Treatment of chronic bronchitis with ivy leaf special extract – multicentre post-marketing surveillance study in 1,350 patients

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Summary
Background and objectives: The changes of clinical symptoms and the tolerability of Prospan\textsuperscript{®} acute Effervescent Cough Tablets were investigated in a multicentre, prospective post-marketing surveillance (PMS) study focusing on patients with chronic bronchitis.

Patients and methods: The study included 1,350 male and female patients aged 4 years and above who were treated in one of 135 participating medical practices and who suffered from chronic bronchitis (with or without airway obstruction). During a scheduled observational period of 4 weeks, the patients had to take 1½ or 2 tablets per day (depending on their age), according to the manufacturer’s dosing recommendations, corresponding to 97.5 or 130 mg of dried ivy leaf extract (about 585 – 780 mg of drug). Treatment success was assessed by observing the changes in the indicating signs of chronic bronchitis between the baseline examination and the end of treatment. Safety was evaluated by the occurrence of adverse events.

Results: In comparison to baseline, the following percentages of patients showed improved symptoms or were cured at treatment end: cough 92.2 %; expectoration 94.2 %; dyspnoea 83.1 %; respiratory pain 86.9 %. In each of the four symptoms at least 38 % of the initially affected patients were completely free of complaints. Three patients (0.2 %) experienced adverse events in which a causal relationship to the drug under investigation could not be excluded (2 x eructation, 1 x nausea). Conclusions: Considering the favourable changes in all investigated clinical symptoms as well as the excellent tolerability in children and adults, the ivy leaf extract preparation Prospan\textsuperscript{®} acute Effervescent Cough Tablets can be considered as a therapeutic option in alleviating the symptoms of chronic bronchitis.