



# Azelastine

**AZELASTINE NEWS**

**May 2008**

**Dose 1 spray per nostril approved in US by FDA**

„.....allergic rhinitis is one or two sprays per nostril twice daily...“

**Efficacy and safety of azelastine nasal spray at a dose of 1 spray per nostril twice daily**

*Lumry W, et al., Ann. Allergy Asthma Immunol. 2007 ; 99:267-272*

**MEDA**

**mc**  




## Azelastine NEWS

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### Is that important?

- the recent studies with outstanding results for Azelastine were performed with the double dose
- the strong objections from our customers: those data may not be relevant for the single dose, which is mainly registered in EU

### Now we have data to argue that Azelastine is effective either single or double dose!!!

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### Citations from Lumry Publication and US SPC

**Azelastine** "...1 or 2 sprays per nostril twice daily provides flexibility in treating patients with SAR...

> ..either as single agent....

> ..or in combination regimen that may include an intranasal corticosteroid". p.271

**Azelastine** "...at a dose of 1 spray per nostril twice daily is effective and has improved tolerability compared with 2 sprays per nostril twice daily . p. 267

**Azelastine** "...allergic rhinitis is one or two sprays per nostril twice daily..."  
(US Prescribing Information)

## **Efficacy and safety of azelastine nasal spray at a dose of 1 spray per nostril twice daily.**

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**BACKGROUND:** Azelastine hydrochloride nasal spray is available worldwide for the treatment of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis. One spray per nostril twice daily is the most commonly recommended dose. **OBJECTIVE:** To determine the efficacy and safety of azelastine nasal spray, 1 spray per nostril twice daily, in patients with SAR. **METHODS:** In 2 studies conducted in the United States we assessed 554 patients with moderate-to-severe SAR who were still symptomatic after a 1-week placebo lead-in period. Patients were randomized to 2 weeks of double-blind treatment with azelastine nasal spray, 1 spray per nostril twice daily, or placebo nasal spray. The primary efficacy variable was change from baseline in total nasal symptom score, consisting of sneezing, itchy nose, runny nose, and nasal congestion. **RESULTS:** Mean differences in total nasal symptom score between the azelastine and placebo groups were significant in both studies: 2.69 vs 1.31 ( $P = .01$ ) in study 1 and 3.68 vs 2.50 ( $P = .02$ ) in study 2. Bitter taste was reported by 8.3% of patients treated with 1 spray per nostril twice daily compared with the labeled incidence of 19.7% with 2 sprays per nostril twice daily. Somnolence was reported by 1 patient (0.4%) using the 1-spray regimen compared with the labeled incidence of 11.5% using the 2-spray regimen. **CONCLUSIONS:** Azelastine nasal spray at a dose of 1 spray per nostril twice daily is effective and has improved tolerability compared with 2 sprays per nostril twice daily in patients with SAR