

D/S- Ace 500 Tab MY

Item code : 2000029875

Length : L - 230 mm & W-100 mm

Paper Type : Offset

Paper GSM : 60 GSM

Color : Single Color (Both side print)

Date : 27 May' 25

ACE 500MG TABLET

DESCRIPTION

A white to off-white caplet shape tablet having break line and embossed "Ace" in one side & embossed "SQUARE" on other side. Each tablet contains Paracetamol 500mg.

INDICATIONS:

For relief of Pain and Fever.

PHARMACODYNAMICS

Analgesic: The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to lesser extent, through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibiting of prostaglandin synthesis or to inhibition of the synthesis of action of other substances that sensitize pain receptors.

Antipyretic: Paracetamol probably 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 rapidly and almost completely absorbed after oral administration. Approximately 90-95% of a dose is metabolized in the liver, primarily by conjugation with glucuronic acid, sulfuric acid and cysteine. Peak concentration can be achieved within 0.5-2 hours. Paracetamol is excreted primarily as conjugates via the kidney.

DOSAGE

Adult and children above 12 years: 0.5-1g every 4 to 6 hours to a maximum of 4 grams daily.

Children 6 to 12 years: 250-500mg every 4 to 6 hours with a maximum of 4 doses in 24 hours.

CONTRAINDICATIONS

Hypersensitivity to paracetamol.

WARNING AND PRECAUTIONS

Caution in hepatic impairment, alcoholism.

This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time.

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.

INTERACTIONS WITH OTHER MEDICAMENTS

Drugs which induce the specific microsomal isoenzyme responsible from the metabolic activation of paracetamol might be expected to increase susceptibility to its toxic effects on the liver humans as in the case in animals.

The absorption of paracetamol may accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when given probenecid. Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol. Drug interaction also reported with

warfarin, rifampicin, chloramphenicol, antiepileptic (carbamazepine, phenobarbital, phenytoin, or primidone), antiviral (interferon alfa and zidovudine) and probenecid.

PREGNANCY AND LACTATION

Paracetamol crosses the placenta but the drug has been used widely as an analgesic in pregnancy and no adverse fetal affects has been recorded.

SIDE EFFECTS

Liver damage may occur in prolonged use or overdosage.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

First empty stomach via induction of emesis or gastric lavage. It is recommended that acetylcysteine administration be instituted as soon as possible after ingestion of an overdose has been reported without waiting for the results of plasma concentration or other laboratory tests. Acetylcysteine is most effective if treatment is started within 10 to 12 hours after ingestion of the overdose. However, it may be of some benefits if treatment is started within 24 hours. For oral administration, the recommended adult dose of acetylcysteine is 140mg per kg of body weight initially, then 70mg per kg of body weight every 4 hours for 17 doses. Each dose should be diluted to a 5% solution with cola, grapefruit juice, orange juice, or water prior to administration because of its unpleasant odor and its irritation and sclerosing properties.

Any dose vomited may be given via duodenal intubation.

Plasma acetaminophen concentration should be determined and liver function test should be performed to ascertain the status of the patient. Renal and cardiac function should be monitored and appropriate therapy instituted if necessary.

Supportive treatment consist of maintaining fluid and electrolyte balance, correcting hypoglycemia and administering vitamin K1 (if prothrombin time ratio exceeds 1.5) and fresh frozen plasma or clotting factor concentrate (if prothrombin ratio exceeds 3.0).

PRESENTATION

1x10's, 10x10's, 50x10's, 100x10's tablets

STORAGE CONDITIONS

Store in a dry place below 30°C. Protect from light.

Keep out of reach of children.

MANUFACTURER

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Revision Date: 27 May 2025