

PARACETAMOL

AEKNIL INFUSION

PARACETAMOL 10 MG/ML

For I.V use only

PRODUCT DESCRIPTION

A clear, colorless solution for infusion, free from extraneous matter.

FORMULATION

Each ml contains

Paracetamol I.P.....10 mg

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

Adults and adolescents weighing 50 kg and over: The recommended dosage of Paracetamol IV is 1000 mg every 6 hours or 650 mg every 4 hours, with a maximum single dose of Paracetamol IV of 1000 mg, a minimum dosing interval of 4 hours, and a maximum daily dose of Paracetamol of 4000 mg per day.

Children \geq 2 to 12 years of age: The recommended dose of Paracetamol IV is 15 mg/kg every 6 hrs or 12.5 mg/kg every 4 hrs, with a maximum single dose of Paracetamol IV of 15 mg/kg, a minimum dosing interval of 4 hrs, and a maximum daily dose of Paracetamol of 75 mg/kg per day.

CONTRAINDICATIONS

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

PRECAUTIONS

Paracetamol should be given with care to patients with impaired kidney or liver function.

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. For single use only. The product should be used within 6 hours of opening.

CAUTION

Prescription-only medicine. To be used by or under the supervision of a medical practitioner only. Do not take any Paracetamol containing medicines concurrently.

Do not use if container is found leaking upon squeezing, contents not clear, contains visible solid particles, or plastic bag appears to be tampered.

SHELF LIFE

2 years

PRESENTATION

100 ml FFS container

Manufactured by

THERAPEUTIC PHARMACEUTICALS
951, Marathe Udyog Bhavan,
A.M Marg, Prabhadevi, Mumbai 400025,
Maharashtra State, India

Date of Revision of Package Insert

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