PRODUCT INFORMATION

Sudafed* Sinus + Anti-inflammatory Pain Relief Caplets

Product description

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: candelilla wax, microcrystalline cellulose, croscarmellose sodium, sodium laurate sulfate, stearic acid, methyl hydroxybenzoate, propyl hydroxybenzoate, Opadry Aqueous Film Coating YS-1-7034 Clear UK, Opadry Aqueous Film Coating YS-1-7717 White UK.

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.

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.

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.

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.
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.

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.

Ibuprofen is contraindicated for use in patients with:
- known hypersensitivity or idiosyncratic reaction to ibuprofen (or any of the other ingredients in the product)
- known hypersensitivity to aspirin and other NSAIDS
- asthma that is aspirin or NSAID sensitive
- active gastrointestinal bleeding or peptic ulceration.

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

Ibuprofen should not be taken with other products containing ibuprofen or with other anti-inflammatory medicines.

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

Precautions

Pseudoephedrine should be used with caution in patients with:
- hypertension
- hyperthyroidism
- diabetes mellitus
- coronary heart disease
- ischaemic heart disease
- glaucoma
- prostatic hypertrophy
- severe hepatic or renal dysfunction.

Ibuprofen should be used with caution in patients with:
- previous history of gastrointestinal haemorrhage or ulcers
- asthma who have not previously taken an NSAID
- hepatic, renal or cardiac impairment.
- pregnancy (see ‘Use in pregnancy’).
Ibuprofen should be taken with caution when using other products containing aspirin and salicylates.

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

Use in pregnancy: Category C
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.

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

Interaction 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 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 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
• Ibuprofen may prolong bleeding time in patients treated with zidovudine.

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

Adverse reactions

Adverse effects of pseudoephedrine include:
• cardiovascular stimulation – elevated blood pressure, tachycardia or arrhythmias
• CNS stimulation – restlessness, insomnia, anxiety, tremors and (rarely) hallucinations
• skin rashes and urinary retention.

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

Adverse effects with non-prescription (OTC) or short-term use ibuprofen are rare and may include:
• gastrointestinal – dyspepsia, heartburn, nausea, loss of appetite, stomach pain, diarrhoea
• CNS – dizziness, fatigue, headache, nervousness
• hypersensitivity reactions - skin rashes and itching. Rarely exfoliative dermatitis and epidermal necrolysis have been reported with ibuprofen.
• rare cases of photosensitivity
• cardiovascular - fluid retention and in some cases oedema. These effects are rare at non-prescription doses.

Allergic reactions such as skin rash, itching, swelling of the face or breathing difficulties may also occur. These are usually transient and reversible on cessation of treatment.
Dosage

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.

Ibuprofen should not be used for more than a few days at a time except on medical advice.

Overdosage

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.

Presentation

Sudafed* Sinus + Anti-inflammatory Pain Relief caplets are white, capsule-shaped, film-coated tablets. They are embossed with 'WL369' on the upper face and plain on the lower face.

Sudafed* Sinus + Anti-inflammatory Pain Relief caplets are available in blister packs of the following sizes:

- 4 caplets (S3) Pharmacist Only Medicine
- 12 caplets (S3) Pharmacist Only Medicine
- 24 caplets# (S3) Pharmacist Only Medicine

# marketed

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

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Name and Address of Sponsor

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*Registered trademark

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