

PARACETAMOL

AEKNIL SYRUP

Paracetamol I.P 150 mg / 5 ml

PRODUCT DESCRIPTION

Pink colored clear syrup solution, sweet to taste.

FORMULATION

Each ml contains

Paracetamol I.P.....150 mg

Syrup base.....q.s.

Colour Erythrosine

CLINICAL PHARMACOLOGY

Paracetamol is a clinically proven analgesic and antipyretic. It produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating centers. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system and to a lesser extent through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Paracetamol produces antipyresis by acting centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

Pharmacokinetics

Paracetamol is distributed throughout most body tissues. About 25% of Paracetamol in blood is bound to plasma proteins. The plasma half-life is 1.25 to 3 hours but may be increased by liver damage and following overdose. Paracetamol is metabolized in the liver. About 85% of a dose of Paracetamol is excreted in urine as free and conjugated Paracetamol within 24 hours.

INDICATIONS

Pyrexia of unknown origin, fever and pain, associated with common childhood disorders, tonsillitis, upper respiratory tract infection, post-immunization reactions, post operative fever, after tonsillectomy and other conditions, where patient is unable to take oral medications but where Paracetamol can be administered with advantage for prevention of febrile convulsion, headache, cold, sinusitis, muscle pain, arthritis and toothache. NOTE: Specific therapy with antibiotics or chemotherapeutic drugs of choice should be carried out whenever indicated.

DOSAGE AND ADMINISTRATION

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: Half to 1 teaspoonful 3 to 4 times daily.

1 to 5 years: 1 teaspoonful 3 to 4 times daily.

6 to 12 years: 1 to 2 teaspoonfuls 3 to 4 times daily.

Adults and children above 12 years: 2 tablespoonfuls every 4 to 6 hours.

CONTRAINDICATIONS

Hypersensitivity to Paracetamol. Repeated administration is contraindicated in patients with anemia, cardiac, pulmonary, renal, and hepatic disease.

ADVERSE REACTIONS

Paracetamol has rarely been found to produce any side effects in therapeutic doses and is usually well tolerated by aspirin sensitive patients. Toxicity may result from a single toxic dose of the drug or from chronic ingestion. The following adverse reactions have been reported: skin eruption, haematological toxicity.

INTERACTIONS WITH OTHER MEDICINES

Paracetamol may enhance the activity of coumarin anticoagulants, but its effect is not generally of clinical significance.

OVERDOSE AND TREATMENT

Symptoms of overdosage may include nausea, vomiting, abdominal pain, diaphoresis, generalized weakness & lethargy. If an overdose of Paracetamol is suspected, blood should be withdrawn immediately for Paracetamol plasma assay, without regard to the presence or absence of symptomatology. The acute hepatotoxicity, nephrotoxicity of paracetamol can be overcome by the administration of sulfhydryl donors, e.g, N-acetyl cysteine which should be given as soon as possible after ingestion. Treatment after 12 hours is not effective. Paracetamol overdose should be treated with gastric lavage if the patient is seen within 24 hours of ingestion of the drug.

STORAGE CONDITIONS

Store in a cool, dry place at temperatures not exceeding 25°C, away from light.

CAUTION

Do not take any Paracetamol containing medicines concurrently.

SHELF LIFE

3 years

PACK PRESENTATION

60 ml / 450 ml glass bottle

Manufactured by

THERAPEUTIC PHARMACEUTICALS

951, Marathe Udyog Bhavan,
A.M Marg, Prabhadevi, Mumbai 400025,
Maharashtra State, INDIA

Date of Revision of Package Insert

March 2016