

Panadol

Brand of paracetamol

PRODUCT INFORMATION LEAFLET

Product Name

Brand Name: Panadol

Generic Name: Paracetamol tablets 500 mg

Qualitative & Quantitative Composition

Each uncoated tablet contains:

Paracetamol B.P.-500 mg

Dosage Form and Strength

Paracetamol Oral tablet 500 mg

Clinical information

Indications:

Paracetamol is an analgesic and antipyretic.

Treatment of mild-to-moderate pain and treatment of fever.

Dosage regimen and method of administration

Dosage:

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

Do not take this medicine for more than 3 days without medical advice.

Do not exceed the stated dose.

Maximum daily dose: 60 mg/kg to be administered in divided doses of 10-15 mg/kg throughout the 24-hour period.

Adults (including the elderly) and children aged 12 years and over:

500 mg to 1000 mg paracetamol (1 to 2 tablets), taken every 4 - 6 hours as required.

Do not take more frequently than every 4 hours. Maximum daily dose: 4000 mg (i.e. 8 tablets per 24 hours).

Age group	Dose	Frequency
6-7 years	240-250 mg	Every 4-6 hours, maximum 4 doses per day
8-9 years	360-375 mg	Every 4-6 hours, maximum 4 doses per day
10-11 years	480-500 mg	Every 4-6 hours, maximum 4 doses per day
12-15 years	480-750 mg	Every 4-6 hours, maximum 4 doses per day
16 years above	0.5-1 g	Every 4-6 hours, maximum 4 doses per day

Children under 6 years: **not recommended for children under the age of 6 years.**

Contra-indications

Do not use Panadol if you are allergic to paracetamol or any of the other ingredients in the product.

Warnings and Precautions

Panadol contains Paracetamol. Do not take more than the recommended dose as it may cause serious harm to your liver. Do not use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol as it may lead to an overdose.

Always read and follow the label

In case of any of the below situations, you may need to avoid using this product altogether or limit the amount of paracetamol that you take.

Check with your doctor before use if you:

- has liver or kidney problems.
- has depleted glutathione levels, such as those who have a severe infection, are severely malnourished, severely underweight as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:
 - deep, rapid, difficult breathing,
 - feeling sick (nausea), being sick (vomiting),
 - loss of appetite.

Contact a doctor immediately if you get a combination of these symptoms. Please see your doctor if your symptoms do not improve.

Before administering, check when paracetamol last administered and cumulative paracetamol dose over previous 24 hours; body-weight under 50 kg; chronic alcohol consumption; chronic dehydration; chronic malnutrition; hepatocellular insufficiency; long-term use (especially in those who are malnourished)

Some patients may be at increased risk of experiencing toxicity at therapeutic doses, particularly those with a body-weight under 50 kg and those with risk factors for hepatotoxicity. Clinical judgement should be used to adjust the dose of oral and intravenous paracetamol in these patients.

Co-administration of enzyme-inducing antiepileptic medications may increase toxicity; doses should be reduced.

Adverse effects

Stop taking this medicine and tell your doctor immediately if:

- you experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience a skin rash or peeling, or mouth ulcers.
- you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatory drugs, and experience a similar reaction with this product.
- you experience unexplained bruising or bleeding.

These reactions are rare.

Drug interaction

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.

Before taking this medicine, make sure you consult your doctor if you are taking warfarin or similar medicines used to thin the blood.

Severe interactions with: Alcohol, Dapsone, Imatinib, Phenindione, Prilocaine

Moderate interactions with: Acenocoumarol, Busulfan, Carbamazepine, Fosphenytoin, Phenobarbital, Phenytoin, Primidone, Rifampicin, Warfarin.

Pregnancy and lactation

Pregnancy: 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.

Lactation: Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breastfeeding.

Hepatic Impairment

This has dose-related toxicity, so avoid large doses.

Patients who have been diagnosed with renal impairment must seek medical advice before taking this medication

Renal Impairment

Patients who have been diagnosed with renal impairment must seek medical advice before taking this medication

Overdose

Important: liver failure and less frequently renal damage can occur following overdose. Underlying liver disease increases the risk of paracetamol-related liver damage.

Symptoms and Signs

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.

Nausea and vomiting, the only early features of poisoning, usually settle within 24 hours. Persistence beyond this time, often associated with the onset of right subcostal pain and tenderness, usually indicates development of hepatic necrosis

Treatment

Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

If overdose is confirmed or suspected, seek immediate advice from your Poison Centre even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

Details of the same are as below:

National Poison Information Centre
National Hospital, Colombo, Sri Lanka
Tel-0112686143 email -www.toxbase.lanka.info

Pharmacology

Pharmacological action:

Paracetamol is an analgesic and antipyretic.

Mechanism of action:

Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

Pharmacodynamic Effects

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 patients taking concomitant medication in whom 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.

Distribution: Binding to the plasma proteins is minimal at therapeutic concentrations.

Metabolism: Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates.

Elimination: Less than 5% is excreted as unmodified paracetamol. The mean plasma half-life is about 2.3 hours.

Pharmaceutical Particulars

Incompatibilities

Not applicable

Shelf life:

24 months from the date of packaging.

Storage condition:

Store below 35°C.

Package size

PP jar with inner poly bag of 1000's

Instructions for Use and Handling

No special instructions for use and handling. Keep all medicines away from the children.

Product description:

Panadol is Paracetamol tablets 500 mg in Plastic jar 1000's

Manufacturer:

SmithKline Beecham Pvt Ltd,
No.121, Galle Road, Kaldemulla, Moratuwa, Sri Lanka.

Marketed by:

SmithKline Beecham (Pvt) Ltd,
Level 34, West Tower, World Trade Centre, Colombo 01, SriLanka

Paracetamol GDS Version 7.0 (3rd Aug 2017)

*Panadol is a trademark owned by or licensed to the GSK Group of companies.

62000000042559