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# Sudafed PE nasal decongestant

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## **Sudafed PE Nasal Decongestant**

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### **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.<sup>1,2</sup>

### **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.<sup>3</sup>

### **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.<sup>4</sup>

### **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.<sup>3</sup>

### **Adverse Effects**

As described in the product information, nervousness, dizziness, and insomnia may occur and warrant discontinuation of *Sudafed PE*.<sup>3</sup> Other systemic effects of phenylephrine include anxiety, weakness, tremor, headache, pallor or

blanching of the skin, respiratory distress, hypertension, precordial pain, and pilomotor response.<sup>1</sup>

### **Drug Interactions**

Nonselective beta-blockers, methyl dopa, 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.<sup>1,5</sup>

### **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.<sup>1,3</sup>

### **Use In Pregnancy**

Phenylephrine is a Pregnancy Category C drug. Therefore, use during pregnancy should be avoided.<sup>5</sup>

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## **Manufacturer**

Pfizer  
235 East 42<sup>nd</sup> 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, phenylephrine 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.<sup>1,2,5</sup> Phenylephrine has a shorter elimination

half-life of 2.5 hours compared to pseudoephedrine with a nine to 16 hour half-life.<sup>5</sup> Furthermore, it is believed that orally administered phenylephrine undergoes first-pass hepatic metabolism, whereas pseudoephedrine does not.<sup>6</sup> In a nasal airway resistance study conducted by Bickerman, the single-dose efficacy of pseudoephedrine 60 mg, phenylpropranolamine 40 mg, phenylephrine 10 mg, and placebo were compared. Pseudoephedrine and phenylpropranolamine decreased nasal airway resistance whereas phenylephrine was no more effective than placebo.<sup>7</sup> The FDA has classified phenylephrine in an oral dose of 10 mg as effective and safe.<sup>8</sup>

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.<sup>5,6</sup> The lowest dose that may elevate blood pressure in normotensive patients, as identified in a single study, was 45 mg or higher.<sup>9</sup> 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.<sup>10</sup>

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.<sup>1,3</sup>

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