P.O. Box 144345 Austin, TX 78714-4345 ▪ 512.926.4900 ▪ Fax: 512.926.2345 ▪ www.herbalgram.org

HerbClip™

File: ■ *Pelargonium sidoides* (EPs 7630)
■ Acute Bronchitis
■ Pediatrics

HC 031061-398

Date: April 15, 2010

RE: *Pelargonium sidoides* Extract Dosages for Acute Bronchitis in the Young

Kamin W, Maydannik V, Malek F, Kieser M. Efficacy and tolerability of EPs 7630 in patients (aged 6-18 years old) with acute bronchitis. *Acta Paediatr*. Jan 11, 2010. [Epub ahead of print] doi: 10.1111/j.1651-2227.2009.01656.x

The EPs® 7630 extract (Umckaloabo®; ISO Medicines; Ettlingen, Germany; marketed by Spitzner Arzneimittel, Ettlingen, Germany; a member of Dr. Willmar Schwabe GmbH; Karlsruhe, Germany; marketed in the US as Zucol™; Nature's Way, Inc.; Springville, Utah) of *Pelargonium sidoides* roots has antibacterial, antiviral, and immunomodulatory properties in vitro. Clinical trials have demonstrated that EPs 7630 is safe and effective in treating acute bronchitis in infants, children, and adults.[1,2] This clinical trial was designed to determine the optimal EPs 7630 solid extract dose in children and adolescents and to assess the safety and efficacy of EPs 7630 in the treatment of acute bronchitis in patients aged 6-18 years.

The study was conducted at 16 multiple sites across the Ukraine between February and May 2006. The patients were aged 6-18 years and had been suffering from acute bronchitis for at least 48 hours. They were randomized, using a computer-generated randomization list, to 4 groups: placebo (n=101), 30 mg/day EPs 7630 (n=100), 60 mg/day EPs 7630 (n=99), and 90 mg/day EPs 7630 (n=99). Dosing occurred 30 minutes before or after meals 3 times daily for 7 days. At screening, the patients' total bronchitis specific symptom (BSS) scores were at least 5 points. The BSS includes 5 symptoms: coughing, sputum production, pulmonary rales at auscultation, chest pain while coughing, and dyspnoea. The symptoms are scored on a scale from 0 (absent) to 4 (very severe) for total possible score of 20. There were no noticeable differences in baseline characteristics.

The change in mean BSS total score from baseline to day 7 was the primary efficacy measure. Secondary efficacy measures included treatment response, onset of effect, change in individual bronchitis symptoms, change in general symptoms, and health status as measured by the questionnaire for the health state of children (FGK). Both patients and physicians completed the Integrative Medicine Outcome Scale (IMOS) to rate treatment outcome. The Integrative Medicine Patient Satisfaction Scale (IMPSS)

was used to assess satisfaction with treatment. Adverse events, laboratory safety parameters, and vital parameters were used to assess safety.

There was 1 early drop-out from the 30 mg EPs 7630 group (withdrawal of consent) who was not included in the data analysis. The average age was 12.5-12.9 years for the 4 groups. The decrease in total BSS score from day 0 to day 7 was greater in the 30, 60, and 90 mg EPs 7630 groups compared to the placebo group (60 mg: P=0.0004; 90 mg: P<0.0001). The authors observed a difference between the placebo and the EPs 7630 groups in total BSS scores on days 3-5, and they write that the difference increased in a dose-dependent manner until day 7. Treatment response as defined by a total BSS score below 3 (criterion 1) was significantly greater in the 60 and 90 mg EPs 7630 groups compared to the placebo group (60 mg: P=0.0339; 90 mg: P=0.0001). Treatment response as defined by a decrease in the total BSS score of at least 7 points (criterion 2) was significantly better in the 90 mg EPs 7630 group compared to the placebo group (P=0.0175). Treatment response defined as combination of criteria 1 and 2 was also significantly greater only in the 90 mg EPs 7630 group (P=0.0093).

The EPs 7630 groups had significant dose-dependent reductions compared to the placebo group in the individual BSS scores for coughing (P<0.0001), sputum (P=0.0016), and pulmonary rales at auscultation (P<0.0001). Individual BSS symptom scores were significantly lower in the 60 and 90 mg EPs 7630 groups compared to placebo: coughing (P=0.0433 and P=0.0002, respectively), sputum (P=0.0499 and P=0.0048, respectively), and pulmonary rales at auscultation (P=0.0014 and P<0.0001, respectively).

The EPs 7630 groups also showed significant dose-dependent decreases in general symptoms from day 0 to day 7, including loss of appetite (P=0.0234), headache (P=0.0112), and vomiting (P=0.0142). The 90 mg EPs 7630 group showed significant improvements compared to the placebo group for headache and loss of appetite (P=0.0128 and P=0.0090, respectively). Significantly more patients in the 60 and 90 mg EPs 7630 groups experienced the onset of treatment effect by day 5 compared to the placebo group (P=0.0060 and P<0.0001, respectively). IMOS and IMPSS scores were better in the EPs 7630 groups compared to the placebo group.

All of the groups showed improvements in health status from day 0 to day 7 as measured by the FGK questionnaire. The 60 and 90 mg EPs 7630 groups experienced significantly greater improvements compared to the placebo group in the FGK item "I am feeling ill" (P=0.0012 and P=0.0001, respectively). The 90 mg EPs 7630 had significantly greater improvements compared to the placebo group for the FGK items "I have trouble playing or learning" and "I sleep bad" (P=0.0063 and P=0.0067, respectively). By day 7, 33.7% of placebo group patients were able to return to school or work, compared to 35.0% in the 30 mg group, 44.4% in the 60 mg group, and 53.5% in the 90 mg EPs 7630 group. Eighty adverse events were reported by 77 patients, but none were considered serious. Gastrointestinal disorders were the most frequently reported (11%) adverse events. The authors report no significant differences between the EPs 7630 groups and the placebo group in the frequency and incidence of adverse events.

The authors conclude that this study demonstrates the safety, tolerability, and efficacy of EPs 7630 tablets in the treatment of acute bronchitis in 6-18 year-old patients. Possible mechanisms of action include improvements in the beating of epithelial cilia. The authors

conclude that 60 mg/day EPs 7630 may be the optimal dose for 6-18 year-old patients when considering benefit versus risk.

—Marissa Oppel-Sutter, MS

References

1.Minigh J. *Pelargonium sidoides* found to be effective as a treatment for acute bronchitis. *HerbClip*. January 31, 2008 (No. 050271-345). Austin, TX: American Botanical Council. Review of *Pelargonium sidoides* preparation (EPs 7630) in the treatment of acute bronchitis in adults and children by Matthys H, Kamin W, funk P, Heger M. *Phytomed*. 2007;14(Supp6):S69-S73.
2.Oliff H. *Pelargonium sidoides* use for acute bronchitis. *HerbClip*. September 15, 2008 (No. 050583-360). Austin, TX: American Botanical Council. Review of *Pelargonium sidoides* for acute bronchitis: A systematic review and meta-analysis by Agbabiaka TB, Guo R, Ernst E. *Phytomed.* 2008;15:378-385.

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