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# Efficacy of Grintuss® pediatric syrup in treating cough in children: a randomized, multicenter, double blind, placebo-controlled clinical trial

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## Abstract

**Background:** Cough is an extremely common problem in pediatrics, mostly triggered and perpetuated by inflammatory processes or mechanical irritation leading to viscous mucous production and increased sensitivity of the cough receptors. Protecting the mucosa might be very useful in limiting the contact with micro-organisms and irritants thus decreasing the inflammation and mucus production. Natural molecular complexes can act as a mechanical barrier limiting cough stimuli with a non pharmacological approach but with an indirect anti-inflammatory action.

**Objective:** Aim of the study was to assess the efficacy of a medical device containing natural functional components in the treatment of cough persisting more than 7 days.

**Methods:** In this randomized, parallel groups, double-blind vs. placebo study, children with cough persisting more than 7 days were enrolled. The clinical efficacy of the study product was assessed evaluating changes in day- and night-time cough scores after 4 and 8 days (t4 and t8) of product administration.

**Results:** In the inter-group analysis, in the study product group compared with the placebo group, a significant difference (t4 study treatment vs. t4 placebo,  $p = 0.03$ ) was observed at t4 in night-time cough score.

Considering the intra-group analysis, only the study product group registered a significant improvement from t0 to t4 in both day-time (t0 vs. t4,  $p = 0.04$ ) and night-time (t0 vs. t4,  $p = 0.003$ ) cough scores.

A significant difference, considering the study product, was also found in the following intra-group analyses: day-time scores at t4 vs. t8 ( $p = 0.01$ ) and at t0 vs. t8 ( $p = 0.001$ ); night-time scores at t4 vs. t8 ( $p = 0.05$ ), and at t0 vs. t8 ( $p = 0.005$ ). Considering a subgroup of patients with higher cough ( $\geq 3$ ) scores, 92.9% of them in the study product group improved at t0 vs. t4 day-time.

**Conclusions:** Grintuss® pediatric syrup showed to possess an interesting profile of efficacy and safety in the treatment of cough persisting more than 7 days.

**Keywords:** Antitussive, Children, Cough, Efficacy, Grintuss®, Barrier effect, Safety

