

SUDAFED® Sinus + Anti-inflammatory Pain Relief Caplets

Pseudoephedrine Hydrochloride, Ibuprofen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SUDAFED® Sinus + Anti-inflammatory Pain Relief caplets.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking SUDAFED® Sinus + Anti-inflammatory Pain Relief against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What SUDAFED® Sinus + Anti-inflammatory Pain Relief is used for

SUDAFED® Sinus + Anti-inflammatory Pain Relief provides relief of the symptoms of sinus pain with sinus congestion caused by cold and flu, allergic rhinitis and sinusitis.

Pseudoephedrine 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).

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason.

This medicine is only available from your pharmacist.

Before you take SUDAFED® Sinus + Anti-inflammatory Pain Relief

When you must not take it

Do not take SUDAFED® Sinus + Anti-inflammatory Pain Relief if you have an allergy to:

- any medicine containing pseudoephedrine
- any medicine containing ibuprofen, aspirin or other NSAIDs
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shock
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin reddening, blisters, rash, itching or hives on the skin.

Do not take this medicine if you have:

- very high blood pressure
- severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days
- asthma that is sensitive to aspirin or NSAIDs
- a stomach or duodenal ulcer
- recently vomited blood or material that looks like coffee grounds
- recently bled from the back passage (rectum), had black sticky bowel motions or bloody diarrhoea.
- alcohol dependence

Do not take this medicine right before or after heart surgery.

Do not take this medicine if you are pregnant or plan to become pregnant.

It may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

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Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have or have had any of the following 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).

Talk to your pharmacist or doctor about taking this medicine if you are over 65 years of age.

Taking this medicine may increase the risk of you getting stomach, heart or kidney problems.

Ask your pharmacist or doctor about taking the medicine if you are breastfeeding.

Small amounts of pseudoephedrine and ibuprofen pass into the breast milk.

Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking SUDAFED® Sinus + Anti-inflammatory Pain Relief.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines and SUDAFED® Sinus + Anti-inflammatory Pain Relief may interfere with each other. These include:

- medicines used to treat depression
- medicines used to treat high blood pressure
- medicines used to treat urinary tract infections and bladder problems
- medicines used to treat behavioural 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.

These medicines may be affected by SUDAFED® Sinus + Anti-inflammatory Pain Relief or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take SUDAFED® Sinus + Anti-inflammatory Pain Relief

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your pharmacist or doctor for help.

How much to take

The recommended dose of SUDAFED® Sinus + Anti-inflammatory Pain Relief, for adults and children over 12 years, is 1 or 2 caplets every 4 to 6 hours when necessary.

Do not exceed 6 caplets in 24 hours.

Do not take more than the recommended dose.

Excessive use may increase the risk of heart attack, stroke or liver damage.

How long to take it

As SUDAFED® Sinus + Anti-inflammatory Pain Relief contains ibuprofen, it should not be used for more than a few days at a time except on medical advice.

If you forget to take it

If 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.

This may increase the chance of you getting an unwanted side effect.

Your next dose should be taken in 4 to 6 hours if you think you need it.

If you are not sure what to do, ask your pharmacist or doctor.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SUDAFED® Sinus + Anti-inflammatory Pain Relief. Do this even if there are no signs of discomfort or poisoning.

While you are using SUDAFED® Sinus + Anti-inflammatory Pain Relief

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve, worsen, or if new symptoms appear.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Things you must 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.

Things to be careful of

If you are over 65 years of age, talk to your pharmacist or doctor about taking this medicine.

Taking this medicine may increase the risk of you getting unwanted effects, such as stomach or heart problems.

Be careful driving or operating machinery until you know how SUDAFED® Sinus + Anti-

inflammatory Pain Relief affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking SUDAFED® Sinus + Anti-inflammatory Pain Relief.

This medicine helps most people with sinus congestion and sinus pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

It is rare to get side effects from ibuprofen or pseudoephedrine if taken for a short period of time and in the doses contained in OTC medicines.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- blurred vision
- dry mouth
- oral discomfort (burning sensation or irritation in the mouth)
- nausea, vomiting, heartburn, indigestion or 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 heart beat
- palpitations
- low body temperature
- tremor
- hallucinations
- thirst
- tinnitus

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- get sunburnt more easily than usual.

The above side effect is rare at low doses of this medicine and when used for a short period of time.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- skin reddening, blisters, rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare at low doses of this medicine and when used for a short period of time.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using SUDAFED® Sinus + Anti-inflammatory Pain Relief

Storage

Keep your medicine in the original pack until it is time to take.

Keep your medicine in a dark dry place where the temperature stays below 30°C.

Do not store SUDAFED® Sinus + Anti-inflammatory Pain Relief or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

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

SUDAFED® Sinus + Anti-inflammatory Pain Relief caplets are available in blister packs of 24 caplets.

Ingredients

SUDAFED® Sinus + Anti-inflammatory Pain Relief caplets contain 30 mg of pseudoephedrine hydrochloride and 200 mg of ibuprofen as the active ingredients.

SUDAFED® Sinus + Anti-inflammatory Pain Relief caplets also contain the following inactive ingredients:

- candelilla wax
- microcrystalline cellulose
- croscarmellose sodium
- sodium lauryl 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.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Name and Address of Sponsor

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007
Australia

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