AUSTRALIAN PRODUCT INFORMATION
PANADOL TABLETS (PARACETAMOL) TABLETS
PANADOL MINI CAPS (PARACETAMOL) TABLETS

1 NAME OF THE MEDICINE

Paracetamol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

PANADOL TABLETS

Active ingredient: Paracetamol 500 mg/tablet

Each tablet contains potassium sorbate as a preservative, which may cause allergic reactions.

PANADOL MINI CAPS

Active ingredient: Paracetamol 500 mg/mini cap

Excipients:

For the full list of excipients, see section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

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.

PANADOL MINI CAPS

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

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC 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.

4.2 DOSE AND METHOD OF ADMINISTRATION

Table 1: Dose and method of 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
To be taken orally with water or other fluid every four to six hours as required.			

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 for the shortest duration of treatment.
- Minimum dosing interval: 4 hours.
- Maximum daily dose for children 12 years of age to adults: 4,000 mg.
- Keep out of sight and reach of children.

4.3 CONTRAINDICATIONS

Contraindicated in patients with a previous history of hypersensitivity to paracetamol or to any of the excipients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified 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 may require liver transplant or lead to death.

If symptoms persist, medical advice must be sought.

Keep out of sight and reach of children.

Use in hepatic impairment

Paracetamol should be used with caution in patients with impaired liver function: 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.

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, are chronic heavy users of alcohol or have sepsis.

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

Use in renal impairment

Paracetamol should be used with caution in patients with 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 kidney impairment must seek medical advice before taking this medication.

Use in the elderly

No data available.

Paediatric use

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

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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; occasional doses have no significant effect. 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 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.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category A

As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

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. Available published data do not contraindicate breastfeeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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.

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.

Table 2: Post marketing data

Body System	Undesirable Effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia	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, especially in patients sensitive to aspirin and other NSAIDS	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

4.9 OVERDOSE

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 may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

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 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 after ingestion.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

PANADOL TABLETS

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

PANADOL MINI CAPS

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

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

PANADOL TABLETS
Store below 30°C.

PANADOL MINI CAPS
Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

PANADOL TABLETS
Blister packs of 2, 12, 16, 20, 48, 50 and 100 tablets.

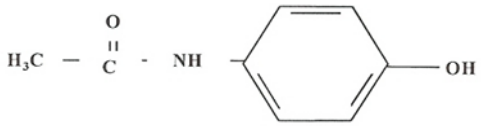
PANADOL MINI CAPS
Blister packs of 12, 16, 20, 48 and 96 tablets.

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



CAS number

103-90-2

7 MEDICINE SCHEDULE (POISONS STANDARD)

Packs of 16 tablets or Mini Caps or less – Unscheduled

Packs larger than 16 tablets or Mini Caps but less than 50 tablets or Mini Caps – S2, Pharmacy Medicine

Packs larger than 50 tablets or Mini Caps – S3, Pharmacist Only Medicine

8 SPONSOR

Haleon Australia Pty Ltd
Level 48, 8 Parramatta Square,
10 Darcy Street, Parramatta NSW
2150

FREECALL AUSTRALIA: 1800 028 533
Website: www.haleon.com

9 DATE OF FIRST APPROVAL

PANADOL TABLETS
(AUST R 13591) 30 August 1991

PANADOL MINI CAPS
(AUST R 81007) 23 November 2001

10 DATE OF REVISION

30 MAY 2024

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Reinstated Product Information