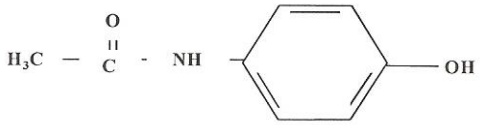
PRODUCT INFORMATION

PANADOL® COLD & FLU MAX HOT LEMON POWDER

NAME OF THE MEDICINE

Active ingredient: Paracetamol

Chemical structure:



CAS[2] Registry Number: 103-90-2

DESCRIPTION

Paracetamol is a white, crystalline powder with a slightly bitter taste. It is sparingly soluble in water, freely soluble in alcohol and very slightly soluble in dichloromethane.

Excipients: Sucrose, Citric acid – anhydrous, Sodium citrate, Lemon flavour 610399E, Starch – maize, Sodium cyclamate, Saccharin sodium, Ascorbic acid, Maltodextrin, Silica – colloidal anhydrous, Curcumin

PHARMACOLOGY

Pharmacodynamics

Paracetamol is a para-aminophenol derivative that exhibits analgesic and anti-pyretic activity. It does not possess anti-inflammatory activity. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system. It is given by mouth for mild to moderate pain and to reduce fever.

Pharmacokinetics

Absorption
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract with peak plasma concentration occurring about 10 to 60 minutes after oral administration.. Food intake delays paracetamol absorption.

Distribution
Paracetamol is distributed into most body tissues. Binding to the plasma proteins is minimal at therapeutic concentrations but increases with increasing doses.

Metabolism
Paracetamol is metabolised extensibly in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates.

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 overdosage (more than 150 mg/kg or 10 g total paracetamol ingested) and, if left untreated, can cause irreversible liver damage.

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

Excretion
Paracetamol is excreted in the urine mainly as the inactive glucuronide and sulphate conjugates. Less than 5% is excreted unchanged. The elimination half-life varies from about one to three hours. Approximately 85% of a dose of paracetamol is excreted in urine as free and conjugated paracetamol within 24 hours of ingestion.

INDICATIONS
For the fast, effective, temporary relief of cold and flu symptoms such as headache, body aches and pain, sore throat. Reduces fever.

CONTRAINDICATIONS
This product is contraindicated in patients with a previous history of hypersensitivity to paracetamol or any of the excipients.

PRECAUTIONS

Contains paracetamol. Do not use with any other paracetamol- containing products. The concomitant use with other products containing paracetamol may lead to an overdose.

Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Paracetamol should be used with caution in patients with:

- Impaired liver function: Underlying liver disease increases the risk of paracetamol-related liver damage

- Impaired kidney function: Administration of paracetamol to patients with moderate to severe renal impairment may result in accumulation of paracetamol conjugates.

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

Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol.

In patients with glutathione depleted states such as sepsis, the use of paracetamol may increase the risk of metabolic acidosis.

If symptoms persist, medical advice must be sought.

Keep out of sight and reach of children.

Contains 3.735 g sucrose per sachet. This should be taken into account in patients with diabetes. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains 129.9 mg (5.6 mmol) sodium per sachet. This should be taken into account by those on a low sodium diet.

Use in pregnancy
Category A
Paracetamol has 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.

Use in lactation
Paracetamol is excreted in small amounts (<0.2%) in breast milk. Maternal ingestion of paracetamol in usual analgesic doses does not appear to present a risk to the breastfed infants.

Use in children
Not recommended for children under 12 years of age.

INTERACTIONS WITH OTHER MEDICINES

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 with increased risk of bleeding. Anticoagulant dosage may require reduction if paracetamol and anticoagulants are taken for a prolonged period of time.

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 drugs.

Paracetamol excretion may be affected and plasma concentrations altered when given with probenecid.

Colestyramine reduces the absorption of paracetamol if given within one hour of paracetamol.

ADVERSE EFFECTS

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled doses 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 (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data).

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

Body System	Undesirable Effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia	Very rare
Immune system disorders	Anaphylaxis	Very rare

	Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome	
Respiratory, thoracic and mediastinal disorders	Bronchospasm, especially in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

DOSAGE AND ADMINISTRATION

Adults and children aged 12 years and over: 1 sachet every 6 hours as necessary. Maximum 4 sachets in 24 hours.

Empty contents of one sachet into a mug, half fill with hot water and then stir well. Add cold water as necessary and sugar if desired.

Should not be used by adults for more than a few days at a time except on medical advice.

Should not be used for children 12 – 17 years of age for more than 48 hours except on medical advice.

Not for use in children under the age of 12 years.

The lowest dose necessary to achieve efficacy should be used.

Do not exceed the stated dose.

Should not be used with other paracetamol-containing products.

Minimum dosing interval: 4 hours
If symptoms persist, medical advice must be sought.

Keep out of sight and reach of children.

Renal and Hepatic impairment

Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication. (See PRECAUTIONS)

OVERDOSAGE

If an overdose is taken or suspected, contact the Poisons Information Centre immediately for advice (131 126), or the patient should go to the nearest hospital straight away. This should be done even if they feel well because of the risk of delayed, serious liver damage. (See ADVERSE EFFECTS)

Management of Paracetamol Overdose

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

Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Administration of N-acetylcysteine or methionine may be required.

Activated charcoal may reduce absorption of paracetamol if given within one hour after oral ingestion. In patients who are not fully conscious or have impaired gag reflex, consideration should be given to administering activated charcoal via a nasogastric tube, once the airway is protected

PRESENTATION AND STORAGE CONDITIONS

Pale yellow, free flowing heterogeneous powder with an odour of lemon.

Packs of 5 and 10 sachets containing 1,000mg Paracetamol per sachet.

Store below 25ºC.

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Consumer Healthcare
82 Hughes Avenue
Ermington, NSW 2115

POISON SCHEDULE OF THE MEDICINE

Unscheduled

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

AUST R 131524 20 September 2006

DATE OF THE MOST RECENT AMENDMENT

16 NOV 2015