IN BRIEF

Oral Phenyline for Nasal Congestion

In 2007, an FDA advisory committee asked that placebo-controlled, dose-ranging trials be conducted to establish the efficacy of the oral decongestant phenyline (Sudafed PE, and others), which is sold over the counter (OTC) as a single agent and in combination with other drugs for treatment of cold and allergy symptoms. Phenyline replaced pseudoephedrine (Sudafed, and others) in many OTC formulations when access to pseudoephedrine-containing products was restricted in an effort to reduce their use in the synthesis of methamphetamine.

CLINICAL STUDIES — In a randomized, open-label, dose-ranging trial in 539 patients with seasonal allergic rhinitis, phenylephrine doses up to four times the recommended dose of 10 mg were no more effective than placebo in reducing symptomatic nasal congestion.1 Other recent studies have also found oral phenylephrine no more effective than placebo in reducing nasal congestion.2-4

ALTERNATIVES — Oral pseudoephedrine reduces nasal congestion, but has no effect on other symptoms such as sneezing, itching, or rhinitis, and tolerance to its effects can occur with repeated use. Potential adverse effects include insomnia, excitability, headache, nervousness, anorexia, palpitations, tachycardia, arrhythmias, hypertension, nausea, vomiting, and urinary retention. Pseudoephedrine should be used cautiously in patients with cardiovascular disease, hypertension, diabetes, hyperthyroidism, narrow-angle glaucoma, or bladder neck obstruction.

Intranasal decongestants such as oxymetazoline (Afrin, and others) are effective and less likely than pseudoephedrine to cause systemic adverse effects, but they can cause stinging, burning, sneezing, dryness of the nose and throat, and, if used for more than 3–5 consecutive days, rebound congestion (rhinitis medicamentosa). Intranasal corticosteroids are the most effective drugs available for prevention and relief of nasal congestion and other seasonal allergic rhinitis symptoms.5

CONCLUSION — Oral phenylephrine is not effective for treatment of nasal congestion.