

SUDAFED Sinus + Anti-inflammatory Pain Relief

Active ingredient(s): *Pseudoephedrine hydrochloride and Ibuprofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sudafed Sinus + Anti-inflammatory Pain Relief. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Sudafed Sinus + Anti-inflammatory Pain Relief.**

Where to find information in this leaflet:

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1. Why am I using Sudafed Sinus + Anti-inflammatory Pain Relief?

Sudafed Sinus + Anti-inflammatory Pain Relief contains the active ingredient Pseudoephedrine hydrochloride and Ibuprofen. Pseudoephedrine hydrochloride belongs to a group of medicines called sympathomimetic decongestants. It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Sudafed Sinus + Anti-inflammatory Pain Relief is used for the temporary relief of symptoms of sinus pain congestion occurring as a result of cold and flu, allergic rhinitis or sinusitis.

2. What should I know before I use Sudafed Sinus + Anti-inflammatory Pain Relief?

Warnings

Do not use Sudafed Sinus + Anti-inflammatory Pain Relief if:

- you are allergic to Pseudoephedrine hydrochloride, or Ibuprofen, aspirin or other NSAIDs, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you are younger than 12 years
- have very high blood pressure
- have severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- have taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days
- have asthma that is sensitive to aspirin or NSAIDs

- have a stomach or duodenal ulcer
- have recently vomited blood or material that looks like coffee grounds
- have recently bled from the back passage (rectum), had black sticky bowel motions or bloody diarrhoea
- have alcohol dependence.

Check with your doctor or pharmacist if you:

- have any other medical conditions
 - high blood pressure
 - overactive thyroid gland
 - diabetes
 - heart disease and poor blood flow in the blood vessels of the heart
 - glaucoma (high pressure in the eyes)
 - fluid retention
 - prostate problems
 - liver or kidney disease
 - asthma
 - gastrointestinal disease
 - stomach or duodenal ulcer
 - signs of gastrointestinal bleeding, such as vomiting blood or bleeding from the back passage (rectum)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Small amounts of pseudoephedrine pass into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Sudafed Sinus + Anti-inflammatory Pain Relief and affect how it works.

These include

- medicines used to treat depression especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to treat high blood pressure
- medicines used to treat urinary tract infections and bladder problems
- medicines used to treat behavioral disorders
- phenylephrine, a medicine used to treat congestion
- appetite suppressants
- warfarin, a medicine used to prevent blood clots

- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to lower blood pressure
- diuretics
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart conditions
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- zidovudine, a medicine used to treat HIV infection
- aspirin, salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines used to treat diabetes.

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sudafed Sinus + Anti-inflammatory Pain Relief.

4. How do I use Sudafed Sinus + Anti-inflammatory Pain Relief?

How much to take

- The recommended dose of Sudafed Sinus + Anti-inflammatory Pain Relief for adults and children over 12 years is 1-2 tablets every 4 to 6 hours, as necessary.
- Follow the instructions provided with the medicine.
- Do not exceed 6 tablets in 24 hours.
- Do not exceed the recommended dosage.

When to take Sudafed Sinus + Anti-inflammatory Pain Relief

- Sudafed Sinus + Anti-inflammatory Pain Relief should be taken every 4 to 6 hours, as necessary.

How to take Sudafed Sinus + Anti-inflammatory Pain Relief

- Swallow the tablets whole.
- Do not use for more than a few days at a time except on medical advice.
- Follow all directions given to you by your pharmacist or doctor carefully. This may differ from the information contained in this leaflet.
- If you forget to take it and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, you may take a dose as soon as you remember if you think you need it. Do not take a double dose to make up for the dose that you missed.
- If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

If you use too much Sudafed Sinus + Anti-inflammatory Pain Relief

If you think that you have used too much Sudafed Sinus + Anti-inflammatory Pain Relief, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Sudafed Sinus + Anti-inflammatory Pain Relief?

Things you should do

Stop use and talk to your doctor or pharmacist if your symptoms persist, worsen, or if new symptoms occur. Your doctor or pharmacist will assess your condition and decide if you should continue to take the medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Sudafed Sinus + Anti-inflammatory Pain Relief.

Things you should not do

- Do not take Sudafed Sinus + Anti-inflammatory Pain Relief to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sudafed Sinus + Anti-inflammatory Pain Relief affects you.

Sudafed Sinus + Anti-inflammatory Pain Relief may cause dizziness in some people.

If this happens, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

- Keep your medicine in the original pack until it is time to take.
- Keep your medicine in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• blurred vision• dry mouth• oral discomfort (burning sensation or irritation in the mouth)• nausea• vomiting• heartburn• indigestion• abdominal pain• loss of appetite• diarrhoea• constipation• difficulty urinating• drowsiness• weakness• fatigue• dizziness• difficulty sleeping• nervousness• excitability• restlessness• fear or anxiety• headache• high blood pressure• rapid or irregular heartbeat• palpitations• low body temperature• tremor• hallucinations• thirst• tinnitus	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• shock• urine/fluid retention• vomiting blood or bleeding from the back passage• chest pain• shortness of breath• wheezing or difficulty breathing• swelling of the face, lips, tongue, or other parts of the body• rash, itching or hives on the skin	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Children and people over 65 years of age may have an increased chance of getting side effects.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Sudafed Sinus + Anti-inflammatory Pain Relief contains

Active ingredient (main ingredient)	Pseudoephedrine hydrochloride Ibuprofen
Other ingredients (inactive ingredients)	Candelilla wax Croscarmellose sodium Microcrystalline cellulose Opadry aqueous film coating YS-1-7034 clear UK Opadry aqueous film coating YS-1-7717 white UK Sodium lauryl sulfate Stearic acid

Do not take this medicine if you are allergic to any of these ingredients.

What Sudafed Sinus + Anti-inflammatory Pain Relief looks like

White, capsule-shaped tablet.

(Aust R 80163).

Who distributes Sudafed Sinus + Anti-inflammatory Pain Relief

Johnson & Johnson Pacific

45 Jones Street

Ultimo NSW 2007

Australia

Phone: 1800 029979

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