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ACAMOL

TABLETS - CAPLETS

Composition

Acamol Tablets
Each tablet contains:

Active Ingredient
Paracetamol 500 mg

Other Ingredients
Maize starch, povidone, stearic acid.

Acamol Caplets
Each caplet contains:

Active Ingredient
Paracetamol coarse granulate powder
equivalent to paracetamol 500 mg

Other Ingredients
Pregelatinized starch, povidone, stearic acid, hypromellose (hydroxypropylmethylcellulose), macrogol 400 and macrogol 8000 (polyethylene glycols).

Mechanism of Action

Paracetamol is a clinically-proven non-salicylate analgesic and antipyretic with rapid absorption and action. It produces analgesia by elevation of the pain threshold, and antipyresis through action on the hypothalamic heat-regulating center.
Paracetamol is particularly suitable for patients with peptic ulcer as it does not cause gastric irritation and also for patients who have salicylate intolerance.

Indications

Relief of pain and fever of different etiologies such as headache, toothache, colds, influenza, rheumatic pain and dysmenorrhea.

Contraindications

Known hypersensitivity to paracetamol or to any other ingredient of the preparation.

Warnings

Paracetamol can cause accidental poisoning in toddlers and infants. Paracetamol-containing products should be kept well out of reach of children.
Potentially fatal hepatotoxicity can result from paracetamol overdosage. However, in rare cases, hepatotoxicity has occurred in patients receiving high or excessive doses within therapeutic doses. Certain patients may be more susceptible to paracetamol hepatotoxicity, e.g., chronic alcoholics, patients with liver disease, or those who are malnourished or taking other drugs that induce hepatic enzymes.

Because of the risk of hepatotoxicity, patients should be cautioned against the inadvertent administration of excessive doses of paracetamol by using multiple paracetamol-containing product at once, such as cough and cold remedies, analgesics or arthritic formulations, antipyretics or products for relief of menstrual symptoms or muscle spasm. Administration of paracetamol to children may be especially prone to error due to the many concentrations and strengths of products available. To avoid dosing errors, all product labels should be checked carefully to ensure calculation of the amount of paracetamol to be given.

Use in Pregnancy

Safety of use in pregnancy has not been established.

Use in Breastfeeding

Although paracetamol appears in very low concentration in breast milk, risk-benefit must be considered before this drug is given to nursing mothers.

Adverse Reactions

Adverse reactions of paracetamol are rare and usually mild.

Hepatotoxicity: see Warnings.
Hematologic: neutropenia and thrombocytopenia purpura have been reported and rarely agranulocytosis.
Hypersensitivity: reactions including skin eruptions, laryngeal edema, bronchospasm, and/or anaphylaxis have occurred rarely. Dose-dependent cross-sensitivity to paracetamol may occur in aspirin-sensitive asthmatics. Low initial doses of paracetamol (less than 1000 mg) are recommended in these patients, with monitoring for about 3 hours following initial doses.
Renal: nephropathy, including papillary renal failure has been reported following consumption of large amounts of paracetamol. Renal tubular necrosis has been associated occasionally with hepatic injury produced by paracetamol overdose.

Precautions

If a sensitivity reaction occurs, discontinue use.

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

Risk-benefit ratio should be taken into consideration in the presence of viral hepatitis and alcoholism, since there is an increased risk of hepatotoxicity.

Drug Interactions

Paracetamol/Oral Anticoagulants: Regular administration of paracetamol may enhance the activity of coumarin anticoagulants when given concurrently. Occasional doses have no significant effect.
Paracetamol/Hepatic Enzyme-Inducing Agents (e.g., Barbiturates, Carbamazepine, Phenytoin)/ Hepatotoxic Medications/Alcohol: Concurrent administration of enzyme inducers and paracetamol may decrease the therapeutic effect of paracetamol, probably because of increased metabolism resulting from induction of hepatic microsomal enzyme activity.
The risk of hepatotoxicity with single toxic doses or prolonged use of high doses of paracetamol may be increased in patients consuming alcoholic beverages or in patients taking other hepatotoxic medications.
Paracetamol/ Salicylates/ Other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): Chronic high-dose administration of paracetamol with salicylates and/or other non-steroidal anti-inflammatory drugs increases the risk of analgesic nephropathy.

Paracetamol/Zidovudine: Paracetamol may competitively inhibit the hepatic glucuronidation and decrease the clearance of zidovudine. Zidovudine may also inhibit the hepatic glucuronidation of paracetamol. Concurrent use should be avoided, because the toxicity of either or both medications may be potentiated.
Paracetamol/Cholestyramine: Cholestyramine may reduce the absorption of paracetamol. Oral doses of cholestyramine and paracetamol should be given at least 1 hour apart.
Paracetamol/Metoclopramide/Domperidone: The speed of absorption of paracetamol may be increased by metoclopramide or domperidone.

Diagnostic Interference

Blood Glucose Determinations

May be falsely decreased when measured by the glucose oxidase/ peroxidase method, but probably not when measured by the hexokinase/ glucose-6-phosphate dehydrogenase (G6PD) method.

Serum Uric Acid Determinations

Falsely increased values may occur when the phosphotungstate uric acid test method is used.

Urine 5-hydroxyindoleacetic Acid (5-HIAA) Determinations

Qualitative screening tests using nitrosonaphthol reagent may produce false-positive test results. The quantitative test is unaffected.

Pancreatic Function Test Using Bentiromide

Administration of paracetamol prior to the bentiromide test will invalidate the test results, because paracetamol is also metabolized to an arylamine and will therefore increase the apparent quantity of para-aminobenzoic acid (PABA) recovered. It is recommended that paracetamol be discontinued at least 3 days prior to administration of bentiromide.

Dosage and Administration

Adults

1-2 tablets or caplets every 4-6 hours, as required.
Do not exceed 8 tablets or caplets per day.

Children 6-12 Years of Age

½-1 tablet every 4-6 hours, as required.
The child should not receive more than 5 doses during 24 hours.

Overdosage

Manifestations

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia, and abdominal pain. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

In massive overdosage, paracetamol may cause hepatic toxicity. In adults and adolescents, hepatic toxicity has been rarely reported following ingestion of acute overdose of less than 7.5 –10 g. Fatalities are infrequent (less than 3-4% of untreated cases) and have been rarely reported with overdoses of less than 15 g. Early symptoms following a potentially hepatotoxic overdose may include nausea, vomiting, stomach pain, diaphoresis, and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48-72 hours post-ingestion.

Serious toxicity or fatalities are extremely infrequent in children, possibly due to differences in the way they metabolize paracetamol. An acute overdosage of less than 150 mg/kg bodyweight in children has not been associated with hepatic toxicity.

Treatment
Adults and Adolescents

Regardless of the quantity of paracetamol reported or assumed to have been ingested, N-acetylcysteine should be administered immediately, if 24 hours or less have elapsed from the time of ingestion.

An initial dose of 150 mg N-acetylcysteine/kg body weight is infused I.V. in 200 ml of 5% Dextrose Injection over 15 minutes. This is followed by I.V infusion of 50 mg N-acetylcysteine/kg body weight in 500 ml of 5% Dextrose Injection over the next 4 hours, and 100 mg N-acetylcysteine/kg body weight in 1 liter of 5% Dextrose Injection over the next 16 hours (providing a total dose of 300 mg/kg body weight of N-acetylcysteine over 20 hours).

In addition to N-acetylcysteine administration, it is recommended that the stomach be emptied promptly by lavage, or by induction of emesis with syrup of ipecac.

A serum paracetamol assay should be obtained as early as possible, but not less than 4 hours following ingestion. If plasma level falls above the lower treatment line on the paracetamol overdose nomogram, acetylcysteine therapy should be continued.

Liver function tests should be performed initially, and repeated at 24-hour intervals.

Children

Induce emesis using syrup of ipecac.

A serum paracetamol assay should be obtained as soon as possible, but not less than 4 hours following ingestion.

If more than 150 mg/kg body weight or an unknown amount was ingested, plasma paracetamol level should be obtained. The plasma paracetamol level should be obtained as soon as possible, but no sooner than 4 hours following ingestion. If plasma level falls above the lower treatment line on the paracetamol overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If a paracetamol assay is not available and the paracetamol ingestion exceeds 150 mg/kg body weight, N-acetylcysteine therapy should be initiated and continued for a full course.

The dosage and administration of N-acetylcysteine in children is the same as recommended for adults and adolescents. However, the quantity of I.V. fluid used in children should be modified, taking into account both age and weight.

Manufacturer

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