

## Astepro® Allergy and Children’s Astepro Allergy (azelastine) – New partial over-the-counter approval

- On June 17, 2021, the [FDA announced](#) the [approval](#) of partial over-the-counter (OTC) use of [Bayer’s Astepro Allergy and Children’s Astepro Allergy \(azelastine\)](#) 0.15%, for the temporary relief of nasal congestion, runny nose, sneezing and itchy nose due to hay fever or other upper respiratory allergies in adults and children 6 years of age and older.
  - Previously, Astepro was available as [prescription](#) in 0.15% and 0.1% strengths for the relief of the symptoms of seasonal allergic rhinitis in patients 2 years of age and older and perennial allergic rhinitis in patients 6 months of age and older.
  - Azelastine 0.1% will remain prescription strength only and is approved for seasonal allergic rhinitis in patients 2 to < 6 years of age and perennial allergic rhinitis in patients 6 months to < 6 years of age.
- Astepro Allergy and Children’s Astepro Allergy are the first antihistamines approved for OTC use for indoor and outdoor allergies.
- Astepro Allergy and Children’s Astepro Allergy are only for use in the nose. The products should not be sprayed in the eyes or mouth.
- When using Astepro Allergy or Children’s Astepro Allergy:
  - Drowsiness may occur: patients should avoid alcoholic drinks; alcohol, sedatives, and tranquilizers may increase drowsiness; patients should be careful when driving a motor vehicle or operating machinery
  - Patients may get a bitter taste in their mouth. To help avoid this, a patient should tilt his head downward while spraying
  - Nasal discomfort or sneezing may occur right after use
  - The bottle should not be shared with anyone else as this may spread germs.
- A patient should stop use and ask a doctor if: an allergic reaction, such as a skin rash, to this product occurs, or the patient has severe or frequent nosebleeds.
- The recommended dose of Astepro Allergy or Children’s Astepro Allergy is as follows:

Patient age	Dosing frequency
Adults and children 12 years and older	This product may be used either once or twice a day: <ul style="list-style-type: none"> <li>• Once daily: use 2 sprays in each nostril; OR</li> <li>• Twice daily: use 1 or 2 sprays in each nostril every 12 hours</li> <li>• Do not use more than 4 sprays in each nostril in a 24 hour period</li> </ul>
Children 6 years to 11 years	An adult should supervise use: <ul style="list-style-type: none"> <li>• 1 spray in each nostril every 12 hours</li> <li>• Do not use more than 2 sprays in each nostril in a 24 hour period</li> </ul>
Children < 6 years	Do not use

- Bayer plans to launch Astepro Allergy and Children's Astepro Allergy in the first quarter of 2022. Astepro Allergy and Children's Astepro Allergy will be available as a 0.15% (205.5 mcg/spray) nasal spray.



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