MEFENAMIC ACID

Aciflam
50 mg / 5 mL Suspension
NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID)

FORMULATION:
Each 5 mL (1 teaspoonful) contains:
Mefenamic Acid, USP ..... 50 mg

PRODUCT DESCRIPTION:
Mefenamic Acid 50 mg / 5 mL Suspension is apple green suspension with Lemon flavor.

PHARMACODYNAMICS:
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 compete for binding at the prostaglandin receptor sites in animal models.

PHARMACOKINETICS:
Mefenamic Acid is absorbed from the gastrointestinal tract. Peak plasma concentrations occur about 2 to 4 hours after ingestion. The plasma elimination half-life is reported to be about 2 to 4 hours. Mefenamic Acid is more than 90%bound to plasma proteins. It is distributed into breast milk. Mefenamic Acid is metabolized by the cytochrome P450 isoenzyme CYP2C9 to 3-hydroxymethyl Mefenamic Acid, which may then be oxidized to 3-carboxymefenamic acid. Over 50% of a dose may be recovered in the urine, as unchanged drug or, mainly, as conjugates of Mefenamic Acid and its metabolites.

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

DOSAGE AND MODE / ROUTE OF ADMINISTRATION:
2 - 4 years old: .....1 - 1½ teaspoonfuls (5 -7.5 mL)
5 - 8 years old: ..... 2 teaspoonfuls (10 mL)
9 - 12 years old: ..... 1 tablespoonful (15ml)
3 to 4 times daily or as prescribed by the physician.
Treatment should not be given for longer than 7 days.

CONTRAINDICATIONS:
Mefenamic Acid is contraindicated in gastrointestinal ulceration or inflammatory bowel disease, renal or hepatic impairment. Hypersensitivity to Mefenamic acid or to any of the excipients. Because the potential exists for cross-sensitivity to aspirin or other Non-steroidal Anti-inflammatory Drugs (NSAIDs), Mefenamic should not be given to patients in whom these drugs induce symptoms of bronchospasm, allergic rhinitis or urticaria.
Patients with active ulceration or chronic inflammation of either the upper or lower gastrointestinal tract and should be avoided in patients with preexisting renal disease.
Treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. Patients with severe renal and hepatic failure. Patients with severe heart failure.

PRECAUTION:
The use of Mefenamic acid with concomitant NSAIDs including COX-2 inhibitors should be avoided.

Cardiovascular Effects:
NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction and stroke which can be fatal. This risk may increase with duration of use. Patients with known cardiovascular disease may be at greater risk. To minimize the potential risk for an adverse cardiovascular event in patients treated with Mefenamic Acid, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous cardiovascular symptoms.
Patients should be informed about the signs and/or symptoms of serious cardiovascular toxicity and the steps to take if they occur.

Hypertension:
As with all NSAIDs, Mefenamic Acid can lead to the onset of new hypertension or worsening or preexisting hypertension, either of which may contribute to the increased incidence of cardiovascular events. NSAIDs, including Mefenamic Acid, should be used with caution in patients with hypertension. Blood pressure should be monitored closely during the initiation of therapy with Mefenamic Acid and throughout the course of therapy.

Fluid Retention and Edema:
As with other drugs known to inhibit prostaglandin synthesis, fluid retention and edema have been observed in some patients taking NSAIDs, including Mefenamic Acid. Therefore Mefenamic Acid should be used with caution in patients with compromised cardiac function and other conditions predisposing to, or worsened by, fluid retention. Patients with preexisting congestive heart failure or hypertension should be closely monitored.

Gastrointestinal (GI) Effects:
If diarrhea occurs, the dosage should be reduced or temporarily suspended. Symptoms may recur in certain patients following subsequent exposure.
NSAIDs including Mefenamic Acid, can cause serious GI adverse events including inflammation, bleeding, ulceration and perforation of the stomach, small intestine or large intestine, which can be fatal. When GI bleeding or ulceration occurs in patients receiving Mefenamic Acid, the treatment should be withdrawn. Patients most at risk of developing these types of GI complications with NSAIDs are the elderly, patients with cardiovascular disease, patients using concomitant aspirin, or patients with a prior history of or active GI disease e.g. ulceration, GI bleeding or inflammatory conditions. Therefore, Mefenamic Acid should be used with caution In these patients.

Skin Reactions:
Serious skin reactions, some of them fatal including exfoliate dermatitis, Stevens-Johnson syndrome and toxicepidermal necrolysis, have been reported very rarely in association with the use of NSAIDs including Mefenamic Acid.
Patients appear to be at highest risk for these events early in the course of therapy, the onset of the event occurring in the majority of cases within the 1st month of treatment. Mefenamic acid should be discontinued at the 1st appearance of skin rash, mucosal lesions or any other sign of hypersensitivity.

Laboratory Tests:
A false-positive reaction for urinary bile using the diazo table test, may result following Mefenamic acid administration. If biliuria is suspected other diagnostic procedures e.g. the Harrison spot test should be performed.

Renal Effects:
In rare cases, NSAIDs including Mefenamic acid, may cause interstitial nephritis, glomerulitis, papillary necrosis and the nephrotic syndrome. NSAIDs inhibit the synthesis or renal prostaglandin which plays a supportive role in the maintenance of renal prostaglandin which plays a supportive role in the maintenance of renal perfusion in patients whose renal blood flow and blood volume are decreased. In these patients administration of an NSAID may precipitate overt renal decomposition, which is typically followed by recovery to pretreatment state upon discontinuation of NSAID therapy. Patients of greatest risk of such a reaction are those with congestive heart failure, liver cirrhosis, nephrotic syndrome, overt renal disease and the elderly. Such patients should be carefully monitored while receiving NSAID therapy.
Discontinuation of NSAID therapy is typically followed by recovery to the pre-treatment state. Since Mefenamic Acid metabolites are eliminated primarily by the kidneys, the drug should not be administered to patients with significantly impaired renal function.

Hematologic Effects:
Mefenamic Acid can inhibit platelet aggregation and may prolong prothrombin time in patients on warfarin therapy.

Hepatic Effects:
Borderline elevations of ≥1 liver function tests may occur in some patients receiving Mefenamic acid therapy. These elevation may progress, may remain essentially unchanged or may be transient with continued therapy. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur, Mefenamic Acid should be discontinued.

PREGNANCY AND LACTATION:
Since there are no adequate and well-controlled studies in pregnant women, 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.

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.

INTERACTIONS:
Anticoagulants: Mefenamic Acid has been shown to displace warfarin from protein binding sites and may enhance the response to oral anticoagulants. Therefore, concurrent administration of Mefenamic Acid with oral anticoagulant drugs requires frequent prothrombin time monitoring.

ADVERSE REACTIONS:
Side effects are negligible at recommended dosage. Gastric irritation is infrequent and maybe minimized by taking medication during meals. Long term continuous administration of Mefenamic Acid in daily doses of 2000 mg or more daily and is an indication to discontinue medication. Maculopapular rash has occurred which disappear on withdrawal of medication.

OVERDOSE AND TREATMENT:
SYMPTOMS: Seizures, acute renal failure, coma, confusional state, vertigo and hallucination have been reported with Mefenamic Acid overdoses. Overdoses has led to fatalities.
TREATMENT: Following accidental overdosage, the stomach should be emptied immediately by including 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 30°C.

AVAILABILITY:
60 mL Amber Bottle

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

Manufactured by:
DRUGMAKER'S LABORATORIES, INC.
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San Pedro, Laguna

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

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