AUSTRALIAN PRODUCT INFORMATION

SUDAFED® Sinus + Pain Relief Tablets (Paracetamol, Pseudoephedrine hydrochloride)

1 Name of the Medicine

Paracetamol

Pseudoephedrine Hydrochloride

2 Qualitative and Quantitative Composition

SUDAFED® Sinus + Pain Relief tablets contain pseudoephedrine hydrochloride 30 mg and paracetamol 500 mg.

For the full list of excipients, see Section 6.1 List of excipients.

3 Pharmaceutical form

SUDAFED® Sinus + Pain Relief tablets are white, flat, round and uncoated. They are scored and coded 'P3F' on one face, and the other face is plain.

4 Clinical Particulars

4.1 Therapeutic Indications

SUDAFED® Sinus + Pain Relief provides effective relief from sinus pain and congestion.

4.2 Dose and Method of administration

The recommended dosage of **SUDAFED®** Sinus + Pain Relief for adults and children 12 years and over is 1 to 2 tablets 3 to 4 times a day. Do not exceed 8 tablets in 24 hours.

SUDAFED® Sinus + Pain Relief should not be taken by children under 12 years of age without medical advice.

Use in Adults
Paracetamol should not be taken for more than a few days at a time except on medical advice.

Use in children
Paracetamol should not be taken for more than 48 hours except on medical advice.

4.3 Contraindications

Pseudoephedrine is contraindicated for use in patients:

- with known hypersensitivity or idiosyncratic reaction to pseudoephedrine (or 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.

Paracetamol is contraindicated for use in patients with known hypersensitivity or idiosyncratic reaction to paracetamol (or any of the other ingredients in the product).

Refer to '4.5 Interactions with other medicines and other forms of interactions' for additional information.

4.4 Special Warnings and Precautions for Use

High Anion Gap Metabolic Acidosis

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

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 or thyroid disease
- diabetes mellitus
- coronary heart disease
- ischaemic heart disease
- glaucoma

- prostatic hypertrophy
- severe hepatic dysfunction.

Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

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.

Serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens - Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported very rarely in patients receiving paracetamol. Patients should be informed about the signs of serious skin reactions and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Paracetamol should be used with caution in patients with:
- impaired hepatic function
- impaired renal function
- chronic alcoholism.

Refer to '4.5 Interactions with other medicines and other forms of interactions' for additional information.

Use in hepatic impairment
Use with caution in patients with hepatic impairment or severe hepatic dysfunction.

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

Use in elderly
No data available.

Paediatric use
No data available.

Effects on laboratory tests
No data available.

4.5 Interactions with Other Medicines and Other Forms of Interactions

The following interactions with the 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.

The following interactions with the paracetamol have been noted:
- anticoagulant drugs (warfarin) - dosage may require reduction if paracetamol and anticoagulants are taken for a prolonged period of time
- paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoclopramide
- paracetamol absorption is decreased by substances that decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- paracetamol may increase chloramphenicol concentrations
- the risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents
- paracetamol excretion may be affected and plasma concentrations altered when given with probenecid
- colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol

  Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Fertility, Pregnancy and Lactation

Effects on Fertility
No Data available.

Use in pregnancy
The pregnancy categorisation is 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.

Paracetamol has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

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.

Paracetamol is excreted in small amounts (< 0.2%) in breast milk. Maternal ingestion of paracetamol in usual analgesic doses does not appear to present a risk to the breastfed infant.

4.7 Effects on the ability to drive and use machines

No data available.

4.8 Adverse Effects (Undesirable Effects)

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

The safety of pseudoephedrine, paracetamol from clinical trial data is based on data from a randomized, placebo-controlled multi-dose clinical trial in the management of symptoms attributed to the paranasal sinus associated with the common cold.

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

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. A dash represents an incidence of less than 1%.

AEs Reported by ≥ 1% of Pseudoephedrine/Paracetamol – treated Subjects in 1 Randomized, Placebo Controlled Trial

System Organ Class Preferred Term	**Pseudoephedrine/ Paracetamol 60 mg/1000 mg multi-dose (N=216) % (frequency)**	**Placebo (N=214) %**
Psychiatric Disorders *Nervousness*	0.4 (Common)	-

The following additional adverse events were reported by ≥ 1% of subjects in randomized, placebo-controlled trials with single ingredient pseudoephedrine: dry mouth, nausea, dizziness, and insomnia.

Adverse drug reactions identified during post-marketing experience with Paracetamol, Pseudoephedrine HCl or the combination appear in the following table. The frequency category was estimated from spontaneous reporting rates 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
Not known	(cannot be estimated from the available data)

Frequency category	Adverse Event Preferred Term
Immune System Disorders	
Very Rare	*Anaphylactic reaction*
Very Rare	*Hypersensitivity*
Psychiatric Disorders	
Very Rare	*Anxiety*
Very Rare	*Euphoric mood*
Very Rare	*Restlessness*
Very Rare	*Hallucinations*
Very rare	*Hallucination, visual*
Very Rare	*Insomnia*
Nervous System Disorders	
Very Rare	*Cerebrovascular accident**
Very Rare	*Headache*
Very Rare	*Paraesthesia*
Very Rare	*Tremor*
Very Rare	*Psychomotor hyperactivity (in the pediatric population)*
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	*Myocardial infarction**
Very Rare	*Palpitations*
Very Rare	*Tachycardia*
Gastrointestinal Disorders	
Very Rare	*Abdominal Pain*
Very Rare	*Colitis ischaemic*
Very Rare	*Diarrhoea*
Very Rare	*Vomiting*

Skin and Subcutaneous Tissue Disorders	
Very Rare	*Pruritus*
Very Rare	*Acute generalised exanthematous pustulosis*
Very Rare	*Angioedema*
Very Rare	*Pruritic rash*
Very Rare	*Rash*
Very Rare	*Urticaria*
Very Rare	*Fixed eruption*
Renal and Urinary Disorders	
Very Rare	*Dysuria*
Very Rare	*Urinary retention*
General Disorders and Administration Site Conditions	
Very Rare	*Feeling jittery*
Very Rare	*Anxiety*
Investigations	
Very Rare	*Blood pressure increased*
Very Rare	*Transaminases increased*
Metabolism and nutrition disorders	
Not known	*High anion gap metabolic acidosis*

* 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.

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 Overdosage

If an overdose is taken or suspected, immediately contact the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand call 0800 764 766) for advice, or go to a hospital straight away even if you feel well because of the risk of delayed, serious liver damage.

Overdosage with paracetamol if left untreated can result in severe, sometimes fatal liver damage, and rarely, acute renal tubular necrosis.

5 Pharmacological Properties

5.1 Pharmacodynamics Properties

Mechanism of action
Pseudoephedrine has direct and indirect sympathomimetic activity and is aneffective 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.

Paracetamol is a p-aminophenol derivative that exhibits analgesic and antipyretic activity. It does not possess anti-inflammatory activity. Paracetamol is thought to produce analgesia through a central inhibition of prostaglandin synthesis.

Clinical trials
No data available.

5.2 Pharmacokinetic Properties

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.

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic doses but increases with increasing doses. The elimination half-life varies from about 1 to 3 hours.

Paracetamol is metabolised extensively in the liver and excreted in the urine mainly as inactive glucuronide and sulfate conjugates. Less than 5% is excreted unchanged. The metabolites of paracetamol include a minor hydroxylated intermediate which has hepatotoxic activity. This intermediate metabolite is detoxified by conjugation with glutathione; however, it can accumulate following paracetamol overdosage (more than 150 mg/kg or 10 g total paracetamol ingested) and if left untreated can cause irreversible liver damage.

Paracetamol is metabolised differently by premature infants, newborns, infants and young children compared to adults, the sulfate conjugate being predominant.

5.3 Preclinical safety data

Genotoxicity
No data available.

Carcinogenicity
No data available.

6 Pharmaceutical Particulars

6.1 List of excipients

SUDAFED® Sinus + Pain Relief tablets contain the excipients: microcrystalline cellulose, hydroxypropylcellulose, magnesium stearate, sodium starch glycollate, pregelatinised wheat starch, stearic acid.

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine. Refer to Section 4.5 – Interactions with other medicines and other forms of interactions.

6.3 Shelf Life

3 years.

6.4 Special Precautions for storage

Store below 30°C. Keep in a dry, dark place.

6.5 Nature and Contents of container

SUDAFED® Sinus + Pain Relief tablets are available in blister packs of the following sizes:

- 4 tablets (S3) Pharmacist Only Medicine
- 24 tablets[#] (S3) Pharmacist Only Medicine

[#] marketed

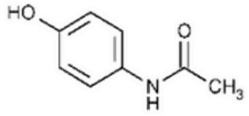
6.6 Special Precautions for disposal

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

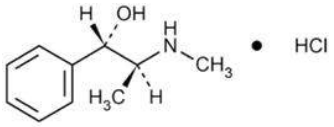
6.7 Physicochemical Properties

Chemical Structure

Paracetamol



Pseudoephedrine Hydrochloride



CAS number

Paracetamol

CAS Registry Number: 103-90-2

Pseudoephedrine Hydrochloride

CAS Registry Number: 345-78-8

7 Medicine Schedule (Poisons Standard)

Schedule 3

8 Sponsor

Kenvue Pacific Australia
New Zealand

Sydney, NSW, Australia
and Auckland New
Zealand

®Registered trademark

9 Date of First Approval

28 September 2006

10 Date of Revision

03 December 2025

Summary table of changes

Section Changed	Summary of new information
4.3	Additional contraindications added
4.4, 4.5, 4.8	Additional warning statements added
8	Update to sponsor details