Acedol®

Paracetamol BP

COMPOSITION
Acedol ® Tablet : Each tablet contains Paracetamol BP 500 mg.
Acedol ® Syrup : Each 5 ml syrup contains Paracetamol BP 120 mg.
Acedol ® Suspension : Each 5 ml suspension contains Paracetamol BP 120 mg.
Acedol ® Paediatric Drops: Each ml drop contains Paracetamol BP 80 mg.
Acedol ® 60 Suppository : Each suppository contains Paracetamol BP 60 mg.
Acedol ® 125 Suppository : Each suppository contains Paracetamol BP 125 mg.
Acedol ® 250 Suppository : Each suppository contains Paracetamol BP 250 mg.
Acedol ® 500 Suppository : Each suppository contains Paracetamol BP 500 mg.

ROUTE OF ADMINISTRATION
Oral and rectal.

MAIN THERAPEUTIC GROUP
Analgesic and antipyretic.

PHARMACOLOGY
Acedol ® (Paracetamol) is one of the safest and most widely used analgesic and antipyretic. **Acedol** ® (Paracetamol) produces analgesic action by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating centre. **Acedol** ® (Paracetamol) exerts significantly milder side effects and most unlikely to produce many of the serious side effects associated with aspirin and other NSAIDs. **Acedol** ® (Paracetamol) is rapidly and completely absorbed from the G.I.T. following oral administration and from rectum after rectal administration. The mean half-life of absorption from the upper small intestine is only 7 minutes. The drug is extensively metabolized in the liver and it has a plasma half-life of 1.5 to 3.0 hours. **Acedol** ® (Paracetamol) is not bound to plasma proteins to any extent.

INDICATION
Fever, common cold and influenza: Headache, toothache, earache, bodyache, myalgia, dysmenorrhoea, neuralgia and sprains. Pain of colic, back pain, post-operative pain, postpartum pain, chronic pain of cancer, inflammatory pain, and post- vaccination pain and fever of children.
Rheumatism and osteoarthritic pain & stiffness of joints in fingers, hips, knees, wrists, elbows, feet, ankles and top & bottom of the spine.

DOSAGE AND ADMINISTRATION

Tablet
Adult : 1-2 tablets every 4 to 6 hours up to a maximum of 4 g (8 tablets) daily.
Children (6-12 years) : 1/2 to 1 tablet 3 to 4 times daily.
For long term treatment, it is wise not to exceed the dose beyond 2.6 gm/day.

Dispersible Tablet
Children
3 months-1 year : 1/2-1 tablet every 4 hours. Maximum 4 tablets in 24 hours.
1-6 years : 1-2 tablets every 4 hours. Maximum 8 tablets in 24 hours.
6-12 years : 2-4 tablets every 4 hours. Maximum 16 tablets in 24 hours.
Drop the tablet in a half glass of water, stir it and drink it.
It should not be given in children under 3 months of age or for more than 3 days without medical advice.

Syrup and Suspension
Children
Under 3 months : 10 mg/kg body weight (reduce to 5 mg/kg if jaundiced) 3 to 4 times daily.
3 months to below 1 year : 1/2 to 1 teaspoonful 3 to 4 times daily.
1 year - 5 years : 1/2 teaspoonful 3 to 4 times daily.
6 years - 12 years: 2-4 teaspoonful 3 to 4 times daily.
Adults : 4-8 teaspoonful 3 to 4 times daily.

Paediatric Drop
Children
Upto 3 months : 0.5 ml (40 mg).
4 to 11 months : 1.0 ml (80 mg).
1 to 2 years : 1.5 ml (120 mg).

Dose can be repeated, every 4 hours according to the weight listed in the following table:

Age : 0 - 3 years			
Weight (kg)	**Dosing**	**Weight (kg)**	**Dosing**
2.5 - 3.9	0.5 ml	11.0 - 11.9	2.0 ml
4.0 - 5.4	0.75 ml	12.0 - 13.4	2.25 ml
5.5 - 6.4	1.0 ml	13.5 - 14.5	2.5 ml
6.5 - 7.9	1.25 ml	14.6 - 15.4	2.75 ml
8.0 - 9.0	1.5 ml	15.5 - 15.9	3.0 ml
9.1 - 10.9	1.75 ml		

* Do not exceed more than 5 dose daily for a maximum of 5 days.

Suppository
Suppository should be administered rectaly.
Children
3 months -1 year : 1-2 suppositories (60-120 mg) ; the dosage should be based on age & weight i.e. 3 months (5 kg)- 60 mg (1 suppository), 1 year (10 kg)- 120 mg (2 suppositories of 60 mg).
Below 5 years : 125-250 mg, 2-3 times daily.
6-12 years : 250-500 mg, 2-3 times daily.
Adults & children over 12 years: 500 mg-1 gm, 2-3 times daily.

CONTRAINDICATION
Known sensitivity to paracetamol.

SIDE EFFECT
Side effects are significantly mild, though haematological reactions have been reported. Pancreatitis, skin rashes, and other allergic reactions occur occasionally.

OVERDOSE
Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).
Risk Factors
If the patient
a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
Or
b) Regularly consumes ethanol in excess of recommended amounts.
Or
c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.
Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.
Management
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.
Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable) but results should not delay initiation of treatment beyond 8 hours after ingestion, as the effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous-N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital.
Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the NPIS or a liver unit.

USE IN PREGNANCY AND LACTATION
Ace is safe in all stages of pregnancy and lactation.

STORAGE CONDITION
Acedol ® Tablet : Store below 30°C. Protect from light and moisture.
Acedol ® Syrup and Suspension : Store below 30°C. Protect from light.
Acedol ® Suppository : Store below 25°C. Protect from light.

Keep out of children's reach.

HOW SUPPLIED
Acedol ® Tablet : Box containing 10 x 10 / 20 x 10 / 50 x 10 tablets in blister pack.
Acedol ® Syrup : Box containing 30 ml / 50 ml / 60 ml / 100 ml syrup in sealed cap bottle and a measuring spoon.
Acedol ® Suspension : Box containing 30 ml / 50 ml / 60 ml / 100 ml suspension in sealed cap bottle and a measuring spoon.
Acedol ® Paediatric Drops: Box containing 15 ml / 30 ml concentrated suspension in sealed cap bottle and a dropper.
Acedol ® 60 Suppository : Box containing 1 x 2 / 1 x 5 / 2 x 5 / 5 x 5 suppositories in blister pack.
Acedol ® 125 Suppository : Box containing 1 x 2 / 1 x 5 / 2 x 5 / 4 x 5 / 5 x 5 suppositories in blister pack.
Acedol ® 250 Suppository : Box containing 1 x 2 / 1 x 5 / 2 x 5 / 4 x 5 / 5 x 5 suppositories in blister pack.
Acedol ® 500 Suppository : Box containing 1 x 2 / 1 x 5 / 2 x 5 / 4 x 5 / 5 x 5 suppositories in blister pack.

SQUARE