AUSTRALIAN PRODUCT INFORMATION

SUDAFED® Sinus + Anti inflammatory Pain Relief

Caplets 1 NAME OF THE MEDICINE

Pseudoephedrine Hydrochloride

Ibuprofen

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

SUDAFED® Sinus + Anti inflammatory Pain Relief caplets contain pseudoephedrine hydrochloride 30 mg and ibuprofen 200 mg.

SUDAFED® Sinus + Anti inflammatory Pain Relief caplets also contain: methyl hydroxybenzoate, propyl hydroxybenzoate. For the full list of excipients, see Section 6.1 List of excipients

3 PHARMACEUTICAL FORM

SUDAFED® Sinus + Anti inflammatory Pain Relief caplets are white, capsule-shaped, film-coated tablets.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

SUDAFED® Sinus + Anti inflammatory Pain Relief provides relief of symptoms of sinus pain with sinus congestion occurring as a result of cold and flu, allergic rhinitis or sinusitis.

4.2 DOSE AND METHOD OF ADMINISTRATION

The recommended dosage of **SUDAFED®** Sinus + Anti inflammatory Pain Relief for adults and children over 12 years is 1 or 2 caplets with fluid every four to six hours when necessary. Do not exceed 6 caplets in 24 hours.

SUDAFED® Sinus + Anti inflammatory Pain Relief should not be used for children under 12 years of age.

SUDAFED® Sinus + Anti inflammatory Pain Relief should not be used for more than a few days at a time except on medical advice, in which case the patient should be reviewed regularly with regards to efficacy, risk factors and ongoing need for treatment. Excessive use can increase the risk of heart attack, stroke or liver damage.

4.3 CONTRAINDICATIONS

SUDAFED® Sinus + Anti inflammatory Pain Relief is contraindicated for use in patients:

- with known hypersensitivity or idiosyncratic reaction to pseudoephedrine or ibuprofen (or any of the other ingredients in the product), other nonsteroidal anti inflammatory drugs or other salicylates

- with severe hypertension or coronary artery disease
- taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days.
- known hypersensitivity to aspirin and other NSAIDS
- asthma that is aspirin or NSAID sensitive
- active gastrointestinal bleeding or peptic ulceration
- renal impairment
- heart failure
- severe liver impairment
- undergoing treatment of perioperative pain in setting of coronary artery bypass surgery (CABG)
- right before or after heart surgery

Use of ibuprofen is contraindicated during the third trimester of pregnancy.

Use of ibuprofen is contraindicated right before or after heart surgery.

SUDAFED® Sinus + Anti inflammatory Pain Relief should not be taken with other products containing ibuprofen or with other anti inflammatory medicines.

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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

SUDAFED® Sinus + Anti inflammatory Pain Relief should be used with caution in patients with:

- hypertension
- hyperthyroidism or thyroid disease
- diabetes mellitus
- coronary heart disease
- ischaemic heart disease
- glaucoma
- prostatic hypertrophy
- previous history of gastrointestinal haemorrhage or ulcers
- asthma who have not previously taken an NSAID
- cardiac impairment or heart disease
- fluid retention
- alcohol dependence
- pregnancy (see 'Use in pregnancy').

and patients taking:

- taking a diuretic
- taking anti coagulants
- taking corticosteroids

Due to the ibuprofen component, this medicine should be taken with caution when using other products containing aspirin and salicylates.

Ibuprofen may cause a severe allergic reaction, especially in patients allergic to aspirin.

Symptoms include hives, facial swelling, asthma (wheezing), shock, skin reddening, rash or blisters with or without pyrexia or erythema. If any of these symptoms occur, patients should stop use and seek medical help right away.

Ibuprofen has very rarely been reported to cause Vanishing Bile Duct Syndrome. Patients should seek medical advice if they develop a sudden onset abdominal pain or chronic abdominal pain associated with loss of appetite and/or new onset itching.

Due to the pseudoephedrine component, this medicine 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 this medicine should be discontinued and a physician should be consulted.

Ibuprofen treats fever and pain which sometimes can be signs of a serious underlying condition. If symptoms persist or get worse, or if new symptoms occur, patients should stop use and consult a physician.

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

Cardiovascular and cerebrovascular effects:
Observational studies have indicated that NSAIDs may be associated with an increased risk of serious cardiovascular events, including myocardial infarction, stroke and Kounis Syndrome, which may increase with dose or duration of use.

Patients with cardiovascular disease, history of atherosclerotic cardiovascular disease or cardiovascular risk factors may also be at greater risk.

Patients should be advised to remain alert for such cardiovascular events, even in the absence of previous cardiovascular symptoms. Patients should be informed about signs and/or symptoms of serious cardiovascular toxicity and the steps to take if they occur.

Fluid retention, hypertension and oedema have been reported in association with NSAID therapy. Patients taking antihypertensives with NSAIDS may have an impaired antihypertensive response.

SUDAFED® Sinus + Anti inflammatory Pain Relief should be used with caution in patients with hypertension (see Contraindications – heart failure).

Use in hepatic impairment
SUDAFED® Sinus + Anti inflammatory Pain Relief should be used with caution for patients with severe hepatic dysfunction or impairment.

As with other NSAIDs elevations of one or more liver function tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may resolve with continued therapy. Meaningful elevations (three times the upper limit of normal) of ALT or AST occurred in controlled clinical trials in less than 1% of patients.

Patients should be advised to remain alert for hepatotoxicity and be informed about the signs and/or symptoms of hepatotoxicity (e.g. nausea, fatigue, lethargy, pruritis, jaundice, abdominal tenderness in the right upper quadrant and “flu-like” symptoms).

Use in renal impairment

SUDAFED® Sinus + Anti inflammatory Pain Relief should be used with caution for patients with severe kidney dysfunction or impairment.

Use in the elderly

Ibuprofen should not be taken by adults over the age of 65 without careful consideration of comorbidities and co-medications because of an increased risk of adverse effects, in particular heart failure, gastro-intestinal ulceration and renal impairment (see also Contraindications).

Paediatric use

SUDAFED® Sinus + Anti inflammatory Pain Relief should not be used for children under 12 years of age.

Effects on laboratory test

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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 ibuprofen have been noted:

- Anticoagulants, including warfarin – ibuprofen interferes with the stability of INR and may increase risk of severe bleeding and sometimes fatal haemorrhage, especially from the gastrointestinal tract. Ibuprofen should only be used in patients taking warfarin if absolutely necessary and they must be closely monitored.
- Ibuprofen may decrease the cardioprotective and antiplatelet activity of aspirin.
- Ibuprofen may decrease renal clearance and increase plasma concentration of lithium
- Ibuprofen may reduce the antihypertensive effect of ACE inhibitors, beta-blockers and diuretics and may cause natriuresis and hyperkalemia in patients under these treatments
- Ibuprofen reduces methotrexate clearance
- Ibuprofen may increase plasma levels of cardiac glycoside
- Ibuprofen may increase the risk of gastrointestinal bleeding especially if taken with corticosteroids or with alcohol use.
- Ibuprofen may prolong bleeding time in patients treated with zidovudine.
- Alcohol use may increase the risk of gastrointestinal bleeding when taking drugs in the NSAID class, including Ibuprofen. Therefore, caution should be taken when using ibuprofen with alcohol.

Ibuprofen may also interact with probenecid, antidiabetic medicines and phenytoin.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy: Category C

Data from epidemiological studies suggest an increased risk of miscarriage after the use of a prostaglandin synthesis inhibitor in early pregnancy.

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.

Ibuprofen inhibits prostaglandin synthesis and, when given during the latter part of pregnancy, may cause closure of the foetal ductus arteriosus, foetal renal impairment, inhibition of platelet aggregation and may delay labour and birth. Use of ibuprofen is thus contraindicated during the third trimester of pregnancy, including the last few days before expected birth.

Further, there is insufficient experience about the safety of use of ibuprofen in humans during pregnancy. Sudafed® Sinus + Anti inflammatory Pain Relief should therefore not be used during the first six months of pregnancy unless the potential benefits to the patient outweigh 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, it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

Ibuprofen appears in breast milk in very low concentrations and is unlikely to affect the breast fed infant adversely

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

It is not known if the combination of ibuprofen and pseudoephedrine has an effect on the ability to drive and use machines.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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

Clinical Trial Data

The safety of the combination of ibuprofen and pseudoephedrine from clinical trial data is based on data from 4 double-blind placebo-controlled single dose randomized studies in the treatment of sinus headache.

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 Subjects Treated with Ibuprofen and Pseudoephedrine combination in 4 Randomized Placebo-Controlled Clinical Trials

System Organ Class Preferred Term	**400 mg ibu/60 mg PSE x 1 dose (N=244) % (frequency)**	**200 mg ibu/30 mg PSE x 1 dose (N=238) % (frequency)**	**Placebo (N=241) % (frequency)**
General Disorders and Administration Site Conditions			
Thirst	0.4 (Uncommon)	1.3 (Common)	0.4 (Uncommon)
Gastrointestinal Disorders			
Abdominal pain upper	- 1.6 (Common)	-	-
Nervous System Disorders			
Dizziness	4.9 (Common)	6.3 (Common)	5.8
Tremor	-	1.7 (Common)	-
Psychiatric Disorders			
Anxiety	1.6 (Common)	0.4 (Uncommon)	-
Nervousness	6.1 (Common)	2.5 (Common)	1.7 (Common)
Eye Disorders			
Eye Disorder	1.2 (Common)	-	-
Ear and Labyrinth Disorders			
Tinnitus	0.4 (Uncommon)	1.7 (Common)	0.4 (Uncommon)

Post Marketing Data

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

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

Infections and Infestations	
Very Rare	*Meningitis aseptic*
Blood and Lymphatic Disorders	
Very rare	*Bone Marrow Suppression*
Very rare	*Eosinophilia*
Very rare	*Thrombocytopenia*
Very rare	*Anaemia*

Immune Disorders	
Very Rare	*Hypersensitivity reactions*
Very Rare	*Angioedema*
Very Rare	*Anaphylactic reaction*
Psychiatric Disorders	
Very Rare	*Anxiety*
Very Rare	*Insomnia*
Very Rare	*Nervousness*
Very Rare	*Euphoric Mood*
Very Rare	*Hallucination*
Very Rare	*Hallucination, visual*
Very Rare	*Restlessness*
Nervous System Disorders	
Very Rare	*Headache*
Very Rare	*Dizziness*
Very Rare	*Psychomotor hyperactivity*
Very Rare	*Stroke*
Very Rare	*Somnolence*
Very Rare	*Posterior Reversible Encephalopathy Syndrome*
Very Rare	*Reversible Cerebral Vasoconstriction Syndrome*
Common	*Tremor*
Rare	*Fatigue*
Eye Disorders	
Very rare	*Vision Blurred*
Very rare	*Visual Impairment*
Cardiac Disorders	
Very rare	*Kounis Syndrome*
Very rare	*Palpitations*
Very rare	*Arrhythmia*
Very rare	*Tachycardia*

Very rare	*Cardiac Failure*
Very rare	*Myocardial Infarction*
Rare	*Fluid retention*
Rare	*Oedema*
Vascular Disorders	
Very Rare	*Bleeding*
Very Rare	*Hypertension*
Respiratory, Thoracic and Mediastinal Disorders	
Very Rare	*Asthmatic Conditions*
Very Rare	*Bronchospasm*

Rare	*Breathing difficulties*
Gastrointestinal Disorders	
Very Rare	*Colitis ischaemic*
Very Rare	*Dry Mouth*
Very Rare	*Nausea*
Very Rare	*Constipation*
Very Rare	*Diarrhoea*
Very Rare	*Gastrointestinal Inflammation*
Very Rare	*Gastrointestinal Haemorrhage*
Very Rare	*Gastrointestinal Ulcer perforation*
Very Rare	*Gastrointestinal Ulceration*
Very Rare	*Gastrointestinal Ulcer haemorrhage*
Very Rare	*Dyspepsia*
Very Rare	*Abdominal pain*
Very Rare	*Oral discomfort (local burning sensation, irritation*
Very Rare	*Pancreatitis*
Very Rare	*Vomiting*
Rare	*Heartburn*
Hepatobiliary Disorders	
Very Rare	*Hepatotoxicity (Hepatic function abnormal, Hepatitis, Transaminases increased)*
Very Rare	*Vanishing bile duct syndrome*
Skin and Subcutaneous Tissue Disorders	
Very Rare	*Acute generalised exanthematous pustulosis*
Very Rare	*Drug reaction with eosinophilia and systemic symptoms (DRESS)*
Very Rare	*Angioedema*

Very Rare	*Rash*
Very Rare	*Pruritus*
Very Rare	*Erythema*
Very Rare	*Erythema Multiforme*
Very Rare	*Stevens-Johnson Syndrome*
Very Rare	*Toxic Epidermal Necrolysis*
Very Rare	*Urticaria*
Very Rare	*Fixed Eruption*
Rare	*Photosensitivity*
Renal and Urinary Disorders	
Very Rare	*Dysuria*
Very Rare	*Urinary Retention*
Very Rare	*Nephritis*
Very Rare	*Nephrotic Syndrome*
Very Rare	*Renal Failure*
Very Rare	*Renal Impairment*
Very Rare	*Renal Papillary Necrosis*
General Disorders and Administrative Site Conditions	
Very Rare	*Feeling Jittery*
Very Rare	*Asthenia*
Very Rare	*Hypothermia*
Metabolism and nutrition disorders	
Rare	*Loss of appetite*

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: https://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Ibuprofen

The toxicity of ibuprofen overdose is dependent upon the amount of drug ingested and the time elapsed since ingestion. Individual response may vary, and each case should be evaluated individually. Although uncommon, serious toxicity and death have been reported in association with acute ibuprofen overdose.

The most frequently reported symptoms of acute ibuprofen overdose include abdominal pain, nausea, vomiting, lethargy and drowsiness. Other central nervous system symptoms following acute overdose include headache, tinnitus, CNS depression and seizures. Metabolic acidosis, coma, acute renal failure, renal tubular acidosis, rhabdomyolysis, hypothermia, fulminant hepatic failure and apnea (primarily in very young children) may rarely

occur, and are more common with severe overdoses of more than 400 mg/kg. Cardiovascular toxicity, including hypotension, bradycardia, tachycardia and atrial fibrillation, also have been reported. Onset of symptoms usually occurs within 4 hours.

Pseudoephedrine
Overdosage may result in nausea, vomiting, sympathomimetic symptoms including central nervous system stimulation, insomnia, tremor, mydriasis, anxiety, agitation, hallucinations, seizures, palpitations, tachycardia, hypertension, and reflex bradycardia. Other effects may include dysrhythmias, hypertensive crisis, intracerebral hemorrhage, myocardial infarction, psychoses, rhabdomyolysis, hypokalemia, and ischemic bowel infarction. Drowsiness has been reported with overdose in children.

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.

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.

Ibuprofen possesses analgesic, antipyretic and anti inflammatory properties, similar to other non-steroidal anti inflammatory drugs (NSAIDs). Its mechanism of action is unknown, but is thought to be through peripheral inhibition of cyclooxygenases and subsequent prostaglandin synthetase inhibition.

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.

Ibuprofen is well absorbed from the gastrointestinal tract. It is highly bound (90-99%) to plasma proteins and is extensively metabolised to inactive compounds in the liver, mainly by glucuronidation. Both the inactive metabolites and a small amount of unchanged ibuprofen are excreted rapidly and completely by the kidney, with 95% of the administered dose eliminated in the urine within four hours of ingestion. The elimination half-life of ibuprofen is in the range of 1.9 to 2.2 hours.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Candelilla wax, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, stearic acid, methyl hydroxybenzoate, propyl hydroxybenzoate, Opadry Aqueous Film Coating YS-17034 Clear UK, Opadry Aqueous Film Coating YS-1-7717 White UK.

6.2 INCOMPATIBILITIES
'Incompatibilities were either not assessed or not identified as part of the registration of this medicine.'

6.3 SHELF LIFE
2 years.

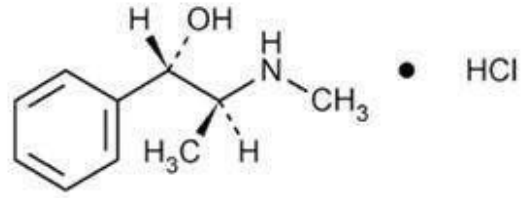
6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store below 25°C. Keep in a dry dark place.

6.5 NATURE AND CONTENTS OF CONTAINER
SUDAFED® Sinus + Anti inflammatory Pain Relief caplets are available in blister packs of Alu/PVC/PVDC in the following sizes:

- 4 caplets
- 12 caplets
- 24 caplets

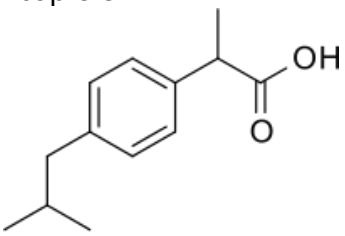
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES
Pseudoephedrine Hydrochloride



CAS Registry Number: 345-78-8

Ibuprofen



CAS Registry Number: 15687-27-1

7 MEDICINE SCHEDULE (POISONS STANDARD)
Pharmacist Only Medicine (Schedule 3)

8 SPONSOR
Johnson & Johnson Pacific
45 Jones Street

Ultimo NSW 2007
Australia

® Registered trademark

9 DATE OF FIRST APPROVAL

Date of first inclusion in the ARTG: 4 October 2006

10 DATE OF REVISION

Date of revision: 18 Nov 2022

Summary table of changes

Section changed	Summary of new information
All	Update to new PI format. Addition of more restrictive safety-related statements to sections 4.3 to 4.8.
4.4 and 4.8	Addition of more restrictive safety- related statements
4.4, 4.8 and 4.9	Addition of more restrictive safety- related statements. Inclusion of additional information in section 4.9
4.8	Additional adverse drug reactions (ADRs) identified during post marketing experience with pseudoephedrine