

## **ASTELIN<sup>®</sup> (AZELASTINE HYDROCHLORIDE) NASAL SPRAY EFFECTIVE IN PATIENTS WHOSE ALLERGY SYMPTOMS RESPONDED INADEQUATELY TO TREATMENT WITH ALLEGRA<sup>®</sup>**

*Clinical Data Published in Leading Medical Journal as Fall Allergy Season Begins*

Somerset, NJ - August 16, 2004 - ASTELIN<sup>®</sup> Nasal Spray provided effective symptom relief for patients with moderate-to-severe seasonal allergic rhinitis who had an unsatisfactory response to treatment with Allegra<sup>®</sup> (fexofenadine hydrochloride), according to a clinical study published in the August issue of *Annals of Allergy, Asthma & Immunology*.

"Our findings show that ASTELIN is an effective treatment option for patients with seasonal allergic rhinitis who do not respond well to fexofenadine," reported Craig LaForce, MD, study investigator and Medical Director, North Carolina Clinical Research. "In fact, ASTELIN is an excellent alternative for patients who find themselves using multiple oral antihistamines or frequently switching antihistamines to find satisfactory relief."

A similar study, published in the August 2003 issue of *Annals of Allergy, Asthma & Immunology*, showed ASTELIN to be an effective option for patients who had experienced unsatisfactory relief of moderate-to-severe allergic rhinitis symptoms with Claritin<sup>®</sup> (loratadine).

"Given the growing body of clinical data that reinforces the efficacy of azelastine nasal spray in treating allergic rhinitis, ASTELIN should be considered an excellent option for first-line treatment," commented Dr. LaForce.

Mid-August marks the beginning of the ragweed (fall allergy) season in much of the United States, according to the American Academy of Allergy, Asthma and Immunology.

### **THE STUDY**

This was a multicenter, placebo-controlled, double-blind trial of 335 patients who had experienced unsatisfactory results with a seven-day course of fexofenadine monotherapy. Patients who had an inadequate response to fexofenadine were divided into three treatment groups: 1) ASTELIN Nasal spray and oral placebo; 2) ASTELIN Nasal Spray and fexofenadine; or 3) placebo nasal spray and oral placebo for a two-week treatment period. The TNSS - defined as the sum of individual symptom severity scores for runny nose, sneezing, itchy nose, and nasal congestion - determined drug efficacy.

After two weeks of treatment, the mean improvement from baseline in TNSS with ASTELIN Nasal Spray was significantly greater than with placebo. Further, the combination of ASTELIN and fexofenadine showed no additional clinical benefit compared to ASTELIN monotherapy.

### **ALLERGIC RHINITIS**

Allergic rhinitis is the fifth most prevalent chronic disease in the United States, affecting up to 40 million adults and children each year. Allergic rhinitis costs the nation approximately \$5.3 billion in direct and indirect costs (including time lost from work and school) and accounts for about 10,000 absences on a typical school day. It also can lead to complications, including sinusitis, Eustachian-tube dysfunction, ear infections, asthma, and sleep disturbances.

Current prescription and over-the-counter treatments include oral and intranasal antihistamines, oral and intranasal decongestants, intranasal corticosteroids, mast-cell stabilizers, and leukotriene- receptor antagonists. If the physician determines that allergen avoidance and pharmacotherapy do not provide sufficient relief, and if symptoms are sufficiently severe, he/she may suggest desensitization (immunotherapy).

**ASTELIN<sup>®</sup> (AZELASTINE HYDROCHLORIDE) NASAL SPRAY, 137 MCG**

ASTELIN Nasal Spray is indicated for the treatment of the symptoms of seasonal allergic rhinitis (patients five years of age and older) and nonallergic vasomotor rhinitis (patients 12 years of age and older). According to the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology, an intranasal antihistamine, such as ASTELIN, is recommended as first-line treatment for allergic rhinitis. ASTELIN is the only antihistamine approved for rhinitis patients with nasal congestion.

The most commonly reported adverse events in seasonal allergic rhinitis and nonallergic vasomotor rhinitis patients 12 years of age and older were bitter taste, headache, somnolence, and nasal burning. The adverse event profile in seasonal allergic rhinitis patients five to 11 years of age was similar to that in the adult population. Discontinuation rates due to adverse events in patients taking ASTELIN in the seasonal allergic rhinitis and nonallergic vasomotor rhinitis clinical trials were no different than those for placebo.

Please see full Prescribing Information, available at [www.astelin.com](http://www.astelin.com).

#### **MEDPOINTE PHARMACEUTICALS**

MedPointe Pharmaceuticals is a privately held, specialty pharmaceutical company with headquarters at 265 Davidson Avenue, Somerset, New Jersey, 08873-4120; 732-564-2200. MedPointe, which specializes in allergy, respiratory, central nervous system, cough-cold, and pediatric products, has a manufacturing facility in Decatur, Illinois. For more information about the company, please visit [www.medpointepharma.com](http://www.medpointepharma.com).

For additional information and/or full Prescribing Information on ASTELIN Nasal Spray, please call 1-800-598-4856 or visit [www.astelin.com](http://www.astelin.com).

*Further inquiries should be directed to [info@meda.us](mailto:info@meda.us)*