AUSTRALIAN PRODUCT INFORMATION

SUDAFED® Sinus and Nasal Decongestant (Pseudoephedrine hydrochloride) tablets

1 NAME OF THE MEDICINE

Pseudoephedrine Hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

SUDAFED® Sinus and Nasal Decongestant also contains lactose. For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

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.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC 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.

4.2 DOSE AND METHOD OF 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.

4.3 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 or uncontrolled hypertension or severe coronary artery disease;
- taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days
- with severe acute or chronic kidney disease/renal failure.

Refer to Section 5.4 'Interactions with other medicines and other forms of interactions' for additional information.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

Pseudoephedrine should be used with caution in patients with:
- hypertension
- hyperthyroidism
- diabetes mellitus
- coronary heart disease
- ischaemic heart disease
- glaucoma
- prostatic hypertrophy

Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) have been reported very rarely with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as formation of small pustules occur, with or without pyrexia or erythema, then treatment with pseudoephedrine should be discontinued and a physician should be consulted. (see Section 4.8)

Use in hepatic impairment

Pseudoephedrine should be used with caution in patients with:
- severe hepatic dysfunction

Use in renal impairment

Pseudoephedrine is contraindicated for use in patients with severe acute or chronic kidney disease/renal failure (see section 4.3 Contraindications).

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

Refer to Section 5.4 'Interactions with other medicines and other forms of interactions' for additional information.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The following interactions with pseudoephedrine have been noted:

- Antidepressant medication e.g. 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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE 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.

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 and Very rare	≥1/10,000 <1/1,000 <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*
Very rare	*Restlessness*
Nervous System Disorders	
Very rare	*Headache*
Very rare	*Psychomotor hyperactivity*
Very rare	*Somnolence*
Very rare	*Paraesthesia*
Very rare	*Cerebrovascular accident*[a]
Very rare	*Posterior Reversible Encephalopathy Syndrome (PRES) (see section 4.4)*
Very rare	*Reversible Cerebral Vasoconstriction Syndrome (RCVS)(see section 4.4)*
Cardiac Disorders	
Very rare	*Arrhythmia*
Very rare	*Palpitations*
Very rare	*Tachycardia*
Very rare	*Myocardial infarction*[a]
Gastrointestinal Disorders	
Very rare	*Vomiting*
Very rare	*Colitis ischaemic*
Skin and Subcutaneous Tissue	
Very rare	*Acute generalised exanthematous*
Very rare	*Angioedema*
Very rare	*Pruritus*
Very rare	*Rash*
Very rare	*Fixed eruption* [b]
Renal and Urinary Disorders	
Very rare	*Dysuria*
Very rare	*Urinary retention*
Investigations	
Very rare	*Blood pressure increased*
Very rare	*Tremor*

a: These events have been reported very rarely in post-marketing safety. A recent postauthorisation safety study (PASS) did not provide any evidence of increased risk of myocardial infarction or cerebrovascular accident associated with the use of vasoconstrictors for nasal decongestion, including pseudoephedrine.
b: The common clinical term for PT Fixed eruption is fixed drug eruption.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information

Centre on 13 11 26 (Australia). In New Zealand call 0800 764 766.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

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.

Clinical trials

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

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Pseudoephedrine is readily absorbed from the gastrointestinal tract.

Distribution
Small amounts are distributed into breast milk.

Metabolism
It has a half-life of about 5-8 hours; elimination is enhanced and half-life reduced accordingly in acid urine.

Excretion
It is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite.

5.3 PRECLINICAL SAFETY DATA
Genotoxicity
No data available.

Carcinogenicity
No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS
SUDAFED® Sinus and Nasal Decongestant contains lactose, magnesium stearate, povidone, maize starch.

6.2 INCOMPATIBILITIES
Refer to Section 4.5 Interactions With Other Medicines And Other Forms of Interactions

6.3 SHELF LIFE
In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store below 30°C. Keep dry.

6.5 NATURE AND CONTENTS OF CONTAINER
SUDAFED® Sinus and Nasal Decongestant blister packs (PVC/PVDC) come in the following sizes:

4 tablets
12 tablets#

marketed

AUST R 11003

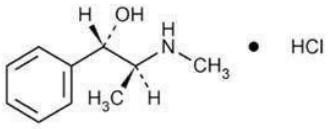
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Pseudoephedrine Hydrochloride



CAS number

CAS Registry Number: 345-78-8

7 MEDICINE SCHEDULE (POISONS STANDARD)

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

4 tablets (S3) Pharmacist Only Medicine
12 tablets# (S3) Pharmacist Only Medicine

marketed

8 SPONSOR

Kenvue Pacific Australia New Zealand

Sydney, NSW, Australia and Auckland New Zealand

®Registered trademark

9 DATE OF FIRST APPROVAL

01 May 2006

10 DATE OF REVISION

30 October 2026

Summary table of changes

Section Changed	Summary of new information
4.4 4.8	Addition of AGEP and fixed eruptions
4.8	Addition of Fixed eruption Addition of footnote for the commonly used medical term for the PT Fixed Eruption