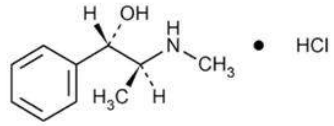
PRODUCT INFORMATION

SUDAFED ® Sinus 12 Hour Relief Tablets

NAME OF THE MEDICINE

Pseudoephedrine Hydrochloride



CAS[2] Registry Number: 345-78-8

DESCRIPTION

SUDAFED ® Sinus 12 Hour Relief prolonged-release tablets contain pseudoephedrine hydrochloride 120 mg.

SUDAFED ® Sinus 12 Hour Relief prolonged-release tablets also contain: candelilla wax, microcrystalline cellulose, hypromellose, magnesium stearate, povidone, purified talc, OPACODE monogramming ink S-1-4176 Blue, OPADRY complete film coating system YS-1-18173-A White.

PHARMACOLOGY

Pharmacokinetics

Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite. It has a half-life of about 5-8 hours; elimination is enhanced and half-life reduced accordingly in acid urine. Small amounts are distributed into breast milk.

Pharmacodynamics/Mechanism of action

Pseudoephedrine has direct and indirect sympathomimetic activity and is an effective decongestant in the upper respiratory tract. It is a stereoisomer of ephedrine and has a similar action, but has been found to have less pressor activity and fewer central nervous system (CNS) effects.

Sympathomimetic agents are used as nasal decongestants to provide symptomatic relief. They act by causing vasoconstriction resulting in redistribution of local blood flow to reduce oedema of the nasal mucosa, thus improving ventilation, drainage and nasal stuffiness.

INDICATIONS

SUDAFED ® Sinus 12 Hour Relief provides temporary symptomatic relief of sinus pain and congestion and nasal congestion of allergic (seasonal) rhinitis, vasomotor (perennial) rhinitis, and the common cold in adults and children over 12 years.

CONTRAINDICATIONS

Pseudoephedrine is contraindicated for use in patients:

- with known hypersensitivity or idiosyncratic reaction to pseudoephedrine
- with known hypersensitivity or idiosyncratic reaction to any of the other ingredients in the product
- with severe hypertension or coronary artery disease
- taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days.

Refer to 'Interactions with other drugs' for additional information.

PRECAUTIONS

Pseudoephedrine should be used with caution in patients with:

- hypertension
- hyperthyroidism
- diabetes mellitus
- coronary heart disease
- ischaemic heart disease
- glaucoma
- prostatic hypertrophy
- severe hepatic or renal dysfunction.

Refer to 'Interactions with other drugs' for additional information.

Use in pregnancy
Category B2: Pseudoephedrine has been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals are inadequate or may be lacking, but available data shows no evidence of an increased occurrence of foetal damage.

Pseudoephedrine should be used in pregnancy only if the potential benefits to the patient are weighed against the possible risk to the foetus.

Use in lactation
Pseudoephedrine is secreted in breast milk in small amounts. It has been estimated that 0.5% to 0.7% of a single dose of pseudoephedrine ingested by the mother will be excreted in the breast milk over 24 hours. Therefore it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

INTERACTIONS WITH OTHER MEDICINES

The following interactions with pseudoephedrine have been noted:

- Antidepressant medication eg tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs) – may cause a serious increase in blood pressure or hypertensive crisis
- other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants – may cause an increase in blood pressure and additive effects
- methyldopa and β-blockers – may cause an increase in blood pressure
- urinary acidifiers enhance elimination of pseudoephedrine
- urinary alkalinisers decrease elimination of pseudoephedrine.

ADVERSE EFFECTS

Adverse effects of pseudoephedrine include:

- cardiovascular stimulation – elevated blood pressure, palpitations, tachycardia or arrhythmias
- CNS stimulation – headache, restlessness, feeling jittery, insomnia, anxiety, euphoric mood, tremor and (rarely) hallucinations
- psychomotor hyperactivity (in the paediatric population)
- skin rashes, dysuria and urinary retention
- hypersensitivity.

Children and the elderly are more likely to experience adverse effects than other age groups.

Clinical Trial Data

The safety of pseudoephedrine from clinical trial data is based on data from 6 randomized, placebo-controlled single dose clinical trials and 6 randomized, placebo-controlled multiple dose clinical trials for the treatment of nasal congestion with allergic rhinitis or common cold or prevention of sinus symptoms/infection after a natural cold.

The following table includes adverse events that occurred where greater than one event was reported, and the incidence was greater than placebo and in 1% of patients or more.

AEs Reported by ≥1% of Pseudoephedrine-treated Subjects in 12 Randomized Placebo-Controlled Clinical Trials

System Organ Class Preferred Term	**Pseudoephedrine 60 mg single-dose (N=229) % (frequency)**	**Pseudoephedrine 60-120 mg multidose (N=496) % (frequency)**	**Placebo (N=709) % (frequency)**
Gastrointestinal Disorders			
Dry mouth	-	3.6 (Common)	1.0 (Common)
Nausea	4.4 (Common)	0.2	1.3 (Common)
Nervous System Disorders			
Dizziness	5.2 (Common)	0.4	2.0 (Common)
Psychiatric Disorders			
Insomnia	2.2 (Common)	2.6 (Common)	0.3
Nervousness	2.6 (Common)	1.8 (Common)	0.7

Post-marketing Data

Additional adverse drug reactions (ADRs) identified during post-marketing experience with pseudoephedrine are included in Table 2. The frequencies are provided according to the following convention:

Very common	≥1/10
Common	≥1/100 and < 1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000 and <1/1,000
Very rare	<1/10,000

In the following table, the ADRs are presented with ADR frequency categories estimated from spontaneous reporting rates where numerator represents total number of reported Company AEs under given PT or medical concept and the denominator represents exposure data calculated from sales data.

Adverse Drug Reactions Identified During Post-Marketing Experience with Pseudoephedrine by Frequency Category Estimated from Spontaneous Reporting Rates

System Organ Classification Frequency category	Adverse Event Preferred Term
Very rare	*Hypersensitivity*
Psychiatric Disorders	
Very rare	*Anxiety*
Very rare	*Euphoric mood*
Very rare	*Hallucination*
Very rare	*Hallucination, visual*
Nervous System Disorders	
Very rare	*Headache*

Very rare	*Psychomotor hyperactivity*
Very rare	*Somnolence*
Cardiac Disorders	
Very rare	*Arrhythmia*
Very rare	*Palpitations*
Very rare	*Tachycardia*
Gastrointestinal Disorders	
Very rare	*Vomiting*
Skin and Subcutaneous Tissue Disorders	
Very rare	*Acute generalised exanthematous pustulosis*
Very rare	*Angioedema*
Very rare	*Pruritus*
Very rare	*Rash*
Renal and Urinary Disorders	
Very rare	*Dysuria*
Very rare	*Urinary retention*
Investigations	
Very rare	*Blood pressure increased*

DOSAGE AND ADMINISTRATION

The recommended dosage of **SUDAFED ®** Sinus 12 Hour Relief for adults and children over 12 years is one prolonged-release tablet every 12 hours. After initial improvement, one prolonged-release tablet every 24 hours may successfully control symptoms.

Do not exceed the recommended dosage.

If symptoms do not improve within 7 days, consult a Doctor before continuing use.

OVERDOSAGE

In case of overdose, immediately contact the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand call 0800 764 766) for advice.

PRESENTATION

SUDAFED ® Sinus 12 Hour Relief prolonged-release tablets are white, smooth, capsule-shaped and film-coated. They are printed with ‘Sudafed 12 Hour’ in blue ink on one side, and the other side is plain.

SUDAFED ® Sinus 12 Hour Relief prolonged-release tablets are available in blister packs of the following sizes:

- 2 prolonged-release tablets (S3) Pharmacist Only Medicine
- 6 prolonged-release tablets[#] (S3) Pharmacist Only Medicine

- 10 prolonged-release tablets (S4) Prescription Only Medicine

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Storage

Store below 30°C. Keep dry.

SPONSOR

Johnson & Johnson Pacific
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Australia

*Registered trademark

TGA approved: 4 October 2006
Date of most recent amendment: 28 February 2017