*For the use only of a Registered Medical Practitioner or Hospital or a Laboratory.*

# PARACETAMOL

# AEKNIL INJECTION

## 150 mg/ml Solution for Injection

For I.M / I.V Use

**PRODUCT DESCRIPTION**
A clear, colorless solution for injection, free from extraneous matter.

**FORMULATION**
Each ml contains
Paracetamol I.P.....150 mg
Lignocaine Hydrochloride I.P (As local anesthetic).....1% w/v
Benzyl Alcohol I.P (As Preservative).....1% v/v

**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, tonsilitis, 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**
Intramuscular route: Adults: 2 - 3 ml every 4 to 6 hours.
Children (2 -12 years / > 33 kg): Up to 2 ml every 4 to 6 hours.
Below 2 years of age: Half to 1 ml every 4 to 6 hours.
Intravenous route: Slow I.V Administration.

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

**WARNINGS AND PRECAUTIONS**
Contains sodium sulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life threatening or less severe asthamatic episodes in certain susceptible persons. Also contains Benzyl Alcohol. This should not be administered to new born or premature infants. 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 sulfinydryl 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 30°C.
Protect from light.

**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.

**SHELF LIFE**
2 years

**PRESENTATION**
2 ml / 3 ml / 4 ml Amber Ampoules and 15 ml vials

**PACKING**
Packs of 5, 10, and 100 Ampoules; 25 x 15 ml vials

**Manufactured by**
THERAPEUTIC PHARMACEUTICALS
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