

NEW**Astepro[®] 0.15%**
(azelastine HCl) Nasal Spray,
205.5 mcg

Product Overview

- ASTEPRO 0.15%, 205.5 mcg, is indicated for the relief of the symptoms of seasonal and perennial allergic rhinitis (SAR and PAR) in patients 12 years of age and older
- The new formulation, ASTEPRO 0.15%, contains a 50% greater concentration of azelastine hydrochloride than original ASTEPRO, (205.5 mcg vs 137 mcg per spray)
- ASTEPRO 0.15% is the only nasal antihistamine that's FDA approved for once- or twice-daily dosing for seasonal allergic rhinitis

Nasal azelastine	Seasonal allergic rhinitis	Perennial allergic rhinitis	Pediatric	Vasomotor rhinitis	Once daily (SAR)	Twice daily
ASTEPRO 0.15%	✓	✓			✓	✓
Original ASTEPRO [®] azelastine hydrochloride Nasal Spray	✓					✓
Astelin [®] (azelastine HCl) Nasal Spray	✓		✓	✓		✓

- ASTEPRO 0.15% provides significant relief of rhinitis symptoms, including nasal congestion, without an added decongestant ($P < .001$)
 - The efficacy and safety of ASTEPRO 0.15% was demonstrated in 5 clinical trials in adult and adolescent patients, 12 years of age and older, with symptoms of seasonal allergic rhinitis (N=2499)
 - An additional clinical trial was conducted with 578 patients who were 12 years of age and older and had symptoms of perennial allergic rhinitis
- ASTEPRO 0.15% provides well-tolerated relief, as shown in clinical trials

Adverse events when dosed 2 sprays per nostril (once or twice daily, respectively) for seasonal or perennial allergic rhinitis

Adverse event	2 sprays once daily	2 sprays twice daily
Bitter taste	4%	6%
Nasal discomfort	4%	3%
Epistaxis	2%	1%
Sneezing	1%	2%

Somnolence was reported in <1% of patients treated with ASTEPRO 0.15%.

- Long-term safety: in a 12-month safety trial, 466 patients (12 years of age and older) with perennial allergic rhinitis were treated with ASTEPRO 0.15%, 2 sprays per nostril twice daily, and 237 patients were treated with mometasone nasal spray, 2 sprays per nostril once daily. The most frequently reported adverse reactions (>5%) with ASTEPRO 0.15% were bitter taste, headache, sinusitis, and epistaxis. Focused nasal examinations were performed and no nasal ulcerations or septal perforations were observed with ASTEPRO 0.15%

Value

- Prescribing ASTEPRO® 0.15% once-daily for SAR patients can provide nearly two months of therapy from a single bottle*
 - Calculation based on 2 sprays per nostril once daily
 - May result in fewer copays per year
 - May make ASTEPRO 0.15% one of the least expensive prescription SAR allergy therapies available on a cost-per-day basis based on Average Wholesale Price

*Based on Average Wholesale Price (AWP) listings for branded therapies for seasonal allergic rhinitis published in Medi-Span Price Rx as of August 1, 2009. AWP does not reflect manufacturer discounts, rebated, and/or copay reduction programs, which may affect patient or plan costs.

NDC No.	Unit of sale
0037-0243-30	30 mL



Indication

- ASTEPRO (azelastine HCl) Nasal Spray 0.15% is indicated for the relief of the symptoms of seasonal and perennial allergic rhinitis in patients 12 years of age and older

Important Safety Information

- Avoid engaging in hazardous occupations requiring complete mental alertness when taking ASTEPRO Nasal Spray 0.15%
- Avoid concurrent use of alcohol or other central nervous system depressants with ASTEPRO Nasal Spray 0.15%
- In clinical studies, the most commonly reported adverse reactions, when dosed at 2 sprays per nostril once or twice daily, respectively, included bitter taste (4%, 6%), nasal discomfort (4%, 3%), epistaxis (2%, 1%), and sneezing (1%, 2%)

Please see accompanying full Prescribing Information.

