Panadol Sinus Relief

Active ingredient(s): Paracetamol 500 mg and Pseudoephedrine Hydrochloride 30 mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using Panadol Sinus 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 Panadol Sinus Relief.

Where to find information in this leaflet:

- 1. Why am I using Panadol Sinus Relief?
- 2. What should I know before I use Panadol Sinus Relief?
- 3. What if I am taking other medicines?
- 4. How do I use Panadol Sinus Relief?
- 5. What should I know while using Panadol Sinus Relief?
- 6. Are there any side effects?
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1. Why am I using Panadol Sinus Relief?

Panadol Sinus Relief contains the active ingredient paracetamol and pseudoephedrine hydrochloride.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

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.

Panadol Sinus Relief is used for the temporary relief of sinus congestion and pain, nasal congestion and runny nose.

2. What should I know before I use Panadol Sinus Relief?

Warnings

Always read and follow the label.

Do not take more than the recommended dose as it may cause serious harm to your liver.

Do not use Panadol Sinus Relief if:

- you are allergic to paracetamol, pseudoephedrine, 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 taking any other prescription or nonprescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.
- you are taking other medicines for the relief of cold and flu, congestion or blocked nose, drugs used to treat depression called tricyclic antidepressants,

- stimulant drugs called amphetamines (sometimes used to treat attention deficit disorders), or appetite suppressants
- you have very high blood pressure or high blood pressure not controlled by your medication
- you have heart disease or problems with your blood vessels
- you have severe acute (sudden) or chronic (long term) kidney disease or kidney failure
- you have taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days
- you are taking an antibiotic called furazolidone or linezolid
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist if you:

- have or have had any other medical conditions such as liver, kidney disease, diabetes, high blood pressure or heart problems
- have an overactive thyroid gland
- have glaucoma (high pressure in the eyes)
- have an occlusive vascular disease (poor blood flow or narrowing of the blood vessels e.g. Raynaud's Phenomenon)
- have a rare tumour of the adrenal gland (phaechromocytoma)
- have psychosis (severe mental health problem in which the person loses contact with reality and is unable to think and judge clearly)

- are about to have surgery. Check with your surgeon when you will need to stop this medication for surgery
- have epilepsy
- have prostate problems
- have an irregular heart beat
- have asthma, bronchitis, chronic lung disorder, or other respiratory problems
- are underweight or malnourished
- regularly drink alcohol you may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- are more than 60 years old, as there is increased possibility of unwanted effects.
- have a severe illness, severe infection including blood infection, are severely malnourished or are a chronic heavy alcohol user as this may increase the risk of metabolic acidosis (a blood and fluid abnormality).
 Signs of metabolic acidosis include:
 - o deep, rapid, difficult breathing
 - feeling sick (nausea), being sick (vomiting)
 - loss of appetite
 - drowsiness

Contact your doctor immediately if you think you may be affected.

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 <u>6</u>. Are there any side effects?

The pseudoephedrine content in this product may induce a positive reaction during antidoping control tests.

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

Consider taking the lowest effective dose for the shortest period of time.

Pregnancy and breastfeeding

Ask your doctor before use if you are pregnant or intend to become pregnant or 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 and paracetamol may interfere with each other. These include:

- Warfarin or similar medicines used to thin the blood
- Metoclopramide, a medicine used to control nausea and vomiting
- Medicines used to treat epilepsy or fits such as phenytoin (anti-convulsants)
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Alcohol

- Probenecid, a medicine used to treat gout or sometimes given with an antibiotic
- Cholestyramine, a medicine used to treat high cholesterol levels in the blood
- Flucloxacillin (an antibiotic), due to a serious risk of blood and fluid abnormality (metabolic acidosis)
- Pain relievers or medicines to treat anxiety, or help you sleep or relax (sedatives and hypnotics)
- Medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressan
- Medicines used to treat heart conditions such as digoxin or similar medicines
- Medicines used to treat high blood pressure such as beta-blockers
- Medicines used to treat urinary tract infections and bladder problems
- Medicines used to treat behavioural disorders
- Phenylephrine, a medicine used to treat congestion
- Other decongestants or cough and cold medicines
- Appetite suppressants
- Furazolidone or linezolid (an antibiotic)
- Medicines to treat acute migraine headache e.g. medicines called ergotamine, methysergide

Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while using this medicine. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Panadol Sinus Relief.

4. How do I use Panadol Sinus 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.

Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

Do not exceed the stated/recommended dose.

How much to take

Swallow with water or other fluid

Do not take more frequently than every 6 hours.

Adults and children aged 12 years and over: Take 2 tablets every six hours as necessary. Do not take more than 8 tablets in 24 hours.

Do not use in children under 12 years.

How long to use it

 Adults: Only take for a few days at a time unless your doctor tells you to take it for longer. Children 12 to 17 years: Only give to children for up to 48 hours at a time unless a doctor has told you to give it for longer.

If you use too much Panadol Sinus Relief

If you think that you have used too much Panadol Sinus Relief, you may need urgent medical attention.

If you think that you or anyone else may have taken too much PANADOL SINUS RELIEF, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 for Australia, 0800 764 766 for NZ), or
- go to the Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning because of the risk of delayed, serious liver damage/failure if left untreated.

5. What should I know while using Panadol Sinus Relief?

Things you should do

See your doctor if your symptoms do not improve.

Remind any doctor, dentist or pharmacist you visit that you are using Panadol Sinus Relief.

Things you should not do

Do not use PANADOL SINUS RELIEF to treat any other complaints unless your pharmacist or doctor tells you to.

Adults: Do not use for more than a few days at a time unless your doctor tells you to.

Children: Do not give Panadol Sinus Relief for more than 48 hours at a time unless a doctor has told you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Panadol Sinus Relief affects you.

This medicine may cause dizziness. If affected do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

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

Store your medicine in a cool dry place where the temperature stays below 30°C.

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

Keep out of sight and reach of children.

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

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?

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using PANADOL SINUS RELIEF.

This medicine helps most people with the relief of sinus congestion and pain, nasal congestion and runny nose but it may have unwanted side effects. 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 list of side effects. You may not experience any of them.

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

Less serious side effects

Less serious side effects	What to do
 nervousness difficulty sleeping dizziness dry mouth fear or anxiety headache tremor increased blood pressure nausea or dyspepsia drowsiness agitation restlessness hallucinations (particularly in children) 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

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

Serious side effects

Serious side effects	What to do
 Sudden chest pain or discomfort Shortness of breath Wheezing or difficulty breathing Swelling of the face, lips, tongue or other parts of the body Allergic skin reactions such as rash, peeling, itching or hives Mouth ulcers Unexplained bruising or bleeding Symptoms of metabolic acidosis which may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea), being sick (vomiting) and loss of appetite. Rapid or irregular heartbeat 	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.

Serious side effects	What to do
 Trouble urinating or urinary retention (more likely to occur if you have an enlarged prostate) A sudden and severe headache or thunderclap headache, either with or without nausea, vomiting, confusion, seizures and/or visual disturbances Sudden abdominal pain or blood in your stools 	

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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.

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 Panadol Sinus Relief Tablets contain

Active ingredient (main ingredient)	Paracetamol 500 mg Pseudoephedrine hydrochloride 30 mg
Other ingredients	Talc - purified
(inactive ingredients)	Starch - Maize
	Starch - pregelatinised maize
	Stearic acid
	Povidone
	Sodium benzoate
Potential allergens	Contains sodium benzoate as a preservative

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

What Panadol Sinus Relief looks like

PANADOL SINUS RELIEF Tablets are white, capsule shaped tablets with flat edges debossed with I-I on one side.

A pack contains 24 tablets

AUST R 35521

Who distributes Panadol Sinus Relief

Haleon Australia

Level 48, 8 Parramatta Square,

10 Darcy Street, Parramatta NSW

2150 and Auckland, New Zealand

This leaflet was prepared in October 2025.