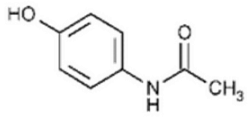
PRODUCT INFORMATION

Sudafed* Sinus + Allergy & Pain Relief Tablets

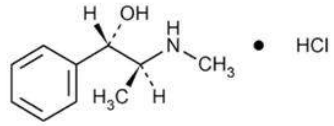
Name of the Medicine

Paracetamol



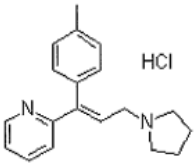
CAS[2] Registry Number: 103-90-2

Pseudoephedrine Hydrochloride



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

Triprolidine Hydrochloride



CAS[2] Registry Number: 6138-79-0

Product description

Sudafed* Sinus + Allergy & Pain Relief tablets contain pseudoephedrine hydrochloride 30 mg, paracetamol 500 mg and triprolidine hydrochloride 1.25 mg.

Sudafed* Sinus + Allergy & Pain Relief tablets also contain: brilliant blue FCF, microcrystalline cellulose, hydroxypropylcellulose, magnesium stearate, povidone, quinoline yellow.

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.

After absorption from the gastro-intestinal tract, triprolidine hydrochloride is metabolised; a carboxylated derivative accounts for about half the dose excreted in the urine. Reported half-lives vary from 3 to 5 hours or more. Triprolidine is 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.

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.

Triprolidine competes with histamine at central and peripheral histamine$_1$-receptor sites, preventing the histamine-receptor interaction and subsequent mediator release.

Triprolidine is a highly lipophilic molecule that readily crosses the blood-brain barrier.

Triprolidine is highly selective for histamine$_1$-receptors but has little effect on histamine$_2$ or histamine$_3$ receptors. Triprolidine also activates 5-hydroxytryptamine (serotonin) and α-adrenergic receptors and blocks cholinergic receptors.

Clinical Trials

Not applicable

Indications

Sudafed* Sinus + Allergy & Pain Relief provides temporary relief of severe sinus pain & congestion, nasal congestion, headache & pain, allergic symptoms such as sneezing, itching and watery eyes.

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). Use of the product should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity.

Triprolidine is contraindicated for use in patients with:

- a history of hypersensitivity to triprolidine or substances of similar chemical structure (or any of the other ingredients in the product)
- narrow-angle glaucoma
- stenosing peptic ulcer
- symptomatic prostatic hypertrophy
- bladder neck obstruction
- with pyloroduodenal obstruction.

Triprolidine is contraindicated for use in:

- newborns or premature infants
- lactating women
- patients taking monoamine oxidase inhibitors (MAOIs).

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

Triprolidine may cause drowsiness and may increase the effects of alcohol. Drowsiness may continue the following day. Those affected should not drive or operate machinery; alcohol should be avoided.

Use with caution in patients with renal or hepatic impairment, patients with epilepsy, and patients with respiratory conditions such as emphysema, chronic bronchitis, or acute or chronic bronchial asthma.

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

Use in children and the elderly
Children and the elderly may experience paradoxical excitation with triprolidine. The elderly are more likely to have CNS depressive side effects, including confusion.

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.

Triprolidine 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.

Triprolidine is excreted in breast milk. 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.

The following interactions with 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.

The following interactions with triprolidine have been noted:
- CNS depressants (alcohol, sedatives, opioid analgesics, hypnotics) – may cause an increase in sedation effects

- monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants (TCAs) – may prolong and intensify the anticholinergic and CNS depressive effects.

Adverse Effects

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

Adverse drug reactions identified during post-marketing experience with paracetamol, pseudoephedrine, the combination of pseudoephedrine and triprolidine, the combination of pseudoephedrine and paracetamol or the combination paracetamol, pseudoephedrine and triprolidine appear in the following table. The frequency category was estimated from spontaneous reporting rates.

Frequency category	Adverse Event Preferred Term
Immune System Disorders	
Very Rare	*Anaphylactic reaction*
Very Rare	*Hypersensitivity*
Psychiatric Disorders	
Very Rare	*Hallucination*
Very Rare	*Anxiety*
Very Rare	*Euphoric mood*
Very Rare	*Insomnia*
Very Rare	*Nervousness*
Very Rare	*Restlessness*
Very Rare	*Irritability*
Nervous System Disorders	
Very Rare	*Dizziness*
Very Rare	*Headache*
Very Rare	*Paraesthesia*
Very Rare	*Psychomotor hyperactivity (in the pediatric population)*
Very Rare	*Somnolence*
Very Rare	*Tremor*
Common	*Impaired performance (impaired driving performance, poor work performance, incoordination, reduced motor skills, and impaired information processing*
Common	*Sedation*
Not Known	*Activation of epileptogenic foci*

Cardiac Disorders	
Very Rare	*Arrhythmia*
Very Rare	*Palpitations*
Very Rare	*Tachycardia*
Respiratory, Thoracic, and Mediastinal Disorders	
Very Rare	*Epistaxis*
Common	*Dry nose*
Gastrointestinal Disorders	
Very Rare	*Abdominal Discomfort*
Very Rare	*Dry mouth*
Very Rare	*Nausea*
Very Rare	*Diarrhoea*
Very Rare	*Vomiting*
Common	*Constipation*
Skin and Subcutaneous Tissue Disorders	
Very Rare	*Pruritus*
Very Rare	*Angioedema*
Very Rare	*Pruritic rash*
Very Rare	*Rash*
Very Rare	*Urticaria*
Renal and Urinary Disorders	
Very Rare	*Dysuria*
Very Rare	*Urinary retention*
Common	*Urinary hesitancy*
General Disorders and Administration Site Conditions	
Very Rare	*Fatigue*
Very Rare	*Feeling jittery*
Investigations	
Very Rare	*Blood pressure increased*
Very Rare	*Transaminases increased*
Blood and lymphatic disorders	
Rare	*Haematological reactions*
Musculoskeletal and connective tissue disorders	
Not known	*Muscle dyskinesias*

Metabolism and nutrition disorders	
Not known	*Appetite stimulation*
Eye disorders	
Not known	*Dry Eyes*
Not known	*Blurred vision*

Dosage and administration

The recommended dosage of Sudafed* Sinus + Allergy & Pain Relief for adults and children over 12 years is two tablets 3 to 4 times daily. Do not exceed the recommended dosage.
Sudafed* Sinus + Allergy & Pain Relief should not be used for 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 and storage conditions

Sudafed* Sinus + Allergy & Pain Relief tablets are turquoise, bevelled, capsule-shaped, flat and uncoated. They are scored on one face and coded ‘S3F’ each side of the score, and plain on the other face.

Sudafed* Sinus + Allergy & Pain Relief tablets are available in blister packs of the following sizes:

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

[#] marketed

Store below 25°C. Keep dry. Protect from light.

AUST R 40335

Name and Address of 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: 13 November 2015