



ELSEVIER

Tolerance, safety and efficacy of *Hedera helix*¹ extract in inflammatory bronchial diseases under clinical practice conditions: A prospective, open, multicentre postmarketing study in 9657 patients

S. Fazio^a, J. Pouso^b, D. Dolinsky^c, A. Fernandez^d, M. Hernandez^e,
G. Clavier^f, M. Hecker^{g,*},²

^aMegapharma, Leyenda Patria 2942/801, CP 11300, Montevideo, Uruguay

^bCufre 1835, Montevideo, Uruguay

^cDe los Juncos M32 S1, Ciudad de la Costa, Canelones, Uruguay

^dRivera 6224, CP 11500, Montevideo, Uruguay

^eLondres No. 105 P. B. COL. COYOACAN C.P. 04000 Deleg. Coyoacan Mexico D.F.

^fAvenida 5 de Julio con calle Arismendi, Puerto La Cruz Estado Anzoátegui, CP 6023 Venezuela

^gEngelhard Arzneimittel GmbH & Co. KG, Herzbergstr. 3, 61138 Niederdorfelden, Germany

Abstract

In this postmarketing study 9657 patients (5181 children) with bronchitis (acute or chronic bronchial inflammatory disease) were treated with a syrup containing dried ivy leaf extract. After 7 days of therapy, 95% of the patients showed improvement or healing of their symptoms. The safety of the therapy was very good with an overall incidence of adverse events of 2.1% (mainly gastrointestinal disorders with 1.5%). In those patients who got concomitant medication as well, it could be shown that the additional application of antibiotics had no benefit respective to efficacy but did increase the relative risk for the occurrence of side effects by 26%. In conclusion, it is to say that the dried ivy leaf extract is effective and well tolerated in patients with bronchitis. In view of the large population considered, future analyses should approach specific issues concerning therapy by age group, concomitant therapy and baseline conditions.

© 2006 Elsevier GmbH. All rights reserved.

Keywords: *Hedera helix*; Bronchitis; Safety; Efficacy

Introduction

Bronchial inflammatory diseases rank first among the causes for seeking primary care, and their symptomatic therapy with herbal extracts is broadly disseminated, particularly in European countries. Those products have been used for over 50 years, being the general perception that they are effective and safe. This is supported by the significant increase of their prescription in countries like Germany (Lemmer, 2001).

*Corresponding author. Tel.: +49 0 6101 539 662;
fax: +49 0 6101 539 663.

E-mail address: m.hecker@engelhard-am.de (M. Hecker).

¹Prospan[®] in Venezuela and worldwide except Mexico: Panoto-s[®],
Argentina: Athos[®] and rest of Latin America: Abrilar[®].

²Includes doctors from Argentina, Centroeamerica, Chile, Colombia,
Dominicana, Ecuador, Mexico, Paraguay, Peru, Uruguay and
Venezuela.