Efficacy and safety of 5-grass-pollen sublingual immunotherapy tablets in pediatric allergic rhinoconjunctivitis.

BACKGROUND: The efficacy and safety of the 300-index of reactivity (IR) dose of 5-grass-pollen sublingual immunotherapy (SLIT) tablets (Stallergènes, Antony, France) have been demonstrated for the treatment of hay fever in adults. OBJECTIVE: We sought to assess the efficacy and safety of this tablet in children and adolescents with grass pollen-related allergic rhinitis. METHODS: In this multinational, randomized, double-blind, placebo-controlled study, 278 children (5-17 years of age) with grass pollen-related rhinoconjunctivitis (confirmed by means of a positive grass pollen skin prick test response and serum-specific IgE measurement) received once-daily SLIT tablets or placebo. Treatment was initiated 4 months before the estimated pollen season and continued throughout the season. The primary outcome was the rhinoconjunctivitis total symptom score (RTSS), a sum of 6 individual symptom scores: sneezing, runny nose, itchy nose, nasal congestion, watery eyes, and itchy eyes. Secondary end points included rescue medication intake, individual scores, and safety. RESULTS: The intent-to-treat population included 266 children (mean age, 10.9 +/- 3.22 years). The RTSS for the 300-IR group was highly significantly different from that of the placebo group (P = .001). The 300-IR group showed a mean improvement for the RTSS of 28.0% over that seen with placebo and a median improvement of 39.3%.
Significant differences between the 300-IR and placebo groups were also observed regarding rescue medication score and proportion of days using rescue medication during the pollen season (P = .0064 and P = .0146, respectively). Adverse events were generally mild or moderate in intensity and expected. No serious side effects were reported. CONCLUSION: Five-grass-pollen SLIT tablets (300 IR) reduce both symptom scores and rescue medication use in children and adolescents with grass pollen-related rhinoconjunctivitis.