PANADOL® SINUS RELIEF ORIGINAL FORMULA TABLETS
PRODUCT INFORMATION

NAME OF THE MEDICINE
Panadol® Sinus Relief Original Formula tablets

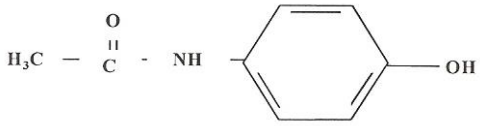
DESCRIPTION

PANADOL SINUS RELIEF ORIGINAL FORMULA is a white, capsule-shaped tablet with flat edges . One face marking PANADOL, SINUS on the other side.

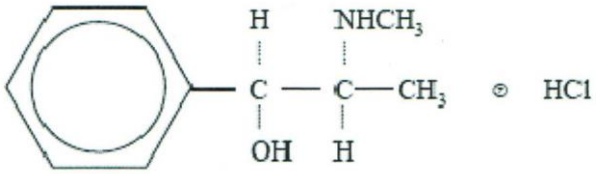
Ingredients

Active Ingredients per caplet:

- Paracetamol - 500 mg



- Pseudoephedrine Hydrochloride - 30 mg



Excipients:

- Talc - purified
- Starch - Maize
- Starch – pregelatinised maize
- Stearic acid
- Povidone
- Sodium benzoate

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PHARMACOLOGY

Pharmacodynamics
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.

Pharmacokinetics
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.

INDICATIONS

PANADOL SINUS RELIEF ORIGINAL FORMULA is used for the temporary relief of sinus congestion and pain, nasal congestion and runny nose.

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 'Interactions with other medicines' for additional information

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.

There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported 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 signs/symptoms of PRES/RCVS develop.

Use with caution in patients taking beta-blockers or other anti-hypertensives because of the pseudoephedrine content (see Interactions).

There have been reports of ischaemic colitis with pseudoephedrine. Pseudoephedrine should be discontinued immediately and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis 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 'Interactions with other medicines' for additional information

Use in pregnancy

Pseudoephedrine – 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.

Use in children

Do not give to children under 12 years of age.

Ability to perform tasks that require judgement, motor or cognitive skills

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

INTERACTIONS WITH OTHER MEDICINES

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
- Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.

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 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 Contraindications).
- Pseudoephedrine may antagonise the effect of certain classes of antihypertensives (eg beta blockers, methyl-dopa, reserpine, debrisoquine, guanethidine) see Precautions).
- 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

ADVERSE 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

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.

DOSAGE AND 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.

OVERDOSAGE

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 ADVERSE 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 eg 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.

PRESENTATION AND STORAGE CONDITIONS

Blister pack of 24 caplets.

Store below 30°C

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Consumer Healthcare Australia Pty Ltd
82 Hughes Avenue
Ermington, NSW 2115

POISONS SCHEDULE OF THE MEDICINE

S3 Pharmacist Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

18 February 1992

DATE OF THE MOST RECENT AMENDMENT

20 December 2017.