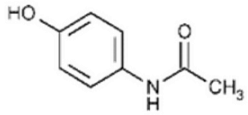
PRODUCT INFORMATION

SUDAFED® Sinus + Pain Relief Tablets

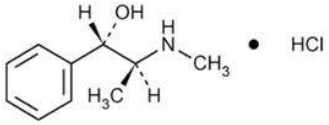
NAME OF THE MEDICINE

Paracetamol



CAS[2] Registry Number: 103-90-2

Pseudoephedrine Hydrochloride



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

DESCRIPTION

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

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

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.

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.

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.

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.

INDICATIONS

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

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 hypertension or coronary artery disease
- taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days.

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

Discontinue use and see a doctor at the first sign of a skin rash or any other sign of hypersensitivity.

Refer to ‘Interactions with other drugs’ for additional information.

PRECAUTIONS

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 or renal dysfunction.

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

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.

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.

INTERACTIONS WITH OTHER MEDICINES

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.

ADVERSE 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.

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*
Nervous System Disorders	
Very Rare	*Headache*
Very Rare	*Psychomotor hyperactivity (in the pediatric population)*
Very Rare	*Insomnia*
Very Rare	*Tremor*
Very Rare	*Hallucinations*
Cardiac Disorders	
Very Rare	*Arrhythmia*
Very Rare	*Palpitations*
Very Rare	*Tachycardia*
Gastrointestinal Disorders	
Very Rare	*Abdominal Pain*
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*
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*

DOSAGE AND 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 to 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.

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

PRESENTATION

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.

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
- 48 tablets (S4) Prescription Only Medicine

[#] marketed

Storage

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

AUST R 63230

SPONSOR

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007
Australia

*Registered trademark

Poison schedule of the medicine

Schedule 3

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