

Plerus

Active ingredient is Pelargonium Sidoidis Root Extract also called EPS 7630.

Clinical Use

- Studies have proven its efficacy as anti-inflammatory and are very effective in treating acute and chronic bronchitis, acute non-GABHS tonsillopharyngitis (sore throat) in children and adults, and in the relieve of the symptoms associated with bronchitis like cough, fever and other symptoms.
- A 2008 systematic review of these findings by the Cochrane Collaboration concluded that this extracts might be effective in treating adults for acute rhinosinusitis and the common cold in adults. They also wrote that it might be effective in relieving the symptoms of acute bronchitis in adults and children, and also the symptoms of sinusitis in adults.
- It has been shown to be anti-mycobacterial with significant antibacterial properties against multi-resistant Staphylococcus aureus strains.
- Gallic acid and its methyl ester present in large amounts in the active extracts were identified as the prominent immunomodulatory principle.

Efficacy in Bronchitis

A meta-analysis of 4 randomized clinical trials, including 1,647 patients, supported the plant's efficacy in reducing bronchitis symptoms. The mechanism of action is associated with EPs 7630 antagonism of bacterial adhesion to intact epithelia, leading to protection from bacteria colonization and infection in the upper respiratory tract.

Clinical data

Clinical trials of EPs 7630 in acute bronchitis have been conducted in children and adults.

The primary outcome or review of efficacy for most of the trials are changes in the Bronchitis Severity Score (ie, coughing, expectoration, chest pain, dyspnea, wheezing) from baseline versus the last observation (ie, final observation typically within 1 week). Inclusion criteria involved patients diagnosed with acute bronchitis within 48 hours who were not receiving antibiotic therapy, and who had no obvious contraindications to therapy. Dosage regimens included either EPs 7630 solution (30 to 90 drops per day) or tablets (10 to 30 mg per day), or placebo for 7 days. Results document the efficacy of EPs 7630 versus placebo in reducing severity of symptoms, improving quality of life, and shortening the duration of sick leave by nearly 2 days. The therapy was well tolerated, with no serious adverse reactions during the trials examined.

REFERENCES

1. National Institute of Allergy and Infectious Diseases. Common Cold. Available at: <http://www3.niaid.nih.gov/healthscience/healthtopics/colds>. Accessed July 16, 2007.
2. Bush A. Update in pediatrics 2005. *Am J Respir Crit Care Med*. 2006; 173:585-592.
3. Johnston SL. Overview of virus-induced airway disease. *Proc Am Thorac Soc*. 2005;2:150-156.
4. Van Kempen M, Bachert C, Van Cauwenberge P. An update on the pathophysiology of rhinovirus upper respiratory tract infections. *Rhinology*. 1999;37(3):97-103.
5. Herendeen NE, Szilagy PG. Infections of the upper respiratory tract. In: Behrman RE, Kliegman RM, Jenson HB, eds. *Nelson Textbook of Pediatrics*. 16th ed. Philadelphia, Pa: W. B. Saunders Company; 2000:1261-1266.
6. Van Cauwenberge PB, van Kempen MJP, Bachert C. The common cold at the turn of the millennium. *Am J Rhinol*. 2000;14:339-343.
7. Dreschers S, Dumitru CA, Adams C, Gulbins E. The cold case: are rhinoviruses perfectly adapted pathogens? *Cell Mol Life Sci*. 2007;64: 181-191.
8. Guillemot D, Carbon C, Vauzelle-Kervroëdan F, et al. Inappropriateness and variability of antibiotic prescription among French office-based physicians. *J Clin Epidemiol*. 1998;51:61-68.
9. Carrie AG, Zhanell GG. Antibacterial use in community practice: assessing quantity, indications and appropriateness, and relationship to the development of antibacterial resistance. *Drugs*. 1999;57: 871-881.
10. Thorpe, JM, Smith SR, Trygstad TK. Trends in emergency department antibiotic prescribing for acute respiratory tract infections. *Ann Pharmacother*. 2004;38:928-935.
11. Rutschmann OT, Domino ME. Antibiotics for upper respiratory tract infections in ambulatory practice in the United States, 1997 - 1999: does physician specialty matter? *J Am Board Fam Pract*. 2004;17:196-200.
12. Emmer C, Besser R. Combating antimicrobial resistance: intervention programs to promote appropriate antibiotic use. *Infect Med*. 2002;19:160-173.
13. Seppala H, Nissinen A, Jarvinen H, et al. Resistance to erythromycin in group A streptococci. *N Engl J Med*. 1992;326:292-297.
14. Felmingham D, Gruneberg RN, the Alexander Project Group. The Alexander Project 1996-1997: latest susceptibility data from this international study of bacterial pathogens from community-acquired lower respiratory tract infections. *J Antimicrob Chemother*. 2000;45:191-203.
15. Bax R, Bywater R, Cornaglia G, et al. Surveillance of antimicrobial resistance—what, how and whither? *Clin Microbiol Infect*. 2001;7:316-325.
16. Masterton RG. Surveillance studies: how can they help the management of infection? *J Antimicrob Chemother*. 2000;46:53-58.
17. Fahey T, Stocks N, Thomas T. Quantitative systematic review of randomised controlled trials comparing antibiotic with placebo for acute cough in adults. *BMJ*. 1998;316:906-910.
18. Mossad SB. Treatment of the common cold. *BMJ*. 1998;317:33-36.
19. Turner RB. Epidemiology, pathogenesis, and treatment of the common cold. *Ann Allergy Immunol*. 1997;78:531-539.
20. Smith MB, Feldman W. Over-the-counter medications: a critical review of the clinical trials between 1950 and 1991. *JAMA*. 1993; 269:2258-2263.
21. Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative

- medicine use in the United States, 1990-1997: results of a follow-up national survey. *JAMA*. 1998;280:1569-1575.
22. Roxas M, Jurenka J. Colds and influenza: a review of diagnosis and conventional, botanical, and nutritional considerations. *Altern Med Rev*. 2007;12:25-48.
23. Melchart D, Linde K, Fischer P, et al. Echinacea for preventing and treating the common cold. In: *The Cochrane Library*. 2001; Issue 1.
24. Kayser O, Kolodziej H, Kiderlen AF. Immunomodulatory principles of *Pelargonium sidoides*. *Phytother Res*. 2001;15:122-126.
25. Kolodziej H, Kayser O, Radtke OA, et al. Pharmacological profile of extracts of *Pelargonium sidoides* and their constituents. *Phytomedicine*. 2003;10(suppl IV):18-24.
26. Kolodziej H. Fascinating metabolic pools of *Pelargonium sidoides* and *Pelargonium reniforme*, traditional and phytomedicinal sources of the herbal medicine Umckaloabo. *Phytomedicine*. 2007;14(suppl VI):9-17.
27. Kolodziej H, Kiderlen AF. In vitro evaluation of antibacterial and immunomodulatory activities of *Pelargonium reniforme*, *Pelargonium sidoides* and the related herbal drug preparation EPs 7630. *Phytomedicine*. 2007;14(suppl VI):18-26.
28. Conrad A, Hansmann C, Engels I, Daschner FD, Frank U. Extract of *Pelargonium sidoides* (EPs 7630) improves phagocytosis, oxidative burst, and intracellular killing of human peripheral blood phagocytes in vitro. *Phytomedicine*. 2007;14(suppl VI):46-51.
29. Conrad A, Jung I, Tioua D, et al. Extract of *Pelargonium sidoides* (EPs 7630) inhibits the interactions of group A-streptococci and host epithelia in vitro. *Phytomedicine*. 2007;14(suppl VI):52-59.
30. Bachert C, Schapowal A, Kieser M, Malek F. Treatment of acute bacterial maxillary sinusitis with EPs 7630-solution: a randomised, double-blind, placebo-controlled trial. *Focus Alternat Complement Ther*. 2006;11:4.
31. Matthys H, Heger M. Treatment of acute bronchitis with a liquid herbal drug preparation from *Pelargonium sidoides* (EPs 7630): a randomised, double-blind, placebo-controlled, multicentre study. *Curr Med Res Opin*. 2007;23:323-331.
32. Chuchalin AG, Berman B, Lehmacher W. Treatment of acute bronchitis in adults with a *Pelargonium sidoides* preparation (EPs 7630): a randomised, double-blind, placebo-controlled trial. *Explore (NY)*. 2005;1:437-445.
33. Haidvogel M, Heger M. Treatment effect and safety of EPs 7630-solution in acute bronchitis in childhood: report of a multicentre observational study. *Phytomedicine*. 2007;14 (suppl VI):60-64.
34. Matthys H, Heger M. EPs 7630-solution—an effective therapeutic option in acute and exacerbating bronchitis. *Phytomedicine*. 2007; 14(suppl VI):65-68.
35. European Agency for the Evaluation of Medicinal Products. Guideline for Good Clinical Practice. Note for Guidance on Good Clinical Practice. 1997. CPMP/ICH/135/95. Available at: <http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf>. Accessed October 4, 2007.
36. World Medical Association Declaration of Helsinki. Recommendations guiding physicians in biomedical research involving human subjects. *JAMA*. 1997;227:925-926.
37. Jackson GG, Dowling HF, Spiesman IG, et al. Transmission of the common cold to volunteers under controlled conditions. *Arch Intern Med*. 1958;101:267-278.
38. Prasad AS, Fitzgerald JT, Bao B, et al. Duration of symptoms and plasma cytokine levels in patients with the common cold treated with zinc acetate: a randomised, double-blind, placebo controlled trial. *Ann Intern Med*. 2000;133:245-252.
39. Mossad SB, Macknin ML, Medendorp SV, et al. Zinc gluconate lozenges for treating the common cold: a randomised, doubleblind,

- placebo-controlled study. *Ann Intern Med.* 1996;125:81-88.
40. DuPuy HJ. The Psychological General Well-Being (PGWB) Index. In: Wenger NK, Mattson ME, Furberg CD, Elinson J, eds. *Assessment of Quality of Life in Clinical Trials of Cardiovascular Therapies*. New York, NY: LeJacq Publishers; 1984:170-183.
41. Brooks R. EuroQol: the current state of play. *Health Policy.* 1996;37:53-72.
42. Kind P. Measuring quality of life in evaluation clinical interventions: an overview. *Ann Med.* 2001;33:323-327.
43. EMEA. Points to Consider on Adjustment for Baseline Covariates. 2003.CPMP/EWP/2863/99. Available at: <http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf>. Accessed October 4, 2007.
44. O'Brien PC, Fleming TR. A multiple testing procedure for clinical trials. *Biometrics.* 1979;35:549-556.
45. Takkouche B, Regueira C, Gestal-Otero JJ. A cohort study of stress and the common cold. *Epidemiology.* 2001;11:345-349.
46. Fraenkel DJ, Bardin PG, Sanderson G, Lampe F, Johnston SL, Holgate ST. Lower airways inflammation during rhinovirus colds in normal and in asthmatic subjects. *Am J Respir Crit Care Med.* 1995;151:879-886.
47. Arroll B, Kenealy T. Are antibiotics effective for acute purulent rhinitis? Systematic review and meta-analysis of placebo controlled randomised trials. *BMJ.* 2006;333:279-281.