

TRANSLATION

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Efficacy and tolerability of ivy-containing cough remedies

Prospan[®] cough syrup¹ for children with recurrent obstructive airways disease

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In the subjective medical judgement of experienced German paediatricians, the ivy-containing cough remedy Prospan[®] proved under the conditions of a multicentre drug surveillance study to be very effective and safe for the treatment of recurrent obstructive airways disease in children aged 6 to 15 years. The treatment results were largely independent of age, sex, weight and concomitant drug therapy. Pulmonary function as well as the accompanying signs of coughing and expectoration improved significantly during the observation period. The optimum dosage proved to be 6 teaspoonfuls (2.5 ml) per day.

Key words

Obstructive bronchitis, ivy-containing cough remedies, coughing, pulmonary function.

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Cough syrup based on a special dried ivy leaf extract (Prospan[®]) has been established for years in the treatment of obstructive airways disease for its bronchospasmolytic and secretolytic properties [2].

The efficacy and tolerability of ivy have been positively assessed in comprehensive studies and monographs

(incl. [3]). The good efficacy of Prospan has been demonstrated in several studies (double-blind study [4] and spirometric examinations [1]).

Post Marketing Surveillance Study

As part of a multicentre drug surveillance study, the efficacy and tolerability of Prospan cough syrup for children and its effect on the symptoms of coughing and expectoration in children with recurrent obstructive bronchitis was to be studied under clinical practice conditions. At the same time, the changes in various pulmonary function

parameters during the observation period were recorded. Some of the patients were on long-term anti-obstructive therapy related to the diagnosis which had to remain unchanged during the observation period. The study was conducted in 8 clinics or specialist practices, predominantly in the nine federal German Länder (see authors and assistants²).

Methodology

113 patients of both sexes (45% girls, 55% boys) aged from 6 to 15 years (mean: 8.98; median: 8 years) were available for evaluation.

Table 1 Pulmonary function

Pulmonary function parameters before and after therapy with Prospan cough syrup for children

Pulm. Function parameters	Mean	*	Significance two-tailed	
FVC before	2.114	0.822		
FVC after, n=103	2.254	0.901	0.000	Significant
FEV1 before	1.854	0.688		
FEV1 after, n=103	2.021	0.801	0.000	Significant
PEF before	3.670	1.433		
PEF after, n=103	4.151	1.649	0.000	Significant
MEF25 before	1.253	0.473		
MEF25 after, n=101	1.408	0.553	0.000	Significant
MEF50 before	2.301	0.814		
MEF50 after, n=102	2.568	0.937	0.000	Significant

Wilcoxon matched pairs test: MW = Mean; * = Standard deviation; n = number of evaluable cases

Documentation:

Documentation was obtained by means of standardised patient record forms. Signs and symptoms and possible side-effects were collected, in some cases semi-quantitatively, by interview or medical examination at the beginning and end of the observation period. In addition, various parameters of the flow-volume curve were measured and in some cases the blood count and CRP determined. The duration of unfitness for school or absence from kindergarten was recorded, concomitant treatments collated and

patients questioned about tolerability and/or side-effects. Finally, the efficacy was assessed by the doctor, and the patients and/or their parents were asked about their assessment of the efficacy and acceptance of the medication.

Assessment methodology:

The data were assessed descriptively, univariately and bivariately, using appropriate statistical methods.

Results

The data from 113 patients with obstructive airways diseases were evaluated, all with the symptoms of coughing and the majority with expectation.

Dosage: 64% of the patients received the recommended daily dose of 3 x 2 (= 6) teaspoons (tsp) of 2.5 ml Prospan cough syrup for children, 32% a higher dose (8 – 10 tsp) and 4% a lower dose (3 – 4 tsp).

Concomitant therapy:

While 27% of the children were on Prospan

monotherapy, 73% received concomitant medication or longterm therapy, predominantly with metered dose aerosols with a combination of DNCG / β_2 -sympathomimetics. In these cases, the existing long-term therapy had to be continued at an unchanged dosage during the study period.

Duration:

The duration of treatment with Prospan cough syrup for children was up to 20 days in 74%, while 26% were treated for longer (21 up to more than 30 days).

Table 2 Doctor's assessments of the symptoms of cough and expectoration

2a Incidence of cough			2b Type of cough		
Incidence	Start n=113 (100%) n (%)	End n=111(100%) n (%)	Type	Start n=113(100%) n (%)	End n=108 (100%) n (%)
None	Ø	67 (60.4%)	None	Ø	65 (60.2%)
Sporadically	26 (23.0%)	41 (36.9%)	Productive	57 (50.4%)	15 (13.9%)
Frequently	87 (77.0%)	3 (2.7%)	Dry	47 (41.5%)	28 (25.9%)
			Paroxysmal	9 (8.0%)	Ø

2c Colour of expectoration			2d Quality of expectoration		
Colour	Start n=111 (100%) n (%)	End n=105(100%) n (%)	Quality	Start n=113(100%) n (%)	End n=111(100%) n (%)
No expectoration	33 (29.7%)	87 (82.9%)	No expectorat.	35 (31.0%)	91 (82.0%)
Colourless	53 (47.7%)	10 (9.5%)	Liquid	10 (8.8%)	14 (12.6%)
White	16 (14.4%)	6 (5.7%)	Semiviscous	33 (29.2%)	6 (5.4%)
Yellow	9 (8.2%)	2 (1.9%)	Viscous	35 (31.0%)	Ø
Green	Ø	Ø			

Pulmonary function significantly improved

The pulmonary function parameters improved significantly on therapy in the observation period (Tab. 1), largely independent of age, sex and weight.

Concomitant therapy had an effect on only a few individual parameters: antibiotics/chemotherapeutics on FEV1 and PEF, broncholytics/antiasthmatics on PEF.

Doctor's assessment: Coughing and expectoration improved

The incidence of coughing and

expectoration was assessed by the doctor at the end of treatment as generally being significantly improved (Tab. 2). There was no relationship between treatment results and age, sex, weight or unfitnes for school/ absence from kindergarten. The concomitant medication of antibiotics/chemotherapeutics and broncholytics/antiasthmatics or nasal decongestants had no significant effect on the incidence and type of coughing. The assessment of the quality and colour of the expectoration, however, was favourably influenced

in a statistically significant manner by additional antibiotics / chemotherapeutics.

Doctor's assessment: Efficacy and tolerability

In the doctor's assessment, 85.7% of patients were rated as "cured" or "essentially improved" (Tab. 3a). The assessment of tolerability was "very good" or "good" in 98.2% of the patients (Tab. 3b). No adverse drug reactions were documented. There were only three treatment discontinuations because of lack of efficacy.

On the basis of the doctors' assess-

ments, efficacy and tolerability were not significantly influenced by age, sex, weight and unfitnes for school or absence from kindergarten, but the daily dose had a significant influence with the recommended dose of 2 x 3 tsp tending to show the best results.

According to the doctors, there were also no significant interactions with the concomitant medication. A negative effect on tolerability was only found with broncholytics and anti-asthmatics (p = 0.0155, Mann-Whitney U test).

Table 3 Doctor's assessments of efficacy and tolerability of Prospan®**3a Efficacy**

Efficacy	End n=112 (100%) n (%)
Cured	62 (55.3%)
Essentially improved	34 (30.4%)
Somewhat improved	13 (11.6%)
Scarcely improved	2 (1.8%)
Worsened	1 (0.9%)

3b Tolerability

Tolerability	End n=112 (100%) n (%)
Very good	77 (68.7%)
Good	33 (29.5%)
Satisfactory	2 (1.8%)
Unsatisfactory	Ø
Worsened	Ø

Discussion

Under the conditions of the drug surveillance study Prospan® cough syrup for children proved very well tolerated and effective in the treatment of recurrent obstructive airways disease in children between the ages of 6 and 15 years.

The symptoms of coughing and expectoration and pulmonary function improved significantly in the observation period. These results confirm the studies by other authors [1, 2].

The treatment results proved to be largely independent of the children's age, sex and bodyweight and also of the concomitant therapy.

There was however a significant relationship with the administered daily dose, with the optimum dosage being 3 x 2 teaspoonfuls of 2.5 ml Prospan cough syrup for children.

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