Sublingual immunotherapy with standardized quality grass allergen tablets: results of the development program

Abstract:
15-25% of the German population suffer from allergic rhinoconjunctivitis, which is caused by grass pollen in half of the cases. Allergen-specific immunotherapy is considered the only causal treatment. For the first time a registered preparation for sublingual immunotherapy designed as a lyophilisated grass pollen tablet is available for the treatment of grass pollen-induced rhinoconjunctivitis. The tablet consists of standard quality-(SQ) standardized grass pollen allergens from timothy (Phleum pratense) in a dosage of 75,000 SQ-T. The application is once daily. This review summarizes the clinical studies for the evaluation of the safety and clinical efficacy of this new preparation. In the early phase of the development program, the main interest was related to safety issues. In total, 3 Phase I studies have been performed. In I of these studies patients were treated outside the pollen season with dosages of up to 1,000,000 SQ-T (> 13 times the dosage of the actual tablet) without severe or serious adverse events. In a dose-finding study, the optimal therapeutic dose was found to be 75,000 SQ-T once daily. With this dose the following studies were performed. In a Phase III study (GT-08) 634 patients were included. A mean reduction of the symptom score of 30% (p< 0.0001) and of the medication score of 38% (p< 0.0001) was demonstrated in the first
treatment year. For the second treatment year (351 patients) a mean reduction of the symptom score of 36% (p< 0.0001) and of the medication score of 46% (p< 0.0001) was found. Serologic analyses revealed a modified systemic response of the immune system with a significant progressive increase of specific IgG4 antibodies after each treatment year.

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