AXPAIN - 650
CAPLET

MAL08051617XZ

COMPOSITION:
Each caplet contains
Paracetamol 650mg

PRESENTATION:
White colour, oblong shape caplet, plain on one side and AXPAIN embossed on the other side.

INDICATIONS:
As a mild analgesic and antipyretic and weak anti-inflammatory. It is recommended for the relieve of painful and febrile conditions, for example, headache, migraine, backache, toothache, aches due to the colds and flu, muscular rheumatism, dysmenorrhea and fever. It is a substitute for aspirin for its analgesic or antipyretic uses in patients who are allergic to aspirin or when aspirin is contraindicated as in patients with gout or peptic ulcer.

PHARMACOLOGY:
Mechanism of Action:
Paracetamol has analgesic and antipyretic properties and weak inflammatory activity. Paracetamol relieves mild to moderate pain, such as headache and dysmenorrhea, in many muscle joint, and peripheral nerve disorders. Analgesia is mediated peripherally and also centrally, whereas antipyresis is produced by a central action on hypothalamic regulatory center.

Pharmacokinetics:
Paracetamol is metabolised primarily by the hepatic microsomal enzymes. It is rapidly and practically completely absorbed from the gastrointestinal tract. Peak plasma concentrations occurring about 10 to 60 minutes after oral administration and the plasma half-time is 1 - 3 hours. Paracetamol is distributed into most body tissues. Binding of the drug to plasma proteins is variable; 20 - 50% may be bound at the concentrations encountered during acute intoxication. Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite (*N*-acetyl-*p*-benzoquinoneimine), is usually produced in very small amounts by cytochrome P450 isoenzymes (mainly CYP2E1 and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate following paracetamol overdosage and cause tissue damage.

DOSAGE AND ADMINISTRATION:
Adult and children above 12 years old : 1 caplet, every 4-6 hours. Not more than 6 caplets per day.

CONTRAINDICATION:
Contraindicated in patients with known hypersensitive to Paracetamol.

PRECAUTION:
Warning:
This preparation contains Paracetamol. Do not take any other Paracetamol containing medicines at the same time. Paracetamol overdose may harm the liver. Follow the recommended dose.

Allergy alert:
Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Precaution:
It should be given with care to patients with impaired kidney or liver function. Chronic use should be avoided.

Use in Pregnancy and Lactation:
Paracetamol is generally considered to be the analgesic choice of pregnant patients. No adverse effects have been observed in breast-feeding infant whose mothers are receiving Paracetamol.

SIDE EFFECTS:
When taken as directed, Paracetamol is virtually free of side effects. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported. Patients allergic to the salicylates do not exhibit cross-sensitivity to paracetamol.

DRUG INTERACTIONS:
Paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when given with probenecid. Cholestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol. The prothrombinopenic effect of the oral anticoagulants may be increased by chronic administration of full doses of Paracetamol; occasional doses of Paracetamol have no significant effect.

OVERDOSAGE AND TREATMENT:
Paracetamol overdose can result in severe liver damage and sometimes acute renal tubular necrosis. Immediate medical attention is essential in the event of overdose, even when there are no obvious symptoms. Administration of antidote such as acetylcysteine or methionine may be required. Activated charcoal may be used to reduce gastrointestinal absorption, if it can be given within 1 hour of the overdose, and if more than 150mg/kg of paracetamol has been ingested. However, if acetylcysteine or methionine is to be given by mouth the charcoal is best cleared from the stomach to prevent it reducing the absorption of the antidote.

STORAGE:
Store below 30^{O}C. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES:
Available in blister packs of 8's x 10, 8's x 6 and 8's x 2.

Further information can be obtained from pharmacist, physician or the manufacturer.

Product Registration Holder & Manufactured By:
Kotra Pharma (M) Sdn. Bhd. (90082-V)
No.1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

Regn - 240323
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