

Ace[®]

Paracetamol BP

COMPOSITION

| | |
|------------------------------|--|
| Tablet | : Each tablet contains Paracetamol BP 500 mg. |
| Extended Release Tablet (XR) | : Each tablet contains Paracetamol BP 665 mg. |
| Syrup (60 ml) | : Each 5 ml syrup contains Paracetamol BP 120 mg. |
| Syrup (100 ml) | : Each 5 ml syrup contains Paracetamol BP 120 mg. |
| Suspension | : Each 5 ml suspension contains Paracetamol BP 120 mg. |
| Paediatric Drop (15 ml) | : Each ml paediatric drop contains Paracetamol BP 80 mg. |
| Paediatric Drop (30ml) | : Each ml paediatric drop contains Paracetamol BP 80 mg. |
| Suppository 60 mg | : Each suppository contains Paracetamol BP 60 mg. |
| Suppository 125 mg | : Each suppository contains Paracetamol BP 125 mg. |
| Suppository 250 mg | : Each suppository contains Paracetamol BP 250 mg. |
| Suppository 500 mg | : Each suppository contains Paracetamol BP 500 mg. |

PHARMACOLOGY

Ace[®] is the formulation of Paracetamol (Acetaminophen) 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 center. **Ace[®]** exerts significantly milder side effects and most unlikely to produce many of the serious side effects associated with aspirin and other NSAIDs.

Paracetamol is rapidly and completely absorbed from the GIT 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. 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 gm (8 tablets) daily.

Children (6-12 years) : ½ 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.

XR Tablet

Adults & Children over 12 years: Two tablets, swallowed whole, every 6 to 8 hours (maximum of 6 tablets in any 24 hours). The tablet must not be crushed.

Syrup/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: ½ 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.

Suppository

Suppository should be administered rectally.

Children 3-12 months: 60-120 mg, 4 times daily. **Children 1-5 years**: 125-250 mg, 4 times daily. **Children 6-12 years**: 250-500 mg, 4 times daily. **Adults & children over 12 years**: 0.5-1 gm 4 times daily.

Paediatric Drop

Children - Up to 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 regulated, every 4 hours according to the weight listed in the table given below :

| 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.

CONTRAINDICATION

Known sensitivity to Paracetamol.

SIDE EFFECTS

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

OVERDOSE

Moderate overdose : 4-10 gm/day.

Excessive overdose : More than 10 gm/day.

Symptoms of overdose include pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12-48 hours after ingestion. In severe poisoning hepatic failure may progress to encephalopathy, coma and death.

USE IN PREGNANCY & LACTATION

Paracetamol is safe in all stage of pregnancy and lactation.

STORAGE

Ace[®] Tablet, Syrup & Suspension: Keep in a cool & dry place, protected from light and moisture.

Ace[®] Suppository: Store below 25° C.

Keep all medicines out of the reach of children.

HOW SUPPLIED

| | |
|---|--|
| Ace[®] Tablet | : Each box contains 500 tablets in blister pack. |
| Ace[®] XR Tablet | : Each box contains 100 tablets in blister pack. |
| Ace[®] Syrup (60 ml) | : 60 ml syrup in sealed cap PET bottle (with measuring cup). |
| Ace[®] Syrup (100 ml) | : 100 ml syrup in sealed cap PET bottle (with measuring cup). |
| Ace[®] Suspension | : 60 ml suspension in sealed cap PET bottle. |
| Ace[®] Paediatric drops (15 ml) | : 15 ml paediatric drop in sealed cap PET bottle (with dropper). |
| Ace[®] Paediatric drops (30 ml) | : 30 ml paediatric drop in sealed cap PET bottle (with dropper). |
| Ace[®] 60 Suppository | : Each box contains 10 suppositories in blister pack. |
| Ace[®] 125 Suppository | : Each box contains 20 suppositories in blister pack. |
| Ace[®] 250 Suppository | : Each box contains 20 suppositories in blister pack. |
| Ace[®] 500 Suppository | : Each box contains 20 suppositories in blister pack. |

Manufactured by :



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BANGLADESH

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