MEFENAMIC ACID

ACIFLAM

500 mg Capsule
NON-STEROIDAL
ANTI-INFLAMMATORY DRUG (NSAID)

PRODUCT DESCRIPTION:
Mefenamic Acid (ACIFLAM) 500 mg Capsule - is a white to off-white powder in EGC size "0", blue cap/ light blue body

FORMULATION:
Each capsule contains:
Mefenamic Acid, USP ..... 500 mg

PHARMACODYNAMICS:
Mechanism of action: Mefenamic acid is a nonsteroidal agent with demonstrated anti-inflammatory, analgesic and antipyretic activity in laboratory animals. Mefenamic acid was found to inhibit prostaglandin synthesis and to complete for binding at the prostaglandin receptor sites in animal models.

PHARMACOKINETICS:
Absorption: Mefenamic acid is rapidly absorbed from the gastrointestinal tract. Following administration of a 1 g oral dose to adults, peak plasma levels of 10g/mL occur in 1-4 hrs, with a t½ of 2 hrs. Plasma levels are proportional to dose, following multiple doses, with no drug accumulation. One (1)g of mefenamic acid administered 4 times daily produces peak blood levels of 20g/mL by the 2nd day of administration.
Distribution: Mefenamic acid is extensively bound to plasma proteins.
Metabolism: Mefenamic acid metabolism is predominantly mediated via cytochrome P450 CYP2C9 in the liver.
Patients who are known or suspected to be poor CYP2C9 metabolizers based on previous history / experience with other CYP2C9 substrates should be administered mefenamic acid with caution as they may have abnormally high plasma levels due to reduced metabolic clearance.
Elimination: Following a single oral dose, 52-67% of the dose was recovered from the urine as unchanged drug or 1 of 2 metabolites. Assay of stools over 3 days accounted for 20-25% of the dose, chiefly as unconjugated metabolite II.
Toxicology:
Preclinical Safety Data: Rats given up to 10 times the human dose showed decreased fertility, delay in parturition and a decreased rate of survival to weaning. No fetal abnormalities were observed in this study and in another study in dogs receiving 10 times the human dose.

INDICATIONS:
For the relief of mild to moderate pain including headache, dental pain, postoperative and postpartum pain, and dysmenorrhea. And also used in musculoskeletal and joint disorders such as osteoarthritis and rhuematoid arthritis.

DOSAGE AND MODE / ROUTE OF ADMINISTRATION :
500 mg capsule
1 capsule three times a day to be taken orally.
Should be taken with full stomach.
Treatment should not exceed 7 days or as prescribed by the physician.

PRECAUTIONS:
Mefenamic Acid is contraindicated in patients with ulceration or inflammation of the gastrointestinal tract. It should be used with caution in patients with impaired renal or liver function. It may enhance the effects of coumarin anti-coagulant and should be avoided in epileptic subjects. Mefenamic Acid should be taken with full stomach.

PREGNANCY AND LACTATION:
Since there are no adequate and well-controlled studies in pregnant woman, this drug should be used only if the potential benefits to the mother justify the possible risk to the fetus. It is not known if mefenamic acid or its metabolites cross the placenta. However, because of the effects of drugs in this class (ie, inhibitors of prostaglandin synthesis) on the fetal cardiovascular system(eg premature closure of the ductus arteriosus), the use of mefenamic acid in pregnant woman is not recommended. Mefenamic acid inhibits prostaglandin synthesis which may result in prolongation of pregnancy and interference with labor when administered late in the pregnancy. Women on mefenamic acid therapy should consult their physician if they decide to become pregnant.

Inhibition of prostaglandin synthesis might adversely affect pregnancy. Data from epidemiological studies suggest an increased risk of spontaneous abortion after use of prostaglandin synthesis inhibitors in early pregnancy. In animals, administration of prostaglandin synthesis inhibitors has been shown to result in increased pre-and post-implantation loss.
Use in lactation: Trace amounts of mefenamic acid may be present in breast milk and transmitted to the nursing infant. Therefore, mefenamic acid should not be taken by nursing mothers.

INTERACTION:
There may be an interaction between mefenamic acid and any of the following:
- ASA, alcohol, angiotensin converting enzyme (ACE) inhibitors (e.g., ramipril) , beta-adrenergic blockers (e.g., metoprolol, atenolol), chamomile, cholestyramine, colestipol, corticosteroids (e.g., dexamethasone, hydrocortisone, prednisone), cyclosporine, digoxin, diuretics (water pills; e.g., spironolactone, triamterene), ginkgo biloba, ginseng ,green tea, heparin, lithium, methotrexate, oral hypoglycemics (anti-diabetes medications; e.g., glyburide, metformin), other NSAIDs (e.g., celecoxib, ibuprofen, ketorolac, naproxen), phenytoin, potassium supplements, probenecid, selective serotonin reuptake inhibitors (SSRIs, e.g. citalopram, fluoxetine, paroxetine, sertraline), tacrolimus, ticlopidine, and warfarin.

An interaction between two medications does not always mean that you must stop taking one of them. Speak to your doctor about how any drug interactions are being managed or should be managed.
Medications other than those listed above may interact with this medication. Tell your doctor or prescriber about all prescription, over-the-counter (non-prescription), and herbal medications you are taking. Also tell them about any supplements you take. Since caffeine, alcohol, the nicotine from cigarettes, or street drugs can affect the action of many medications, you should let your prescriber know if you use them.

ADVERSE DRUG REACTIONS:
Side effects are negligible at recommended dosage. Gastric irritation is infrequent and may be minimized by taking medications during meals. Long term continuous administration of Mefenamic Acid in daily doses of 2000 mg or more is not recommended. Diarrhea may occur on long term continuous dosage of 2000 mg or more daily and is an indication to discontinue medication. Maculopapular rash may occur which disappear on withdrawal of medication.

OVERDOSE AND TREATMENT:
Seizures,acute renal failure, coma, confusional state, vertigo and hallucination have been reported with mefenamic acid overdoses. Overdose has led to fatalities.
Treatment: Following accidental overdosage, the stomach should be emptied immediately by inducing emesis or gastric lavage followed by the administration of activated charcoal. Vital functions should be monitored and supported. Hemodialysis is of little value since mefenamic acid and its metabolites are firmly bound to plasma proteins.

STORAGE CONDITION:
Store at temperatures not exceeding 30ºC.
Protect from light and keep container tightly closed.

AVAILABILITY:
500 mg Capsule: Alu-transparent PVC Blister pack by 10's box of 100's

Manufactured by:
Drugmaker's Laboratories, Inc.
E & E Industrial Complex, Brgy. San Antonio, San Pedro, Laguna

CAUTIONS:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph**

Registration Number:
500 mg Capsule : **DRP-5533**

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