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THE SAFETY OF ACAMOLI COLD IN CHILDREN WITH COMMON COLD

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Background: The common cold is the most universal of all infections. At present, only symptomatic treatment is available for uncomplicated cases of the common cold. Since no single medication affects all cold symptoms, combination products may provide relief more than the use of several single-ingredient products. However, these products may cause some undesired adverse reactions.
Objective: In this study we aimed to follow possible adverse effects among children receiving a combination therapy of Acamoli Cold®.
Design: Children with common cold received Acamoli Cold® (Teva Pharmaceutical Industries Ltd, Israel)(each 5ml contains 1mg chlorpheniramine, 15 mg pseudoephedrine and 160 mg acetaminophen). In each case the age of the patient, gender, diagnosis, number of doses, duration of treatment, antibiotic treatment if needed, parents satisfaction, and adverse reactions were reported.
Results: 891 children from 14 pediatric clinics participated in the study. The patients, aged 4.3±3.6 years (range 4 months to17 years), received 5.5±3.3(range 1-28) doses of acamoli cold for 2.7±1.5(1-14)days. General feeling was improved in 765 (86%) children, and 14.5% were re-examined by the physician. 13.5% of the children were eventually treated with antibiotics. Adverse reactions were reported among 45 (5%) patients; drowsiness was observed in 30(3.3%); 7(0.8%) children vomited, restlessness was reported in 4(0.44%) children, rash in 3(0.33%) patients, and tremor in 1(0.11%) patient.
Conclusions: The adverse reactions following the administration of acamoli cold reported in our study were low in frequency, mild and disappeared spontaneously. However, continuing reporting on its tolerability is needed.