SPMC
Paracetamol Tablets BP 500 mg

PRESENTATION:

Paracetamol tablets BP 500 mg packs of 1000 tablets. Each white color, Oblong tablets contain Paracetamol BP 500 mg.

INDICATIONS & DOSAGE:

Mild to moderate pain | Pyrexia
Adult: 0.5–1 g every 4–6 hours; maximum 4 g per day
Mild to moderate pain in patients with risk factors for hepatotoxicity | Pyrexia in patients with risk factors for hepatotoxicity
Child 3–5 months: 60 mg every 4–6 hours; maximum 4 doses per day
Child 6 months–1 year: 120 mg every 4–6 hours; maximum 4 doses per day
Child 2–3 years: 180 mg every 4–6 hours; maximum 4 doses per day
Child 4–5 years: 240 mg every 4–6 hours; maximum 4 doses per day
Child 6–7 years: 240–250 mg every 4–6 hours; maximum 4 doses per day
Child 8–9 years: 360–375 mg every 4–6 hours; maximum 4 doses per day
Child 10–11 years: 480–500 mg every 4–6 hours; maximum 4 doses per day
Child 12–15 years: 480–750 mg every 4–6 hours; maximum 4 doses per day
Child 16–17 years: 0.5–1 g every 4–6 hours; maximum 4 doses per day
Prophylaxis of post-immunisation pyrexia following immunisation with meningococcal group B vaccine given as part of the routine immunization schedule
Child 2 months: 60 mg, first dose to be given at the time of vaccination, then 60 mg after 4–6 hours, then 60 mg after 4–6 hours, use weight-based doses for preterm infants born at less than 32 weeks gestation and currently weighing less than 4 kg—see oral doses for
pain and pyrexia with discomfort
Child 4 months: 60 mg, first dose to be given at the time of vaccination, then 60 mg after 4–6 hours, then 60 mg after 4–6 hours, use weight-based doses for preterm infants born at less than 32 weeks gestation and currently weighing less than 4 kg—see oral doses for pain and pyrexia with discomfort.
Post-immunisation pyrexia in infants
Child 2–3 months: 60 mg for 1 dose, then 60 mg after 4–6 hours if required
Child 4 months: 60 mg for 1 dose, then 60 mg after 4–6 hours; maximum 4 doses per day

SIDE EFFECTS:

GENERAL SIDE-EFFECTS
Rare or very rare- Thrombocytopenia
SPECIFIC SIDE-EFFECTS
With oral use Agranulocytosis. bronchospasm. Hepatic function abnormal. severe cutaneous adverse reactions (SCARs)

CAUTIONS:

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)

CAUTIONS, FURTHER INFORMATION:

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.

CONTRAINDICATIONS:

Hypersensitivity. Severe hepatic impairment or active liver disease (IV).

PREGNANCY:

Not known to be harmful.

BREAST FEEDING:

Amount too small to be harmful.

HEPATIC IMPAIRMENT:

Dose-related toxicity—avoid large doses.

RENAL IMPAIRMENT:

Dose adjustments Increase infusion dose interval to every 6 hours if eGFR less than 30 mL/minute/1.73m2.

INTERACTIONS:

Decreased absorption with cholestyramine. Decreased serum concentrations with rifampicin and some anticonvulsants (e.g. phenytoin, phenobarbital, carbamazepine, primidone). Enhances the anticoagulant effect of warfarin and other coumarins with prolonged use. Increased absorption with metoclopramide and domperidone. Increased serum concentration with probenecid. May increase serum concentration of chloramphenicol.

PRESCRIBING AND DISPENSING INFORMATION:

BP directs that when Paediatric Paracetamol Oral Suspension or Paediatric Paracetamol Mixture is prescribed Paracetamol Oral Suspension 120 mg/5mL should be dispensed.

OVERDOSE:

Liver damage and less frequently renal damage can occur following overdose. 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.
For specific details on the management of poisoning, see Paracetamol, under Emergency treatment of poisoning

STORAGE:

Keep tightly closed in cool and dry place. Protect from light. Store below 30^0C. Keep away from children.

Manufactured by:
State Pharmaceutical Manufacturing Corporation
No.11, Sir John Kotalawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka.