AUSTRALIAN PRODUCT INFORMATION

PANADOL SINUS RELIEF ORIGINAL FORMULA TABLETS

1 NAME OF THE MEDICINE

Paracetamol

Pseudoephedrine Hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Panadol Sinus Relief Original Formula Tablets contain pseudoephedrine hydrochloride 30 mg and paracetamol 500 mg.

Excipient with known effect: sodium benzoate as a preservative.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Panadol Sinus Relief Original Formula Tablets are white, capsule-shaped tablets with flat edges debossed with I – I on one side.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Panadol Sinus Relief Original Formula Tablets are used for the temporary relief of sinus congestion and pain, nasal congestion and runny nose.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults and children 12 years and over:

2 capsule-shaped tablets (caplets) taken with water every 6 hours as necessary, maximum 8 caplets within 24 hours.

Use in adults

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

Use in children aged 12 to 17 years

Paracetamol should not be taken for more than 48 hours except on medical advice. Do not use in children below 12 years of age.

Do not exceed the stated dose or frequency of dosing. Minimum dosage interval: 6 hours.

Do not use with other paracetamol-containing or decongestant products including cough and cold preparations.

Seek medical advice if symptoms persist for more than 7 days.

4.3 CONTRAINDICATIONS

This product is contraindicated for use in patients:

- with known hypersensitivity or idiosyncratic reaction to paracetamol, pseudoephedrine or any of the other ingredients in the product;
- with severe hypertension or severe coronary artery disease;
- who are receiving other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psycho-stimulants)
- who are receiving monoamine oxidase inhibitors (MAOIs) or for two weeks after stopping a MAOI drug
- with severe renal impairment

Refer to Section 4.5 Interactions with other medicines and other forms of interactions for additional information.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

This product should be used with caution in patients with:

- cardiovascular disease,
- arrhythmias
- hypertension
- prostatic enlargement
- phaeochromocytoma
- hyperthyroidism
- diabetes mellitus
- raised intra-ocular pressure including glaucoma
- epilepsy
- bronchitis
- bronchiectasis
- bronchial asthma
- Liver and kidney impairment. Caution should be exercised in patients with kidney impairment and in those with hepatic impairment due to the paracetamol content of this medicine. Underlying liver disease increases the risk of paracetamol- related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
- In patients with glutathione depleted states such as sepsis, the use of paracetamol may increase the risk of metabolic acidosis.

Use with caution in patients taking beta-blockers or other anti-hypertensives because of the pseudoephedrine content. See Section 4.5 Interactions with other medicines and other forms of interactions.

There have been reports of acute systemic vasoconstrictive events with pseudoephedrine. Significant examples include:

- Acute Coronary Syndrome (ACS): Symptoms include sudden chest pain, tightness, heavy sweating and dyspnoea at rest.
- Ischaemic colitis: Symptoms include sudden abdominal pain and rectal bleeding.
- Posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS): Symptoms included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment.

Pseudoephedrine should be discontinued immediately and medical advice sought if any signs/symptoms vasoconstrictive events develop.

Medical advice should be sought if the symptoms persist, or is accompanied by a high fever, skin rash or persistent headache.

If symptoms persist, medical advice must be sought. Keep out of sight and reach of children.

Patients should be advised not to drive or operate machinery if affected by dizziness. Refer to Section 4.5 Interactions with other medicines and other forms of interactions for additional information.

High Anion Gap Metabolic Acidosis

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Use in hepatic impairment

Caution should be exercised in patients with hepatic impairment due to the paracetamol content of this medicine.

Underlying liver disease increases the risk of paracetamol-related liver damage.

Patients who have been diagnosed with liver impairment must seek medical advice before taking this medication.

Use in renal impairment

Caution should be exercised in patients with kidney impairment due to the paracetamol content of this medicine.

Patients who have been diagnosed with kidney impairment must seek medical advice before taking this medication.

This product is contraindicated for use in patients with severe renal impairment.

Use in the elderly

No data available.

Paediatric use

Do not give to children under 12 years of age.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Paracetamol

The following interactions with paracetamol have been noted:

- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol-containing products with increased risk of bleeding; occasional doses have no significant effect.
- Paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoclopramide.
- Paracetamol absorption is decreased by substances that decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties, and narcotic analgesics.
- Paracetamol may increase chloramphenicol concentrations.
- The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents.
- Paracetamol excretion may be affected and plasma concentrations altered when given with probenecid.
- Cholestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.
- Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

Pseudoephedrine

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.
- Concomitant administration of pseudoephedrine and MAOIs (or within two weeks of stopping of MAOI) may lead to hypertensive crisis. See Section 4.3 Contraindications.
- Other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psycho-stimulants which interfere with the catabolism of sympathomimetic amines may occasionally cause a rise in blood pressure. See 4.3 Contraindications.
- Pseudoephedrine may antagonise the effect of certain classes of antihypertensives (eg beta blockers, methyl-dopa, reserpine, debrisoquine, guanethidine). See Section 4.4 Special warnings and precautions for use.
- methyldopa and β-blockers – may cause an increase in blood pressure.
- urinary acidifiers enhance elimination of pseudoephedrine.
- urinary alkalinisers decrease elimination of pseudoephedrine.
- pseudoephedrine-containing products may antagonise the effect of certain classes of antihypertensives.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No Data available.

Use in pregnancy – Pregnancy Category B2

Drugs which have 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.

Paracetamol – Category A

Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

This product should be used in pregnancy only if the potential benefits to the patient are weighed against the possible risk to the foetus.

This product should not be used in pregnancy without medical advice.

Use in lactation.

This product should not be used whilst breastfeeding without medical advice Paracetamol is excreted in small amounts (< 0.2%) in breast milk but the effect of this on breast fed infants

is unknown. Maternal ingestion of paracetamol in usual analgesic doses does not appear to present a risk to the breastfed infants.

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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients should be advised not to drive or operate machinery if affected by dizziness.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse events from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class and frequency.

The following convention has been utilised for the classification of undesirable effects: very common (>/= 1/10), common (>= 1/100, <1/10), uncommon (>=1/1000, <1/100), rare (>= 1/10000, <1/1000), very rare (<1/10000), not known (cannot be estimated from the available data).

Adverse event frequencies have been estimated from spontaneous reports received through post-marketing data.

Paracetamol

Body System	Undesirable effect	Frequency
Blood and lymphatic system disorders	Thrombocytopaenia	Very rare
Immune System disorders	Anaphylaxis Cutaneous hypersensitivity reactions including among others, skin rashes, angioedema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs.	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis: Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.	Unknown (cannot be estimated from the available data)

Pseudoephedrine

Body System	Undesirable effect	Frequency
Psychiatric disorders	Nervousness, Insomnia	Common
	Agitation, restlessness	Uncommon
	Hallucinations	Rare
Nervous System Disorders	Dizziness, tremors	Common
Cardiac Disorders	Tachycardia or arrhythmia, palpitations	Rare
Vascular disorders	Increased blood pressure[1]	Rare
Gastrointestinal Disorders	Vomiting, Dry Mouth, Nausea	Common
Skin and Subcutaneous Tissue Disorders	Rash, Allergic dermatitis[2]	Rare
Renal and Urinary Disorders	Dysuria, Urinary retention[3]	Uncommon

1. Increases in systolic blood pressure have been observed. At therapeutic doses, the effects of pseudoephedrine on blood pressure are not clinically significant.
2. A variety of allergic skin reactions, with or without systemic features such as bronchospasm and angioedema have been reported following use of pseudoephedrine.
3. Urinary retention is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Poisons Information Centre

If an overdose is taken or suspected, immediately contact the Poisons Information Centre (in Australia, call 131 126) for advice, or the patient should go to the hospital straight away even if they feel well because of the risk of delayed, serious liver damage. See Section 4.8 Adverse effects (undesirable effects).

Treatment-Paracetamol

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed with hepatic dysfunction.

Immediate medical management is required in the event of overdose, even if the symptoms of overdose are not present.

Administration of N-acetylcysteine or methionine may be required.

Treatment-Pseudoephedrine
Pseudoephedrine overdose may result in symptoms due to central nervous system and cardiovascular stimulation e.g. excitement, restlessness, hallucinations, hypertension and arrhythmias. In severe cases, psychosis, convulsions, coma and hypertensive crisis may occur. Serum potassium levels may be low due to the extracellular to intracellular shifts in potassium.

Treatment should consist of standard supportive measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Paracetamol is a p-aminophenol derivative that exhibits analgesic and antipyretic activity. It does not possess anti-inflammatory activity. Paracetamol is thought to produce analgesia through a central inhibition of prostaglandin synthesis.

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.

Clinical trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

Paracetamol
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic doses but increases with increasing doses. The elimination half-life varies from about 1 to 3 hours.

Paracetamol is metabolised extensively in the liver and excreted in the urine mainly as inactive glucuronide and sulphate conjugates. Less than 5% is excreted unchanged. The metabolites of paracetamol include a minor hydroxylated intermediate which has hepatotoxic activity. This intermediate metabolite is detoxified by conjugation with glutathione, however, it can accumulate following paracetamol over dosage (more than 150mg/kg or 10g total paracetamol ingested) and if left untreated can cause irreversible liver damage.

Paracetamol is metabolised differently by premature infants, newborns, infants and young children compared to adults, the sulphate conjugate being predominant.

Pseudoephedrine
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. Small amounts are distributed into breast milk.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Panadol Sinus Original Formula Tablets contain the excipients:

- Purified talc
- Maize starch
- Pregelatinised maize starch
- Stearic acid
- Povidone
- Sodium benzoate

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine. Refer to Section 4.5 – Interactions with other medicines and other forms of interactions.

6.3 SHELF LIFE

3 Years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Panadol Sinus Original Formula Tablets are available in blister packs of the following sizes:

- 24 tablets

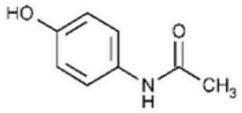
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

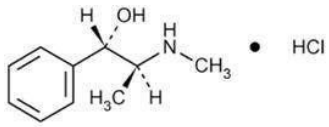
6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Paracetamol



Pseudoephedrine Hydrochloride



CAS number

Paracetamol

CAS Registry Number: 103-90-2

Pseudoephedrine Hydrochloride

CAS Registry Number: 345-78-8

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 3 Pharmacist Only Medicine

8 SPONSOR

Haleon Australia Pty Ltd
Sydney, Australia

9 DATE OF FIRST APPROVAL

18 February 1992

10 DATE OF REVISION

10 July 2025

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.4 **4.5** **4.8**	Addition of information related to high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis