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IN BRIEF

OTC Azelastine Nasal Spray 0.15% (Astepro Allergy) for Allergic Rhinitis

The 0.15% nasal spray formulation of the H₁-antihistamine azelastine hydrochloride (*Astepro Allergy*; *Children's Astepro Allergy* – Bayer) is now available over the counter (OTC) for temporary relief of nasal congestion, runny nose, sneezing, and itchy nose due to allergic rhinitis in adults and children ≥6 years old. It is the first intranasal antihistamine

to be approved by the FDA for OTC use. Other drugs that are available OTC for treatment of allergic rhinitis symptoms include oral antihistamines, intranasal corticosteroids, and mast cell stabilizers.¹

EFFICACY – Intranasal antihistamines are recommended for initial treatment of intermittent allergic rhinitis symptoms.² They have an onset of action of ~15-30 minutes, which is more rapid than that of oral antihistamines (60 minutes) or intranasal corticosteroids (~12 hours). They are at least as effective as oral H₁-antihistamines in relieving nasal itching, sneezing, and rhinorrhea, and they are more effective in relieving nasal congestion. In patients with moderate to severe symptoms, the combination of an intranasal antihistamine and an intranasal corticosteroid has been shown to be more effective than either drug alone.³

ADVERSE EFFECTS – Intranasal H₁-antihistamines can cause dysgeusia, nasal discomfort, epistaxis, and headache. Somnolence has occurred in some patients.

DOSAGE AND ADMINISTRATION – *Astepro Allergy* and *Children's Astepro Allergy* are supplied in bottles containing 60 or 120 metered-dose pump sprays. Each spray delivers 205.5 mcg of azelastine hydrochloride. The spray bottle must be primed before first use and if not used for ≥3 days. The recommended dosages for adults and children are listed in Table 1. ■

Table 1. Intranasal H₁-Antihistamines

Drug	Usual Dosage	Cost ¹
Azelastine 0.1% ² – generic	≥12 yrs: 1-2 sprays per nostril bid ³ 6 mos-11 yrs: 1 spray per nostril bid	\$18.00
Azelastine 0.15% – generic ⁴	≥12 yrs: 1-2 sprays per nostril bid or 2 sprays per nostril once/day ⁶	30.00
<i>Astepro Allergy</i> ⁵ (Bayer)		15.00 ⁷
<i>Children's Astepro Allergy</i> ⁵ (Bayer)	6-11 yrs: 1 spray per nostril bid	15.00 ⁷
Olopatadine 0.6% ⁸ – generic	≥12 yrs: 2 sprays per nostril bid	50.00
<i>Patanase</i> (Novartis)	6-11 yrs: 1 spray per nostril bid	304.00

1. Approximate WAC for 30 days' treatment at the lowest usual adult dosage. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource@ Monthly, October 5, 2022. Reprinted with permission by First Databank, Inc. All rights reserved. ©2022. www.fdbhealth.com/drug-pricing-policy.
2. FDA-approved for seasonal allergic rhinitis (≥2 years), perennial allergic rhinitis (6 months to 11 years), and vasomotor rhinitis (≥12 years). Also available in a fixed-dose combination with fluticasone (*Dymista*, and generic) for treatment of seasonal allergic rhinitis (≥6 years).
3. Dosage for seasonal allergic rhinitis. Dosage for vasomotor rhinitis is 2 sprays per nostril bid.
4. Prescription product is FDA-approved for seasonal and perennial allergic rhinitis (≥6 years old).
5. Available over the counter.
6. Dosage for seasonal allergic rhinitis. Dosage for perennial allergic rhinitis is 2 sprays per nostril bid.
7. Approximate cost for a 60-spray bottle (a 120-spray bottle costs about \$24.00) at walmart.com. Accessed October 13, 2022.
8. FDA-approved only for treatment of seasonal allergic rhinitis.

1. OTC drugs for seasonal allergies. *Med Lett Drugs Ther* 2019; 61:57.
2. MS Dykewicz et al. Rhinitis 2020: a practice parameter update. *J Allergy Clin Immunol* 2020; 146:721.
3. Drugs for allergic rhinitis and allergic conjunctivitis. *Med Lett Drugs Ther* 2021; 63:57.

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