Proprietary (Trade) Name: PANADOL

Active ingredient:
Paracetamol (BP)  120 mg/5mL (Children’s PANADOL Colourfree Suspension)
125 mg/suppository (PANADOL Suppositories 125 mg)
250 mg/suppository (PANADOL Suppositories 250 mg)

PRESENTATIONS

Children’s PANADOL 3 Months – 12 Years Colourfree Suspension
An opaque, white, viscous suspension with small white crystals dispersed uniformly throughout the suspension.

PANADOL 125 mg suppositories
Off-white to ivory coloured, 6 minim, opaque, tear-shaped, soft gelatin capsule containing a milky white viscous liquid.

PANADOL 250 mg suppositories
Off-white to ivory coloured, 10 minim, opaque, tear-shaped, soft gelatin capsule containing a milky white viscous liquid.

INDICATIONS

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

DOSAGE AND ADMINISTRATION

Children’s PANADOL 3 Months – 12 Years Colourfree Suspension

<table>
<thead>
<tr>
<th>AGE</th>
<th>DOSAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 – 12 months</td>
<td>2.5 – 5 mL</td>
</tr>
<tr>
<td>1 – 5 years</td>
<td>5 - 10 mL</td>
</tr>
<tr>
<td>6 – 12 years</td>
<td>10 - 20 mL</td>
</tr>
</tbody>
</table>
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.

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 125 mg Suppositories

<table>
<thead>
<tr>
<th>AGE</th>
<th>DOSE</th>
<th>MAXIMUM DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mths – 3 yrs</td>
<td>1 suppository</td>
<td>4 in 24 hours</td>
</tr>
<tr>
<td>4 – 5 years</td>
<td>2 suppositories</td>
<td>8 in 24 hours</td>
</tr>
</tbody>
</table>

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.

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.

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 250 mg Suppositories

<table>
<thead>
<tr>
<th>AGE</th>
<th>AVERAGE WEIGHT</th>
<th>DOSE</th>
<th>MAXIMUM DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 - 8 years</td>
<td>18 - 25 kg</td>
<td>1 suppository</td>
<td>4 in 24 hours</td>
</tr>
<tr>
<td>9 - 12 years</td>
<td>28 - 41 kg</td>
<td>2 suppositories</td>
<td>8 in 24 hours</td>
</tr>
</tbody>
</table>

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.

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.

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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.

If symptoms persist, medical advice must be sought.

Keep out of sight and reach of children.

Children’s PANADOL 3 Months – 12 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.
**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.

Paracetamol crosses the placental barrier. Animal studies with paracetamol have not identified any risk to pregnancy or embryo-foetal development.

**Use in lactation**

Paracetamol is excreted in breast milk. Human studies with paracetamol have not identified any risk to lactation or the breast-fed offspring.

**Use in children**

Paracetamol is suitable for children from 1 month of age.

**Effects on ability to drive and use machines**

Paracetamol is unlikely to cause an effect on the ability to drive or use machinery.

**Other**

*Pre-clinical*

Preclinical safety data on paracetamol in the literature have not revealed findings that are of relevance to the recommended dosage and use of the product.

**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 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 (≥1/1,000, <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>
<thead>
<tr>
<th>Body System</th>
<th>Undesirable Effect</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Thrombocytopenia</td>
<td>Very rare</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Anaphylaxis</td>
<td>Very rare</td>
</tr>
<tr>
<td></td>
<td>Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome</td>
<td>Very rare</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Bronchospasm</td>
<td>Very rare</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>Hepatic dysfunction</td>
<td>Very rare</td>
</tr>
</tbody>
</table>

**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 PANADOL medication is prolonged.

Paracetamol absorption is increased by substances that increase gastric emptying, eg metoclopramide.

Paracetamol absorption is decreased by substances that decrease gastric emptying, eg 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.

**OVERDOSE**

Paracetamol overdose may cause liver failure.

**Treatment**

Immediate medical management is required in the event of an overdose, even if the symptoms of overdose are not present.
If an overdose is taken or suspected, contact the Poisons Information Centre immediately for advice (0800 764 766), 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.)

Administration of N-acetylcysteine or methionine may be required.

In cooperative adults, activated charcoal may reduce absorption of the medicine if given within one hour after ingestion.

FURTHER INFORMATION

Actions

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

Pharmacodynamics

The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for patients with a history of disease or on concomitant medication, where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of gastrointestinal bleeding or the elderly).

Pharmacokinetics

Absorption

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Food intake delays paracetamol absorption. Rectal absorption is slower than with oral administration and varies between individuals.

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 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 200 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 glucuronide and sulphate conjugates. Less than 5% is excreted as unmodified paracetamol with 85% to 90% of the administered dose eliminated in the urine within 24 hours of ingestion. The elimination half-life varies from one to three hours.

**Chemical structure:**

![Chemical structure of paracetamol](image)

**Excipients:**

*Children’s PANADOL 3 Months – 12 Years Colourfree Suspension*
Maltitol solution, Sorbitol solution (70 per cent) (crystallising), Water – purified, Xanthan gum, Nipasept sodium, Strawberry flavour L 10055, Imitation candied sugar 510155U, Malic acid, Citric acid – anhydrous

*Panadol 125 mg Suppositories*
Gelatin, Glycerol, Macrogol 400, Macrogol 8000, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Titanium dioxide, Vanillin, Water-purified

*Panadol 250 mg Suppositories*
Gelatin, Glycerol, Macrogol 400, Macrogol 8000, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Titanium dioxide, Vanillin, Water-purified

**PHARMACEUTICAL PRECAUTIONS**

**Shelf life**
*Children’s PANADOL 3 Months – 12 Years Colourfree Suspension*
18 months

*PANADOL 125 mg Suppositories*
24 months

*PANADOL 250 mg Suppositories*
24 months
Special Conditions for Storage

*Children’s PANADOL 3 Months – 12 Years Colourfree Suspension*
Store below 25°C.

*PANADOL 125 mg Suppositories*
Store below 25°C.

*PANADOL 250 mg Suppositories*
Store below 25°C.

PACKAGE QUANTITIES

*Children’s PANADOL 3 Months – 12 Years Colourfree Suspension*
Bottles of 20 mL, 100 mL, 200 mL and 1,000 mL

*PANADOL 125 mg Suppositories*
Bottles of 20 suppositories

*PANADOL 250 mg Suppositories*
Bottles of 20 suppositories

MEDICINE SCHEDULE

Pharmacy only
Children’s PANADOL 3 Months – 12 Years Colourfree Suspension
PANADOL 125 mg Suppositories
PANADOL 250 mg Suppositories

SPONSOR DETAILS

GlaxoSmithKline Consumer Healthcare,
11th Floor, Zurich House,
21 Queen St
Auckland

Telephone: (09) 367 2970

DATE OF PREPARATION

02.07.2012

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