

Retrospective documentation of the tolerance of the herbal medicinal product Prospan[®] Cough Syrup

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Summary

Within this retrospective documentation 310 physicians from Germany documented the tolerance of Prospan[®] Cough Syrup applied to 52 478 children. The data from 01.01.2002 until 30.06.2002 were included therefore.

Adverse drug reactions were documented in 115 cases (incidence of 0.22%).

The results of this huge amount of data show the excellent tolerance of Prospan[®] Cough Syrup and give evidence for the safety of this product in children.

Introduction

Prospan[®] Cough Syrup with an extract of dried ivy leaves as the herbal active ingredient is a well known medicinal product for the treatment of respiratory tract diseases which cause productive cough like acute or chronic forms of bronchitis. The active ingredient is an extract (produced in a special extraction process) of dried leaves of *Hedera helix* L. (Araliaceae). The first medicinal product with an extract of dried ivy leaves was marketed in Germany in 1950 (Prospan[®] Drops). Later on it was the aim of the producer – Engelhard Arzneimittel – to create dosage forms more convenient for children, last but not least due to the good efficacy and safety of the product. Therefore Engelhard Arzneimittel developed a syrup with a taste very well accepted by children, laying as well special emphasis on the use of unproblematic excipients (1).

Results from controlled clinical trials show a significant secretolytic and spasmolytic efficacy of Prospan[®] as well as a clinically relevant improvement of lung function (2-10). In a placebo controlled clinical trial Prospan[®] showed superiority to placebo with statistical significance and clinical relevance (8).

Furthermore it could be shown that non-ethanolic dosage forms have to be dosed 2.5 times higher than ethanolic ones to show an equivalent efficacy (5).

Several formerly conducted studies documented the excellent efficacy and safety of the application of Prospan[®] to 525 children (13). Out of these 356 children were treated with Prospan[®] Cough Syrup.

The actual retrospective documentation should reveal data concerning the number of adverse drug reactions in a huge amount of pediatric patients in different groups of age.

Method

The given data of 52 478 children are based on a retrospective documentation of 310 german physicians with regard to the tolerance of Prospan[®] Cough Syrup in children of different age groups. The documentation was based on the doctor's card index and included the following groups of patient's age: < 1 year, 1-5 years, 6-9 years, ≥ 10 years. The number of treated patients and adverse drug reactions, which were documented according to type and frequency of a given reaction, were evaluated descriptively. An estimation of missing entries was not being performed, missing or not evaluable data were left as such.

Results

The physicians documented the data of 52 478 patients. The group of children aged from 1-5 years was the greatest one with 26 566 patients (51%), followed by the group aged from 6-9 years (n=13 046; 25%). 15 % of children (n=8071) were younger than 1 year and 9% (n=4795) were 10 years and older (Fig. 1).

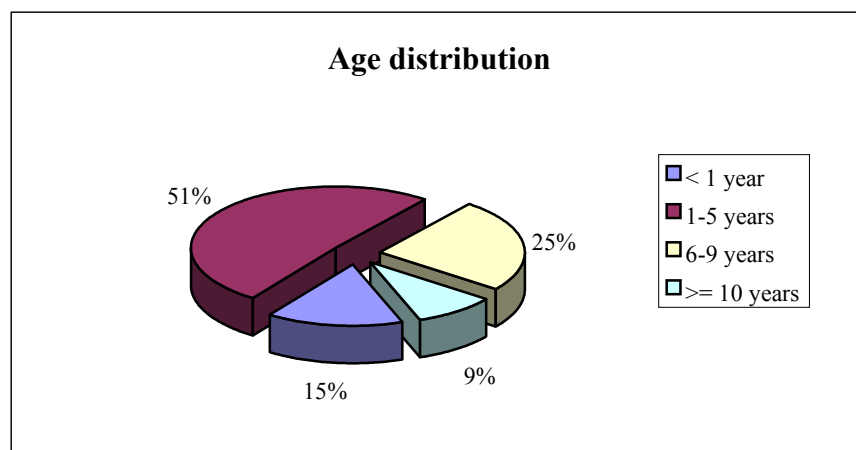


Fig. 1: Number of patients (%) per group of age; total of 52 478 patients

Tolerance of Prospan® Cough Syrup

The total sum of documented adverse drug reactions was 115 (incidence of 0.22%). As shown in Fig. 2, the most often recorded adverse reactions were gastrointestinal disturbances in 0.17% of the children (with diarrhoea in 0.1%, enteritis in 0.04% and vomiting in 0.02%), followed by allergic skin reactions (0.04%).

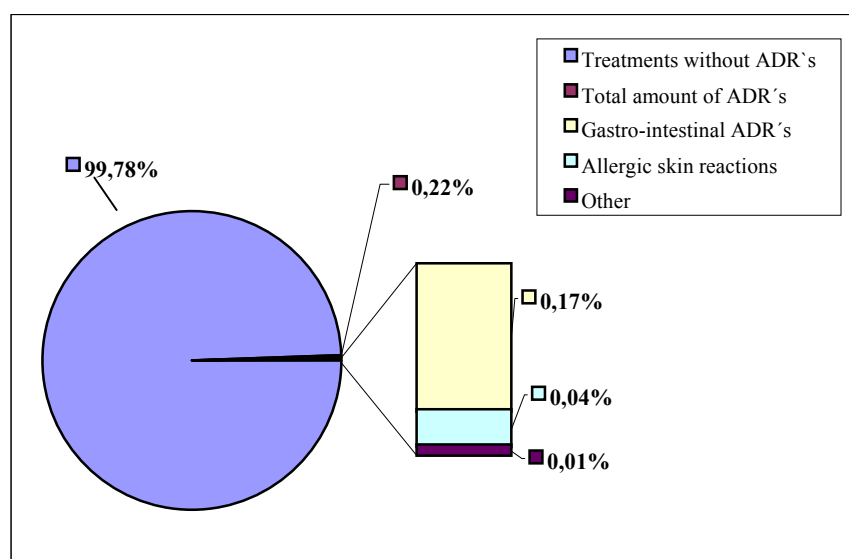


Fig. 2: Percentage of reported ADR's for the documented cases (52 478 cases including 115 ADR's in total, corresponding to 0.22 %). The column shows the distribution in percent of all ADR's on different organ systems (the sum corresponds to the total amount of 0.22 % ADR's).

In most cases, the gastrointestinal disturbances probably are caused by the content of sorbitol which is known to have a laxative effect (11).

With regard to the number of adverse drug reactions per patient group it is to notice that younger children suffer more often from adverse reactions than older ones. With growing age the part of patients with ADR's decreases from 0.4% (for the patient group < 1 year) to 0.13% (for the patients aged 10 years and older) (Fig. 3).

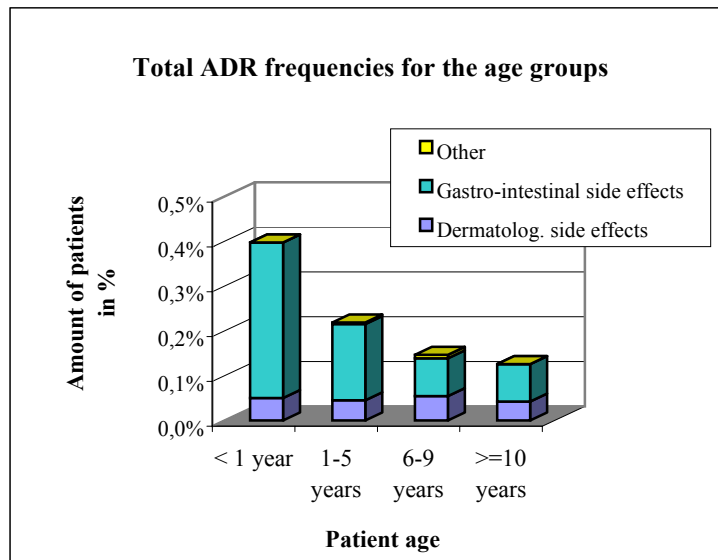


Fig. 3: Number of adverse drug reactions (%) per patient group

This correlates with an age related incidence for every single reaction: diarrhoea predominantly is listed for children < 1 year (0,27%), whereas the groups of older children suffered only in 0,09%, 0,04% and 0,04%, respectively, from diarrhoea.

Discussion

Even after having obtained the marketing authorization the manufacturer has the duty to supervise his marketed products with respect to adverse drug reactions. Very rare reactions can only be recognized in case of a broad use of the medication (12).

Therefore the aim of this retrospective documentation was to gain more information concerning the risk profile in the treatment of children with Prospan[®] Cough Syrup.

The results of this extensive documentation for 52 478 patients show the excellent tolerance and safety of Prospan[®] Cough Syrup in the treatment of children. These results are also in correlation with experiences of formerly conducted studies with Prospan[®] Cough Syrup.

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