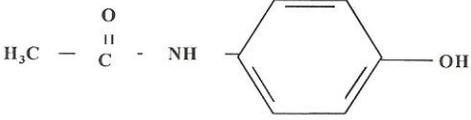


PRODUCT INFORMATION
PANADOL[®] TABLETS
PANADOL[®] MINI CAPS
PANADOL[®] SUPPOSITORIES

NAME OF THE MEDICINE

Active ingredients	Chemical structure	CAS Registry Number
Paracetamol		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.

PANADOL Tablets

Active Ingredient: Paracetamol 500 mg/tablet

Excipients: Starch – pregelatinised maize, Starch – maize, Talc – purified, Stearic acid, Hypromellose, Povidone, Glycerol triacetate, Potassium sorbate, Carnauba wax

PANADOL Mini Caps

Active ingredient: Paracetamol 500 mg/mini cap

Excipients: Gelatin capsules hard, Starch – pregelatinised maize, Croscarmellose sodium, Povidone, Stearic acid, Hypromellose, Titanium dioxide, Quinoline yellow, Brilliant blue FCF, Allura red AC

PANADOL Suppositories

Active ingredient: Paracetamol 500 mg/suppository

Excipient: Hard fat

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 or rectally (suppositories) 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. Following rectal administration of paracetamol, there is considerable variation in peak plasma concentrations attained, and time to reach peak plasma concentrations is substantially longer than after oral administration.

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 extensively in the liver and excreted in the urine mainly as inactive 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 overdose (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 after ingestion.

INDICATIONS

For fast effective temporary relief of pain and discomfort associated with headache, muscular aches, period pain, arthritis/osteoarthritis, toothache, migraine headache, cold & flu symptoms, tension headache, sinus pain/headache and backache. Reduces fever.

CONTRAINDICATIONS

These products are 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.

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

PANADOL Tablets and PANADOL Mini Caps are not recommended for children under seven years of age.

PANADOL Suppositories are not recommended for children under 10 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 ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1,000$), 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 Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome	Very rare
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

Product	12 years to adults	7 to 12 years	Under 7 years
PANADOL Tablets*	1 to 2 tablets. Maximum daily dose: 8 tablets	½ to 1 tablet Maximum daily dose: 4 tablets	Not recommended
PANADOL Mini Caps*	1 to 2 mini caps Maximum daily dose: 8 mini caps in 24 hours	1 mini cap Maximum daily dose: 4 mini caps in 24 hours	Not recommended
<i>*To be taken orally with water or other fluid every four to six hours as required.</i>			

Product	12 years to adults	10 to 12 years	Under 10 years
PANADOL Suppositories ⁺	2 suppositories Maximum daily dose: 8 suppositories in 24 hours	1 suppository Maximum daily dose: 4 suppositories in 24 hours	Not recommended
<i>*To be inserted into the rectum up to 4 times in 24 hours as required. For ease of insertion, suppository can be moistened just prior to insertion.</i>			

General Dosage Instructions:

Adults: Do not use for more than a few days at a time without medical advice.

Children 7-17 years: Do not use for more than 48 hours except on medical advice.

- Should not be used with other paracetamol-containing products.
- Minimum dosing interval: 4 hours. .
- If symptoms persist, medical advice must be sought.
- Do not exceed the stated dose.
- The lowest dose necessary to achieve efficacy should be used.
- 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.

Treatment

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 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**PANADOL Tablets**

White, film-coated tablet with bevelled edge, shallow convex, double radius 1.27 cm diameter. Marked PANADOL on one side and with a break bar on the reverse side.

Blister packs of 2, 12, 20, 50 and 100 tablets.

Store below 30°C.

PANADOL Mini Caps

Capsule shaped tablet with a gelatin coating which is one half green and the other half white.

Blister packs of 12, 20, and 48.

Store below 25°C.

PANADOL Suppositories

Clean white mass moulded into a cylindrical suppository with rounded top.

Strip packs of 24.

Store below 30°C.

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Consumer Healthcare
82 Hughes Avenue
Ermington, NSW 2115

POISON SCHEDULE OF THE MEDICINE

Packs of 20 tablets or Mini Caps or less - Unscheduled

Packs larger than 20 tablets or Mini Caps - S2, Pharmacy Medicine

Suppositories - S2, Pharmacy Medicine

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

PANADOL Tablets	AUST R 13591	30 August 1991
PANADOL Mini Caps	AUST R 81007	23 November 2001
PANADOL Suppositories	AUST R 15488	10 September 1991

DATE OF MOST RECENT AMENDMENT

09 NOV 2015

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