
Efficacy and tolerance of ivy extract (Prospan®) in patients suffering from respiratory tract diseases

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In 2 post-marketing observation trials the efficacy and tolerance of a special dried ivy leaf extract (Prospan®) in various forms of administration (cough syrup and effervescent cough tablets) were determined in a total of 248 patients who were suffering from inflammatory diseases of the respiratory tract. † Therapy proved to be effective and very well tolerated, whereby the results of controlled clinical studies with a larger range of administration were confirmed.

Introduction

The dried ivy leaf extract, manufactured according to a special procedure, used for the studies is an expectorant, which has been on the market for more than 25 years. This expectorant is administered to adults and children of every age with the indication "acute catarrh of the respiratory tract accompanied by coughing, symptomatic treatment of chronic bronchial diseases". The product has an expectorant and anti-obstructive effect due to its secretolytic and bronchospasmolytic properties. The efficacy and very good tolerance of the various forms of administration has been proved through the results of clinical studies (1-5). In a double-blind, placebo-controlled trial, the special extract proved, with regard to an improvement in pulmonary function in patients suffering from bronchial asthma, to be clinically clearly and statistically significantly better than placebo (5). Furthermore, it was proved that aqueous preparations for oral administration have to be dosed approximately 2.5 higher than ethanolic forms of administration (2,4,6). The recommended dosages for the corresponding preparations were therefore adjusted.

Far-reaching findings as to the efficacy and tolerance of these dosages from daily medical practice should be documented in the present post-marketing observation trials.

Method

The open, multicentrically designed post-marketing observation trials, without control groups, were carried out according to the requirements of the German Drug Law, the declaration of Helsinki/Tokyo and the principles for the conduct of clinical trials on medicinal products.

Efficacy was assessed by the doctor and noted on a 4-level scale from "symptom-free" to "worsened", with reference to symptoms and signs. Individual dosages as well as the duration of treatment were recorded as additional parameters. The assessment of tolerance resulted from the occurrence of adverse events and from a general assessment made by the individual doctor.

Patients

248 patients at an age of 0 to 79 years were included in the documentary account.

Admission criteria

- Patients of both sexes suffering from inflammatory and /or obstructive diseases of the respiratory tract.
- Effervescent cough tablets: age \geq 4 years
- Cough syrup: age 0-9 years

Exclusion criteria

- Treatment with another expectorant or antitussive
- Known fructose intolerance (due to the content of sorbitol)
- Intolerance to one of the components
- Severe respiratory tract diseases (asthma, mucoviscidosis, quinsy angina, bronchopneumonia)

Medication

The dosage and duration of treatment were based on the recommendations stated in the patient information leaflet and were adapted according to each individual clinical picture and course of disease.

Evaluation

Qualitative characteristics were described in detail by means of a descriptive process; quantitative characteristics by means of descriptive parameters.

The evaluation of tolerance took place with the Intention-to-treat Population (ITT), the analysis of efficacy was carried out with the Per-Protocol-Treatment Population (PPT).

Missing values remained as such.

Results

Patients

A total of 248 patients (138 female, 110 male) were admitted to the study; 176 (71%) thereof were younger than 15 years.

120 patients were treated with cough syrup and 128 with effervescent cough tablets. 13 patients were excluded from the analysis of efficacy due to violation of the admission and exclusion criteria.

The most frequently cited indications were "bronchitis" (45%) and "respiratory tract infection" (29%). All patients apart from one suffered from cough, more than half (63%) expectorated, in 16% and 23% of the patients, shortness of breath and respiratory pain were diagnosed respectively (multiple entries were possible).
