3-1-2005

Sudafed PE nasal decongestant

Joseph A. Woelfel
University of the Pacific, jwoelfel@pacific.edu

Detail-Document #210302
−This Detail-Document accompanies the related article published in−
PHARMACIST'S LETTER / PRESCRIBER'S LETTER
March 2005 ~ Volume 21 ~ Number 210302

Sudafed PE Nasal Decongestant

Lead author: Joseph A. Woelfel, Ph.D., FASCP, R.Ph., Assistant Editor

What It Is

Sudafed PE Nasal Decongestant is a new OTC version of *Sudafed Nasal Decongestant*. It contains 10 mg of phenylephrine instead of 30 mg of pseudoephedrine as the only active ingredient.

How It Works

Phenylephrine is a sympathomimetic amine that primarily exhibits direct alpha-adrenergic receptor stimulation. Because of its potent vasoconstrictor effects on nasal vasculature, it causes shrinkage of nasal mucosa, thereby acting as a decongestant.[1,2]

Indications

The indications for *Sudafed PE* are the same as the indications for *Sudafed*. These include temporary relief of nasal congestion due to the common cold, hay fever, or other upper respiratory allergies, and nasal congestion associated with sinusitis. It is also indicated for temporary relief of sinus congestion and pressure.[3]

How Supplied

Sudafed PE is supplied in a tablet dosage form in boxes of 18, 36, and 72 tablets. The AWP for a box of 18 tablets is $4.29 as compared with *Sudafed* in a box of 24 tablets at $4.29.[4]

Dosage

The dosage for adults and children 12 years of age and over is one tablet taken every 4 hours with not more than six doses in a 24 hour period. For children under 12 years, the advice of a physician must be sought.[3]

Adverse Effects

As described in the product information, nervousness, dizziness, and insomnia may occur and warrant discontinuation of *Sudafed PE*.[3] Other systemic effects of phenylephrine include anxiety, weakness, tremor, headache, pallor or blanching of the skin, respiratory distress, hypertension, precordial pain, and pilomotor response.[1]

Drug Interactions

Nonselective beta-blockers, methyldopa, reserpine, guanethidine, and tricyclic antidepressants may increase hypertensive effects of phenylephrine. MAO inhibitors potentiate cardiac and pressor effects of phenylephrine. Concurrent use of any of these agents should be avoided. Coadministration of phenylephrine with cocaine may cause malignant arrhythmias, and use with ephedra or yohimbe can result in excessive CNS stimulation.[1,5]

Contraindications

Sudafed PE is contraindicated in hypersensitivity to phenylephrine or any component of the formulation, as well as other sympathomimetic drugs; in severe hypertension, ventricular tachycardia, and severe coronary artery disease. It is contraindicated with MAOI therapy.

Precautions

Sudafed PE should be used with caution and a physician should be consulted prior to use in patients with hyperthyroidism, diabetes mellitus, hypertension, ischemic heart disease, and urinary retention. Patients experiencing nervousness, dizziness, or insomnia during current use should discontinue treatment. Treatment with *Sudafed PE* should cease whenever symptoms persist for seven days or are accompanied by fever.[1,3]

Use In Pregnancy

Phenylephrine is a Pregnancy Category C drug. Therefore, use during pregnancy should be avoided.[5]

More. . .

Manufacturer

Pfizer
235 East 42nd Street
New York, NY 10017
800-438-1985
www.pfizer.com

Commentary

Pfizer's decision to market *Sudafed PE* results from the current and ongoing problem of methamphetamine manufacturing using pseudoephedrine as a chemical precursor. Pfizer will continue to market *Sudafed* with its pseudoephedrine content. This action enables Pfizer to maintain an overt "front shelf" presence of its *Sudafed PE* product wherever over-the-counter products are sold. At the same time, Pfizer retains the broad availability of *Sudafed* even in states requiring pseudoephedrine product storage behind-the-counter. *Sudafed PE* is currently available at the wholesale distribution level.

The Meth Watch program sponsored by the Consumer Healthcare Products Association (CHPA) is active in several states. Its goal is to promote cooperation between retailers and law enforcement to prevent diversion of legitimate products for purposes of methamphetamine production. The program encourages restricted access and observation of precursor ingredient purchase such as over-the-counter cold, cough, or allergy medicines containing pseudoephedrine or ephedrine as well as household supply items such as rubbing alcohol, lye, iodine, and others used to manufacture methamphetamine. Please see *Detail-Document #200809*, *Methamphetamine and the Meth Watch Program* for more information on this topic.

The substitution of phenylephrine for pseudoephedrine will eliminate the chemical conversion possibility of methamphetamine production from *Sudafed PE*.

The nasal decongestant efficacy of oral phenylephrine vs. pseudoephedrine may not be the same. Pharmacologically, phenylephedrine is a direct alpha-adrenergic agonist in therapeutic doses whereas pseudoephedrine has both alpha- and, to a lesser degree, beta-adrenergic activity. Pseudoephedrine also exerts an indirect effect causing release of norepinephrine from storage sites.[1,2,5] Phenylephrine has a shorter elimination half-life of 2.5 hours compared to pseudoephedrine with a nine to 16 hour half-life.[5] Furthermore, it is believed that orally administered phenylephrine undergoes first-pass hepatic metabolism, whereas pseudoephedrine does not.[6] In a nasal airway resistance study conducted by Bickerman, the single-dose efficacy of pseudoephedrine 60 mg, phenylpropanolamine 40 mg, phenylephrine 10 mg, and placebo were compared. Pseudoephedrine and phenylpropanolamine decreased nasal airway resistance whereas phenylephrine was no more effective than placebo.[7] The FDA has classified phenylephrine in an oral dose of 10 mg as effective and safe.[8]

With phenylephrine's first-pass metabolism and its short elimination half-life, yet its unopposed pure alpha-agonist effects, it is unknown if it presents a more favorable safety profile than pseudoephedrine.[5,6] The lowest dose that may elevate blood pressure in normotensive patients, as identified in a single study, was 45 mg or higher.[9] No clear evidence exists that either drug is safer in patients with hypertension. Randomized controlled trials or meta-analyses directly comparing phenylephrine with pseudoephedrine are not available. Both drugs can prolong QT intervals.[10]

As identified in the product label, *Sudafed PE* should be used with caution and a physician should be consulted prior to use in patients with hyperthyroidism, diabetes mellitus, hypertension, ischemic heart disease, and urinary retention. Patients experiencing nervousness, dizziness, or insomnia during current use should discontinue treatment. Treatment with *Sudafed PE* should cease whenever symptoms persist for seven days or are accompanied by fever.[1,3]

Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and Internet links in this article were current as of the date of publication.

References

1. AHFS Drug Information 2005. American Society of Health-System Pharmacists. Bethesda, MD. January 2005. pp. 1301-05.

More. . .

2. Clinical Pharmacology 2005. Gold Standard Publishers. Tampa, FL. 2005.
3. Product information for *Sudafed PE Nasal Decongestant*. Pfizer. New York, NY 10017. http://www.allergy-cold.com/conaffairs/allergy_cold_cough_sinus65.shtml. (Accessed February 15, 2005).
4. Cardinal Health Inc. http://www.cardinal.com. (Accessed February 15, 2005).
5. Lexi-Comp Online 2005. Lexi-Comp, Inc. Hudson, OH. http://www.lexi.com. (Accessed February 15, 2005).
6. Hendeles L. Selecting a decongestant. *Pharmacotherapy* 1993;13:129S-34S.
7. Bickerman HA. Physiologic and pharmacologic studies on nasal airway resistance (RN). Presented at a conference sponsored by the Scientific Development Committee of the Proprietary Association, Washington, DC. December 8, 1971.
8. Department of Health and Human Services, Food and Drug Administration, Code of Federal Regulations. Cold, cough, allergy, bronchodilator, and antiasthmatic drug products for over-the-counter human use.;. April 1, 2001;5:235-52. http://www.fda.gov/cder/otcmonographs/Allergy/Cold,Cough, Allergy(341).htm. (Accessed February 11, 2005).
9. Bradley JG. Nonprescription drugs and hypertension: which ones affect blood pressure? *Post Grad Med* 1991;89:195-202.
10. Woelfel JA. Drug-induced long QT interval and sudden cardiac death. *Pharmacist's Letter/Prescriber's Letter* 2004;20(11):201111.

Cite this Detail-Document as follows: Sudafed PE Nasal Decongestant. Pharmacist's Letter/Prescriber's Letter 2005;21(3):210302.

PHARMACIST'S LETTER

The most practical knowledge in the least time…

PRESCRIBER'S LETTER

3120 West March Lane, P.O. Box 8190, Stockton, CA 95208 ~ TEL (209) 472-2240 ~ FAX (209) 472-2249