

# (12) United States Patent

Dang et al.

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# (54) COMPOSITIONS COMPRISING AZELASTINE AND METHODS OF USE THEREOF

(75) Inventors: **Phuong Grace Dang**, Corona, CA (US);

Brian D. Lawrence, Somerset, NJ (US); Gul Balwani, West Windsor, NJ (US); Alexander D. D'Addio, Piscataway, NJ

(73) Assignee: MEDA Pharmaceuticals Inc.,

Somerset, NJ (US)

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- (52) **U.S. Cl.** ........... **424/45**; 424/464; 424/489; 514/2.3; 514/171
- (58) **Field of Classification Search** ....................... 514/217.05; See application file for complete search history.

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Primary Examiner — Brandon Fetterolf Assistant Examiner — Dennis Heyer (74) Attorney, Agent, or Firm — Sterne, Kessler, Goldstein & Fox P.L.L.C.

## ABSTRACT

The present invention provides pharmaceutical compositions comprising azelastine, or a pharmaceutically acceptable salt or ester thereof including azelastine hydrochloride, and optionally one or more additional active agents. Preferred such compositions further comprise one or more pharmaceutically acceptable carriers or excipients that reduce the amount of post-nasal drip, and/or that minimize or mask the unpleasant bitter taste associated with post-nasal drip, of the compositions into the oral cavity, upon intranasal or ocular administration of the compositions. Especially effective excipients used in the compositions of the present invention are hypromellose as a viscosity modifier and sucralose as a taste-masking agent. The invention also provides methods of treating or preventing certain disorders, or symptomatic relief therefrom, by administering the compositions of the invention to a patient, e.g., for the symptomatic relief of allergic rhinitis, non-allergic vasomotor rhinitis, allergic conjunctivitis, as well as other disorders. The compositions and methods of the present invention provide significant value in terms of patient acceptability, convenience, and compliance.

### 28 Claims, No Drawings