

# Sudafed Sinus + Allergy & Pain Relief Tablets

*Pseudoephedrine hydrochloride, Paracetamol, Triprolidine hydrochloride*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Sudafed Sinus + Allergy & Pain Relief Tablets. 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 + Allergy & 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 + Allergy & Pain Relief is used for

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

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.

Paracetamol works to stop the pain messages from getting through to the

brain. It also acts in the brain to reduce fever.

Triprolidine belongs to a group of medicines called 'antihistamines'. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine.

Histamine is produced by the body in response to foreign substances that the body is allergic to.

**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 + Allergy & Pain Relief

#### *When you must not take it*

**Do not take Sudafed Sinus + Allergy & Pain Relief if you have an allergy to:**

- any medicine containing pseudoephedrine
- any medicine containing paracetamol
- any medicine containing triprolidine or other antihistamines
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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.

**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).

**Do not take this medicine if you have or have had any of the following medical conditions:**

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems.

**Do not take this medicine if you are also taking monoamine oxidase inhibitors (a type of medicine used to treat depression), or if you have taken monoamine oxidase inhibitors in the last 14 days.**

**Do not give this medicine to newborn or premature babies.**

**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.**

### ***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:**

- a respiratory condition (such as emphysema, chronic bronchitis or acute or chronic asthma)
- 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)
- prostate problems
- liver or kidney disease
- alcohol dependence
- epilepsy.

**Tell your pharmacist or doctor if you take sedatives.**

**Tell your pharmacist or doctor if you are pregnant or plan to become pregnant.**

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

**Tell your pharmacist or doctor if you are breastfeeding or plan to breastfeed.**

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine while breastfeeding.

**If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Sudafed Sinus + Allergy & 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 + Allergy & Pain Relief may interfere with each other. These include:

- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to treat heart conditions
- 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
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- medicines used to help you sleep or relax (sedatives and hypnotics)
- opioid analgesics, medicines used to treat pain
- alcohol.

These medicines may be affected by Sudafed Sinus + Allergy & 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 + Allergy & 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 pack, ask your pharmacist or doctor for help.**

### ***How much to take***

The recommended dose of Sudafed Sinus + Allergy & Pain Relief, for adults and children over 12 years, is two tablets 3 to 4 times daily.

**Do not take more than the recommended dose.**

**If you are over 65 years of age, talk to your pharmacist or doctor about how much to take.**

You may have an increased chance of getting side effects.

### ***How to take it***

Swallow tablets with a glass of water as required.

### ***When to take it***

Take the recommended dose 3 to 4 times a day, as required.

### ***How long to take it***

As Sudafed Sinus + Allergy & Pain Relief contains paracetamol, take only for a few days at a time unless your doctor tells you to take it for longer.

### ***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.

**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 + Allergy & Pain Relief. Do this even if there are no signs of discomfort or poisoning.**

---

## **While you are using Sudafed Sinus + Allergy & 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 for more than a few days at a time unless your doctor tells you to.**

**Do not drink alcohol while taking Sudafed Sinus + Allergy & Pain Relief.**

The sedative effects of alcohol may be increased.

Drinking large quantities of alcohol while taking paracetamol may also increase the risk of liver side effects.

**Do not take Sudafed Sinus + Allergy & 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 doctor tells you to.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Sudafed Sinus + Allergy & Pain Relief affects you.**

This medicine may cause dizziness or sleepiness 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 + Allergy & Pain Relief.**

This medicine helps most people with sinus pain & allergy symptoms, 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.**

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

- nausea or dyspepsia
- constipation
- drowsiness or sleepiness
- dizziness
- difficulty sleeping
- nervousness and irritability
- excitability
- restlessness
- fear or anxiety
- dry mouth, nose and throat
- twitching or jerking muscles
- rapid heart beat

- tremor
- hallucinations.

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

Children and people over 65 years of age may have an increased chance of getting side effects.

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

- difficult or painful urination
- seizures (fits).

The above list includes serious side effects that may require medical attention. These side effects are rare.

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

- urine retention
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for 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 + Allergy & Pain Relief**

---

### ***Storage***

**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.**

**Do not store Sudafed Sinus + Allergy & 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 + Allergy & Pain Relief are turquoise, capsule-shaped, flat, uncoated tablets. 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 20 tablets.

### ***Ingredients***

Sudafed Sinus + Allergy & Pain Relief tablets contain 30 mg of pseudoephedrine hydrochloride, 500 mg of paracetamol and 1.25 mg triprolidine hydrochloride as the active ingredients.

Sudafed Sinus + Allergy & Pain Relief tablets also contain the following inactive ingredients:

- brilliant blue FCF
- microcrystalline cellulose
- hydroxypropylcellulose
- magnesium stearate
- povidone
- quinoline yellow.

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

SUDAFED is a registered trademark.

This leaflet was prepared in November 2015.

Australian Register Number:

AUST R 40335