Press release, February 20, 2015

DYMISTA® approved in children 6 to 11 years of age with seasonal allergic rhinitis

Meda announces the approval by FDA (U.S. Food and Drug Administration) of Dymista, a single formulation azelastine hydrochloride and fluticasone propionate nasal spray for the relief of symptoms of seasonal allergic rhinitis in patients 6-11 years of age who require treatment with both components. Dymista was previously indicated only for adults and children 12 and older. The approved dosing for Dymista in children 6 to 11 is 1 spray/nostril BID (same as the dosing for adolescents and adults with SAR).

The efficacy and safety of Dymista was demonstrated in 2 pediatric trials where children 6 to 11 were treated with Dymista (1 spray per nostril twice daily). One of these trials was a 2-week trial comparing efficacy of Dymista and placebo in 304 children 6 to 11 years of age with SAR. The other trial was a 12-week open-label trial comparing the safety of Dymista and fluticasone nasal spray in 353 children 6 to 11 years of age with allergic rhinitis.

According to William Berger, MD, practicing allergist, Allergy and Asthma Associates of Southern California and Medical Director at Southern California Research Center, Mission Viejo, California, "The approval of Dymista for pediatric patients 6 to 11 years provides for a new, effective and safe treatment option for those suffering from Seasonal Allergic Rhinitis. Patients with SAR struggle to bring their symptoms under control; Dymista offers rapid onset of symptom improvement within 30 minutes of administration and allows for nasal symptom relief patients are seeking, all with a single nasal spray."

The efficacy and safety of Dymista has been documented in several studies involving over 4,000 patients, including long-term safety studies with more than 600 patients 12 years and older and in more than 350 patients aged 6 to 11 years.

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