AUSTRALIAN PRODUCT INFORMATION

PANADOL CHILDREN 1 MONTH to 1 YEAR colourfree baby drops
PANADOL CHILDREN 1to 5 YEARS COLOURFREE SUSPENSION
PANADOL CHILDREN 5 to 12 YEARS ELIXIR
PANADOL CHILDREN 5 to 12 YEARS COLOURFREE SUSPENSION
PANADOL CHILDREN CHEWABLE 3+ YEARS tablets
PANADOL CHILDREN SOLUBLE 7+ YEARS tablets
PANADOL CHILDREN 6 MONTHS to 5 YEARS SUPPOSITORIES
PANADOL CHILDREN 5 to12 YEARS SUPPOSITORIES

1 NAME OF THE MEDICINE

Paracetamol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Paracetamol

PANADOL CHILDREN 1 MONTH to 1 YEAR colourfree baby drops
Active ingredient: Paracetamol 100 mg/mL
Contains: saccharin, hydroxybenzoates

PANADOL CHILDREN 1 to 5 YEARS COLOURFREE SUSPENSION
Active ingredient: Paracetamol 24 mg/mL
Contains: hydrozybenzoates, sucralose, sorbitol (11.96 mg/104 mL) and maltitol (38.58 mg/104 mL) which may have a laxative effect or cause diarrhoea.

PANADOL CHILDREN 5 to 12 YEARS ELIXIR
Active ingredient: Paracetamol 48 mg/mL
Contains: hydroxybenzoates, saccharin, benzoic acid, potassium sorbate and sorbitol (7.28 g/ 52 mL) which may have a laxative effect or cause diarrhoea.

PANADOL CHILDREN 5 to 12 YEARS COLOURFREE SUSPENSION
Active ingredient: Paracetamol 48 mg/mL
Contains: hydroxybenzoates, sucralose, sorbitol (5.98 g/52 mL) and maltitol (19.29 g/52 mL) which may have a laxative effect or cause diarrhoea.

PANADOL CHILDREN CHEWABLE 3+ YEARS tablets
Active ingredient: Paracetamol 120 mg/tablet.
Contains: saccharin, mannitol (6.4g/20 tablets) which may have a laxative effect or cause diarrhoea.

PANADOL CHILDREN SOLUBLE 7+ YEARS tablets
Active ingredient: Paracetamol 250 mg/tablet
Contains: saccharin, aspartame. Each tablet contains sodium 213mg (9.2mmol) – this should be taken into account by those on a low sodium diet.

PANADOL CHILDREN 6 MONTHS to 5 YEARS SUPPOSITORIES
Active ingredient: Paracetamol 125 mg/suppository

PANADOL CHILDREN 5 to 12 YEARS SUPPOSITORIES
Active ingredient: Paracetamol 250 mg/suppository

Excipients:

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

3 PHARMACEUTICAL FORM

PANADOL CHILDREN 1 MONTH to 1 YEAR colourfree baby drops
A clear, colourless to very light pink semi-viscous liquid, free from black specks, precipitate or other foreign matter.

PANADOL CHILDREN 1 to 5 YEARS COLOURFREE SUSPENSION
An opaque, white, viscous suspension with small white crystals dispersed uniformly throughout the suspension.

PANADOL CHILDREN 5 to 12 YEARS ELIXIR
A clear, light, red coloured syrupy liquid.

PANADOL CHILDREN 5 to 12 YEARS COLOURFREE SUSPENSION
An opaque, white viscous suspension with small white crystals dispersed uniformly throughout the suspension.

PANADOL CHILDREN CHEWABLE 3+ YEARS tablets
White to off-white, cherry flavoured tablets with "PANADOL:" marking on one side and breakline on the other side, free from foreign matter.

PANADOL CHILDREN SOLUBLE 7+ YEARS tablets
A large, round, white, flat tablet, 16 mm diameter bevelled-edged. Plain on both faces.

PANADOL CHILDREN 6 MONTHS to 5 YEARS SUPPOSITORIES
Clean white mass moulded into a cylindrical suppository with rounded top.

PANADOL CHILDREN 5 to 12 YEARS SUPPOSITORIES
Clean white mass moulded into a cylindrical suppository with rounded top.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the effective temporary relief of pain and discomfort associated with teething, headache, earache, immunisation, toothache, cold & flu symptoms. Reduces fever.

4.2 DOSE AND METHOD OF ADMINISTRATION

PANADOL CHILDREN 1 MONTH to 1 YEAR colourfree baby drops

AGE	AVERAGE WEIGHT	DOSE
1 - 3 months	4 – 6 kg	0.6 – 0.9 mL
3 – 6 months	6 – 8 kg	0.9 – 1.2 mL
6 – 12 months	8 – 10 kg	1.2 – 1.5 mL
1 – 2 years	10 – 12 kg	1.5 – 1.8 mL

Seek medical advice before giving to children under 6 months.

Maximum daily dose: 60 mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24 hour period.

Check dropper/syringe markings carefully before use.

Initial dose as per dosage table above.

Repeat 4 – 6 hourly up to 4 times per day if required. No more than 4 doses in any 24 hour period.

Should not be used for more than 48 hours at a time except on medical advice.

If your child is above 12 kg, dose at 15 mg of paracetamol per kg of body weight.

May be given in water or fruit juice.

Shake thoroughly before use.

Take with water or other fluid.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Should not be used with other paracetamol-containing products.

Do not use in infants under 1 month.

Minimum dosing interval: 4 hours

PANADOL CHILDREN 1 to 5 YEARS COLOURFREE SUSPENSION

AGE	AVERAGE WEIGHT	DOSE
1 – 2 years	10 - 12 kg	6 - 8 mL
2 – 3 years	12 - 14 kg	8 - 9 mL
3 – 4 years	14 - 16 kg	9 - 10 mL
4 – 5 years	16 – 18 kg	10 – 11 mL

Maximum daily dose: 60 mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24 hour period.

Initial dose as per dosage table above.

Repeat 4 – 6 hourly up to 4 times per day if required.

Should not be used for more than 48 hours at a time except on medical advice.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

May be given in water or fruit juice.

Shake thoroughly before use.

Take with water or other fluid.

Do not exceed the stated dose.

Should not be used with other paracetamol-containing products.

Minimum dosing interval: 4 hours

PANADOL CHILDREN 5 to 12 YEARS ELIXIR
PANADOL CHILDREN 5 to 12 YEARS COLOURFREE SUSPENSION

AGE	AVERAGE WEIGHT	DOSE
5 – 6 years	18 – 20 kg	6 mL
6 – 7 years	20 – 22 kg	6 - 7 mL
7 – 8 years	22 – 25 kg	7 - 8 mL
8 – 9 years	25 – 28 kg	8 - 9 mL
9 – 10 years	28 – 32 kg	9 - 10 mL
10 – 11 years	32 – 36 kg	10 - 11 mL
11 – 12 years	36 – 41 kg	11 - 13 mL

Maximum daily dose: 60 mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24 hour period.

Initial dose as per dosage table above.

Repeat 4 – 6 hourly up to 4 times per day if required. No more than 4 doses in any 24 hour period.

Should not be used for more than 48 hours at a time except on medical advice.

May be given in water or fruit juice.

Shake thoroughly before use.

Take with water or other fluid.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Should not be used with other paracetamol-containing products.

Minimum dosing interval: 4 hours

PANADOL CHILDREN CHEWABLE 3+ YEARS tablets

AGE	AVERAGE WEIGHT	DOSE	MAXIMUM
3 – 6 years	14 – 20 kg	2 tablets	8 tablets in 24 hours
6 – 9 years	20 – 28 kg	3 tablets	12 tablets in 24 hours
9 – 11 years	28 – 36 kg	4 tablets	16 tablets in 24 hours
11 – 12 years	36 – 41 kg	5 tablets	20 tablets in 24 hours

Maximum daily dose: 60 mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24 hour period.

Take every 4 – 6 hours as necessary up to a maximum of 4 doses per 24 hours.

Taste is improved if the tablet is not chewed but simply dissolved in the mouth.

Should not be used for more than 48 hours at a time except on medical advice.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Should not be used with other paracetamol-containing products.

Do not use in children below the age of 3. Minimum dosing interval: 4 hours

PANADOL CHILDREN SOLUBLE 7+ YEARS tablets

AGE	AVERAGE WEIGHT	DOSE	MAXIMUM
7 - 10 years	22 - 32 kg	1 – 1½ tablets	6 tablets in 24 hours
10 - 12 years	32 – 41 kg	1½ - 2 tablets	8 tablets in 24 hours

Maximum daily dose: 60 mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24 hour period.

Take every 4 – 6 hours as necessary up to a maximum of 4 doses per 24 hours.

Dissolve the tablet in a glass of water at room temperature.

Can be taken with fruit juice.

Should not be used for more than 48 hours at a time except on medical advice.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Should not be used with other paracetamol-containing products.

Do not use in children below the age of 7 except on medical advice.

Do not use if you are a phenylketonuric.

Minimum dosing interval: 4 hours

PANADOL CHILDREN 6 MONTHS to 5 YEARS SUPPOSITORIES

AGE	AVERAGE WEIGHT	DOSE	MAXIMUM
6 mths – 4 yrs	8 - 16 kg	1 suppository	4 suppositories in 24 hours
4 – 5 years	16 - 18 kg	2 suppositories	8 suppositories in 24 hours

Maximum daily dose: 60 mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24 hour period.

Insert in the rectum every 4 – 6 hours as required. No more than 4 doses in any 24 hour period.

For ease of insertion, the suppository can be moistened just before insertion.

Insert the large or thick end first.

Should not be used for more than 48 hours at a time except on medical advice.
Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Should not be used with other paracetamol-containing products.

Do not use in children below the age of 2 except on medical advice.

Minimum dosing interval: 4 hours

PANADOL CHILDREN 5 to 12 YEARS SUPPOSITORIES

AGE	AVERAGE WEIGHT	DOSE	MAXIMUM
5 - 9 years	18 - 28 kg	1 suppository	4 suppositories in 24 hours
9 - 12 years	28 - 41 kg	2 suppositories	8 suppositories in 24 hours

Maximum daily dose: 60 mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24 hour period.

Insert in the rectum every 4 – 6 hours as required. No more than 4 doses in any 24 hour period.

For ease of insertion, the suppository can be moistened just before insertion.

Insert the large or thick end first.

Should not be used for more than 48 hours at a time except on medical advice.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Should not be used with other paracetamol-containing products.

Do not use in children below the age of 5 except on medical advice.

Minimum dosing interval: 4 hours

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.

In patients with glutathione depleted states, 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.

PANADOL CHILDREN 1 MONTH to 1 YEAR colourfree baby drops contains methyl and propyl hydroxybenzoates that may cause allergic reactions (possibly delayed).

PANADOL CHILDREN 1 to 5 Years Colourfree Suspension contains maltitol and sorbitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Contains 115 mg/mL sorbitol.

PANADOL CHILDREN 5 to 12 YEARS ELIXIR contains 140 mg/mL sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Each PANADOL CHILDREN 5 – 12 Years Colourfree Suspension contains maltitol and sorbitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Contains 371 mg/mL sorbitol.

Each PANADOL CHILDREN SOLUBLE 7+ YEARS tablet contains 213 mg (9.2 mmol) sodium which should be taken into consideration by patients on a controlled sodium diet.

Each PANADOL CHILDREN SOLUBLE 7+ YEARS tablet contains aspartame, a source of phenylalanine. Patients with phenylketonuria should not take this medicine.

Use in hepatic impairment

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

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 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 or have sepsis.

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 liver or kidney impairment must seek medical advice before taking this medication

Use in the elderly

No data available

Paediatric use

No data available

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.

Colestyramine 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

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.

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.

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 contradict 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 dose in adults and children 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 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, the Poisons Information Centre should be contacted immediately for advice (131 126), or the patient should be taken to hospital straight away, even if they feel well, because of the risk of delayed, serious liver damage.
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.

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

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

PANADOL CHILDREN 1 MONTH to 1 YEAR colourfree baby drops
Excipients: Macrogol 400, Glycerol, Saccharin sodium, Sodium chloride, Vanilla 054468 T7, Sodium citrate, Citric acid – anhydrous, Methyl hydroxybenzoate, Cherry 51849 T7, Propyl hydroxybenzoate, Water – purified

PANADOL CHILDREN 1 to 5 Years Colourfree Suspension
Excipients: Maltitol solution, Sorbitol solution (70 per cent) (non-crystallising), Water – purified, Carbomer 934P, Sodium Nipasept, Sodium hydroxide, Malic acid, Sucralose, Xanthan gum, Acesulfame potassium, Edetate sodium, either Strawberry 539421 T or Orange 539420 T

PANADOL CHILDREN 5 to 12 YEARS ELIXIR
Excipients: Glycerol, Water – purified, Macrogol 1500, Sorbitol solution (70 per cent) (crystallising), Propylene glycol, Allura red AC, Saccharin sodium, Benzoic acid, Imitation candied sugar 510155U, Potassium sorbate, Raspberry flavour 21820

PANADOL CHILDREN 5 to 12 Years Colourfree Suspension

Excipients: Maltitol solution, Sorbitol solution (70 per cent) (non-crystallising), Water – purified, Carbomer 934P, Sodium Nipasept, Sodium hydroxide, Malic acid, Sucralose, Xanthan gum, Acesulfame potassium, edetate sodium and either Orange 539420 T or strawberry 539421 T

PANADOL CHILDREN CHEWABLE 3+ YEARS tablets
Excipients: Mannitol, Starch – maize, Ethylcellulose, Stearic acid, Saccharin sodium, Cherry Trusil Artificial flavour 5-9098 34179

PANADOL CHILDREN SOLUBLE 7+ YEARS tablets
Excipients: Sodium bicarbonate, Citric acid – anhydrous, Sodium carbonate anhydrous, Strawberry flavour permaseal 75051-31, Sorbitol, Aspartame, Saccharin sodium, Dimethicone 200, Povidone, Imitation candied sugar flavour 650122U, Sodium lauryl sulphate

PANADOL CHILDREN 6 MONTHS to 5 YEARS SUPPOSITORIES
Excipients: Hard fat.

PANADOL CHILDREN 5 to 12 YEARS SUPPOSITORIES
Excipients: Hard fat.

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 CHILDREN 1 MONTH to 1 YEAR colourfree baby drops
Store below 25°C.

PANADOL CHILDREN 1 to 5 YEARS COLOURFREE SUSPENSION
Store below 30°C.

PANADOL CHILDREN 5 to 12 YEARS ELIXIR
Store below 30°C.

PANADOL CHILDREN 5 to 12 YEARS COLOURFREE SUSPENSION
Store below 30°C.

PANADOL CHILDREN CHEWABLE 3+ YEARS tablets
Store below 30°C.

PANADOL CHILDREN SOLUBLE 7+ YEARS tablets
Store below 30°C.

PANADOL CHILDREN 6 MONTHS to 5 YEARS SUPPOSITORIES
Store below 25°C.

PANADOL CHILDREN 5 to12 YEARS SUPPOSITORIES
Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

PANADOL CHILDREN 1 MONTH to 1 YEAR colourfree baby drops
Bottles of 20 mL.

PANADOL CHILDREN 1 to 5 YEARS COLOURFREE SUSPENSION
Bottles of 100 mL and 200 mL.

PANADOL CHILDREN 5 to 12 YEARS ELIXIR
Bottles of 100 mL and 200 mL.

PANADOL CHILDREN 5 to 12 YEARS COLOURFREE SUSPENSION
Bottles of 100 mL and 200 mL.

PANADOL CHILDREN CHEWABLE 3+ YEARS tablets
Blister packs of 24 tablets.

PANADOL CHILDREN SOLUBLE 7+ YEARS tablets
Strip packs of 16 tablets.

PANADOL CHILDREN 6 MONTHS to 5 YEARS SUPPOSITORIES
Blister pack of 10 suppositories.

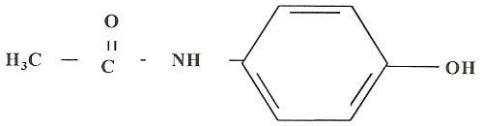
PANADOL CHILDREN 5 to12 YEARS SUPPOSITORIES
Blister pack of 10 suppositories.

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)

Soluble Tablets – Unscheduled

Baby Drops, Elixir, Suspension, Chewable Tablets – S2, Pharmacy Medicine

Suppositories – S2, Pharmacy Medicine

8 SPONSOR

GlaxoSmithKline Consumer Healthcare Australia
82 Hughes Avenue
Ermington
NSW 2115

9 DATE OF FIRST APPROVAL

PANADOL CHILDREN 1 Month to 1 Year Colourfree Baby Drops with syringe
(AUST R 83363) 2 July 2002

PANADOL CHILDREN 1 Month to 1 Year Colourfree Baby Drops with dropper
(AUST R 46375) 20 October 1993

PANADOL CHILDREN 1 to 5 Years Colourfree Suspension
(AUST R 178300 & 178301) 10 December 2010

PANADOL CHILDREN 5 to 12 Years Elixir
(AUST R 15506) 10 September 1991

PANADOL CHILDREN 5 to 12 Years Colourfree Suspension
(AUST R 178302 & 178303) 10 December 2010

PANADOL CHILDREN CHEWABLE 3+ Years Tablets
(AUST R 159902) 06 March 2009

PANADOL CHILDREN SOLUBLE 7+ Years Tablets
(AUST R 49816) 01 August 1994

PANADOL CHILDREN 6 Months to 5 Years Suppositories
(AUST R XXXXX) DD MMM YYYY

PANADOL CHILDREN 5 to 12 Years Suppositories
(AUST R XXXXX) DD MMM YYYY

10 DATE OF REVISION

21 February 2020

Summary table of changes

Section Changed	Summary of new information

3.0	Update of visual identification of 125mg and 250mg suppositories to reflect updated specification.
4.2	Update of dosing table for 125mg and 250mg suppositories.
6.1	Update of excipients for 125mg and 250mg suppositories.
6.5	Update of pack size for 125mg and 250mg suppositories.
9.0	Update of AUST R number for 125mg and 250mg suppositories.