

Evaluation of the treatment outcome by the investigator and the satisfaction of patients with the treatment were each significantly better in the EPs 7630 group compared with the placebo group (P<0.0001 for both).

Three adverse events were observed in 2 of the 111 patients in the EPs 7630 group, but a causal relationship was excluded in all 3 cases. Clinical laboratory parameters showed only marginal group differences.

These results support the efficacy, tolerability, and safety of the herbal drug preparation EPs 7630 in children and adolescents aged 1-18 years suffering from acute bronchitis. This confirms a previously published observational study in children ages 0-12 years.[5]

According to the authors, the treatment benefit was most pronounced for the symptoms "coughing" and "rales at auscultation," which could be explained by the improvement of ciliary beating as found in vitro.[6] They suggest that this could be an important mode of action independent of antibacterial activity as most episodes of acute bronchitis are caused by viruses.

The authors point out that even in diseases requiring antimicrobial therapy, initial treatment with EPs 7630 could "bridge the time between presentation of the patient and the final decision on an appropriate antibiosis, thus reducing the risk of uncritical antibiotic treatment."

A previous systematic review of 6 clinical trials on the use of EPs 7630 by patients with bronchitis concluded there is "encouraging evidence from currently available data that *P. sidoides* is effective compared to placebo for patients with acute bronchitis."[7]

—Shari Henson

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