



Ace[®]
Paracetamol
Analgesic & Antipyretic

COMPOSITION

- Ace[®] Tablet : Each tablet contains Paracetamol BP 500 mg.
Ace[®] Syrup : Each 5 ml syrup contains Paracetamol BP 120 mg.
Ace[®] Suspension : Each 5 ml suspension contains Paracetamol BP 120 mg.
Ace[®] Paediatric Drops (15 ml) : Each ml drop contains Paracetamol BP 80 mg.
Ace[®] Paediatric Drops (30 ml) : Each ml drop contains Paracetamol BP 80 mg.
Ace[®] Suppository (125 mg) : Each suppository contains 125 mg Paracetamol BP.
Ace[®] Suppository (250 mg) : Each suppository contains 250 mg Paracetamol BP.

PHARMACOLOGY

Ace[®] is the formulation of Paracetamol, which is one of the safest and most widely used analgesic and antipyretic. Ace[®] produces analgesic action by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating centre. Ace[®] exerts significantly milder side effects and most unlikely to produce many of the serious side effects associated with aspirin and other NSAIDs. Ace[®] 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. Ace[®] 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.

CNS PREPARATIONS

Ace[®]

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.

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.

1-5 years : 1/2 teaspoonful 3 to 4 times daily.

6-12 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
2.5 - 3.9	0.5 ml
4.0 - 5.4	0.75 ml
5.5 - 6.4	1.0 ml
6.5 - 7.9	1.25 ml
8.0 - 9.0	1.5 ml
9.1 - 10.9	1.75 ml
11.0 - 11.9	2.0 ml
12.0 - 13.4	2.25 ml
13.5 - 14.5	2.5 ml
14.6 - 15.4	2.75 ml
15.5 - 15.9	3.0 ml

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

Suppository

Suppository should be administered rectally.

Children below 5 years : 125-250 mg, 2-3 times daily.

Children 6-12 years : 250-500 mg, 2-3 times daily.

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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.

OVER DOSE

Moderate overdose : 4-10 gm/day.

Excessive overdose : More than 10 gm/day.

Symptoms of overdose include pallor, nausea, vomiting, anorexia & abdominal pain. Liver damage may become apparent 12-48 hours after ingestion.

In severe poisoning hepatic failure may progress to encephalopathy, coma & death.

USE IN PREGNANCY AND LACTATION

Paracetamol is safe in all stages of pregnancy and lactation.

STORAGE CONDITION

Ace[®] tablet, syrup and suspension: Store at a cool and dry place, protect from light and moisture. Ace[®] suppository : Store below 30° C.

HOW SUPPLIED

Ace [®] Tablet	:Box containing 50x10 tablets in blister pack.
Ace [®] Syrup	:50 ml syrup in sealed cap bottle.
Ace [®] Suspension	:60 ml suspension in sealed cap bottle.
Ace [®] Paediatric Drops (15 ml)	:15 ml concentrated suspension in sealed cap bottle with dropper.
Ace [®] Paediatric Drops (30 ml)	:30 ml concentrated suspension in sealed cap bottle with dropper.
Ace [®] Suppository (125 mg)	:Box containing 2 x 5 suppositories in blister pack.
Ace [®] Suppository (250 mg)	:Box containing 2 x 5 suppositories in blister pack.

