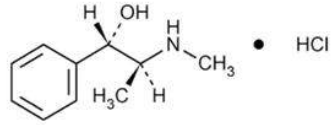
PRODUCT INFORMATION

SUDAFED ® Sinus and Nasal Decongestant

NAME OF THE MEDICINE

Pseudoephedrine Hydrochloride



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

DESCRIPTION

SUDAFED ® Sinus and Nasal Decongestant tablets contain pseudoephedrine hydrochloride 60 mg.

SUDAFED ® Sinus and Nasal Decongestant also contains lactose, magnesium stearate, povidone, maize starch.

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 and Nasal Decongestant provides symptomatic relief of sinus and nasal congestion due to allergic (seasonal) rhinitis, vasomotor (perennial) rhinitis, sinusitis, the common cold and flu.

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 medicines' 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 medicines' 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 pseudoephedrine 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 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 dose of **SUDAFED ®** Sinus and Nasal Decongestant for adults and children 12 years and over is 1 tablet 3 to 4 times a day.

SUDAFED ® Sinus and Nasal Decongestant should not be used for children under 12 years.

No more than 4 tablets should be taken in 24 hours.

SUDAFED ® Sinus and Nasal Decongestant should not be used for more than 7 days except on medical advice.

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 and Nasal Decongestant tablets are white, biconvex, round and uncoated. They are embossed with ‘S7A’ and scored on the upper face, and the bottom face is plain.

SUDAFED ® Sinus and Nasal Decongestant blister packs come in the following sizes:

4 tablets (S3) Pharmacist Only Medicine
12 tablets[#] (S3) Pharmacist Only Medicine
30 tablets (S4) Prescription Only Medicine
60 tablets (S4) Prescription Only Medicine
90 tablets (S4) Prescription Only Medicine
marketed

Storage

Store below 30°C. Keep dry.

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SPONSOR

Johnson & Johnson Pacific
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*Registered trademark

Notification submitted: 01 May 2006
Date of most recent amendment: 28 February 2017