Proprietary (Trade) Name: Panadol Rapid caplets; Panadol Rapid Soluble tablets

Active ingredient: Paracetamol (BP) 500 mg/caplet or tablet

PRESENTATIONS

Panadol Rapid caplets
White, film-coated, capsule-shaped tablets with flat edges. One face of the tablet is debossed with the letter “P”. Tablet cannot be halved.

Panadol Rapid Soluble tablets
Large white round flat, 7/8” diameter, bevelled-edge tablet, plain on both faces.

INDICATIONS

For fast relief of acute pain.

Fast effective temporary relief of pain and discomfort associated with headache/tension headache, migraine headache, toothache, muscular aches, cold and flu symptoms, sore throat and period pain. Helps reduce fever.

DOSAGE AND ADMINISTRATION

Panadol Rapid caplets
Adults and children aged 12 years and over: 2 caplets every four to six hours (maximum of 8 caplets in 24 hours)

Do not use for more than a few days at a time in adults except on medical advice.

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

Children under 12 years: Not recommended for children under the age of 12 years.
Take with water or other fluid.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used.

Should not be used with other paracetamol-containing products.

Minimum dosing interval: 4 hours

**PANADOL Rapid Soluble tablets**

*Adults and children aged 12 years and over:* 1 to 2 tablets every four to six hours (maximum of 8 tablets in 24 hours)

Do not use for more than a few days at a time in adults except on medical advice.

*Children 7 to under 12 years:* ½ to 1 tablet every four to six hours (maximum of 4 tablets in 24 hours)

Should not be used for more than 48 hours for children 7 – 17 except on medical advice.

*Children under 7 years:* Not recommended for children under the age of 7 years.

Dissolve in a glass of water at room temperature.

Do not exceed the stated dose.

Should not be used with other paracetamol-containing products.

Minimum dosing interval: 4 hours

**Renal and Hepatic impairment**

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

**CONTRAINDICATIONS**

These products are contraindicated in patients with a previous history of hypersensitivity to paracetamol or any of the excipients.
WARNINGS AND 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 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.

Two PANADOL Rapid caplets contain 344 mg (15 mmol) sodium, which should be taken into account by those on a low sodium diet.

Each PANADOL Rapid Soluble tablet contains 425.5 mg (18.5 mmol) sodium which should be taken into account by those on a low sodium diet.

Each PANADOL Rapid Soluble tablet contains 50 mg sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

PANADOL Rapid Soluble tablets contain PHENYLALANINE and should not to be used by PHENYLKETONURICS. Phenylalanine is present in the ingredient aspartame.
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
Not recommended for children six years of age and except on medical advice.

Effects on ability to drive and use machines
PANADOL Rapid caplets and PANADOL Rapid Soluble tablets are 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>
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</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Thrombocytopenia</td>
<td>Very rare</td>
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</tbody>
</table>
| Immune system disorders | Anaphylaxis  
Anaphylaxis hypersensitivity reactions  
Including skin rashes, angioedema and Stevens Johnson syndrome | Very rare |
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<tbody>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Bronchospasm in patients sensitive to aspirin and other NSAIDs</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>Hepatic dysfunction</td>
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</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 which can lead to liver transplant or death.

High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. In addition, high doses of sodium
bicarbonate may cause hypernatraemia; electrolytes should be monitored and patients managed accordingly.

**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 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 is given by mouth 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).

Sodium bicarbonate has no known analgesic activity.

*Pharmacokinetics*

*Absorption*
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Food intake delays paracetamol absorption.

In human volunteer pharmacokinetic studies, mean maximum plasma concentrations were reached at least twice as fast for PANADOL Rapid (fast disintegrating tablets) compared to standard paracetamol tablets (PANADOL) at
both a one and two tablet dose and these were statistically significant. The extent of absorption for PANADOL Rapid is equivalent to that for standard PANADOL tablets as shown by AUC at both a one and two tablet dose.

In a human volunteer pharmacokinetic study with PANADOL Rapid Soluble tablets, maximum serum concentration was reached after 20 minutes (median t\text{max}) in the fasted state and was significantly faster than standard paracetamol (PANADOL) tablets (p=0.007). The rate of absorption over the first 20 minutes after dosing (AUC\text{0 20 minutes}) was significantly greater than for standard PANADOL tablets (p=0.0028). The extent of absorption (AUC\text{0 infinity}) is equivalent to that for standard PANADOL tablets in the fasted state.

**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](attachment:image.png)
**Excipients:**

*Panadol Rapid*
Sodium bicarbonate, Cellulose – microcrystalline, Starch – pregelatinised maize, Starch – maize, Water – purified, Hypromellose, Magnesium stearate, Titanium dioxide, Polydextrose, Povidone, Calcium phosphate, Glycerol triacetate, Potassium sorbate, Macrogol, Carnauba wax

*Panadol Rapid Soluble*
Sodium bicarbonate, Citric acid, Sodium carbonate, Sorbitol, Lemon flavour, aspartame, Dimeticone, Povidone, Saccharin sodium, Sugar flavour, Sodium laurilsulfate

**PHARMACEUTICAL PRECAUTIONS**

**Shelf life**

*Panadol Rapid*
36 months from date of manufacture.

*Panadol Rapid Soluble*
36 months from date of manufacture.

**Special Conditions for Storage**

*Panadol Rapid*
Store below 30ºC.

*Panadol Rapid Soluble*
Store below 30ºC.

**PACKAGE QUANTITIES**

*Panadol Rapid*
Blister packs of 10, 20, and 40 caplets

*Panadol Rapid Soluble*
Blister packs of 12 and 20 tablets
MEDICINE SCHEDULE

Packs of 20 caplets or tablets or less - General sale

Packs of more than 20 caplets or tablets - Pharmacy only

SPONSOR DETAILS

GlaxoSmithKline Consumer Healthcare,  
11th Floor, Zurich House,  
21 Queen St  
Auckland 1010, New Zealand

DATE OF PREPARATION

30 SEP 2015

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