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## on Drugs and Therapeutics

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## on Drugs and Therapeutics

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### IN BRIEF

#### Oral Phenylephrine 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 phenylephrine (*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. Phenylephrine 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.<sup>1</sup> Other recent studies have also found oral phenylephrine no more effective than placebo in reducing nasal congestion.<sup>2-4</sup>

**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.<sup>5</sup>

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

1. EO Meltzer et al. Oral phenylephrine HCl for nasal congestion in seasonal allergic rhinitis: a randomized, open-label, placebo-controlled study. *J Allergy Clin Immunol Pract* 2015; 3:702.
2. EO Meltzer et al. Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients. *Ann Allergy Asthma Immunol* 2015 November 7 (epub).
3. F Horak et al. A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber. *Ann Allergy Asthma Immunol* 2009; 102:116.
4. JH Day et al. Efficacy of loratadine-montelukast on nasal congestion in patients with seasonal allergic rhinitis in an environmental exposure unit. *Allergy Asthma Immunol* 2009; 102:328.
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