Primera

MEFENAMIC ACID
LEZPAIN

Rx

500 mg Tablet

NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID)

FORMULATION:
Each tablet contains:
Mefenamic acid, USP…….500 mg

PRODUCT DESCRIPTION:
Mefenamic acid (Lezpain) 500 mg tablet is an oral Non-Steroidal Anti-Inflammatory Drug. It is an off-white capsule form tablet.

PHARMACODYNAMICS:
Mefenamic acid has a Non-steroidal anti-inflammatory, analgesic, antipyretic properties. Mefenamic acid is a potent inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

PHARMACOKINETICS:
Absorption
Mefenamic acid is rapidly absorbed after oral administration. In two 500 mg single oral dose studies, the mean extent of absorption was 30.5 mcg/hr/mL (17%CV). Following a single 1 gram oral dose, mean peak plasma levels ranging from 10-20 mcg/mL have been reported. Peak plasma levels are attained in 2 to 4 hours and the elimination half-life approximates 2 hours. Following multiple doses, plasma levels are proportional to dose with no evidence of drug accumulation. The effect of food on the rate and extent of absorption of mefenamic acid has not been studied.
Distribution
Mefenamic acid has been reported as being greater than 90% bound to albumin. The relationship of unbound fraction to drug concentration has not been studied. The apparent volume of distribution estimated following a 500 mg oral dose of mefenamic acid was 1.06 L/kg.
Metabolism
Mefenamic acid is metabolized by cytochrome P450 enzyme CYP2C9 to 3-hydroxymethyl mefenamic acid. Further oxidation to a 3-carboxymefenamic acid may occur. The metabolites may undergo glucuronidation and mefenamic acid is also glucuronidated directly. A peak plasma level approximating 20 mcg/mL was observed at 3 hours for the hydroxy metabolite and its glucuronide after a single 1 gram dose. Similarly, a peak plasma level of 8 mcg/mL was observed at 6-8 hours for the carboxy metabolite and its glucuronide.
Excretion
Approximately 52% of mefenamic acid dose is excreted into the urine. The fecal route of elimination accounts for up to 20% of the dose. The elimination half-life of mefenamic acid is approximately two hours. The metabolites may accumulate in patients with renal or hepatic failure. The mefenamic acid glucuronide may bind irreversibly to plasma proteins.

INDICATIONS:
For the relief of headache, muscular and traumatic pain, post-operative, post-extraction and post-partum pain.

DOSAGE AND ADMINISTRATION:
Take 1 tablet 3 times a day or as prescribed by the physician. Preferably taken with food.

WARNING:

ABSOLUTE CONTRAINDICATIONS:
Not to be given to those patients who have history of:
- Stroke: cerebrovascular accident, CVA
- Heart attack: myocardial infarction, MI
- Coronary artery bypass graft, CABG
- Uncontrolled hypertension
- Congestive heart failure (CHF) NYHA II-IV

A. Contraindicated in patients with history of hypersensitivity to ASA or any other NSAIDs.
B. NSAIDs are contraindicated in patients with previous or active peptic ulceration.
C. Use with caution in patients with cardiac, liver and renal disease. Dose adjustment like using the lowest effective dose and monitoring of renal and liver function should be instituted.

PRECAUTIONS:
Mefenamic acid should be used with caution in patients with impaired renal or liver functions. It may enhance the effects of coumarin anticoagulants and should be avoided in patients with seizure.

PREGNANCY AND LACTATION:
Pregnancy
There is 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 risks to the fetus. The use of mefenamic acid in pregnant women is not recommended and should be avoided during trimester of the pregnancy. NSAIDs may cause fetal renal dysfunction which may result in reduction of amniotic fluid volume in severe case.
Lactation
Small quantity of mefenamic acid may be present in breast milk and transmitted to nursing infants. Mefenamic acid should not be taken by lactating mother.

DRUG INTERACTIONS:
- Acetylsalicylic acid
  Mefenamic acid may interfere with the antiplatelet effects of low dose of ASA, and it may interfere with the aspirin prophylactic treatment of cardiovascular disease. There is an increase of bleeding by inhibition of platelet function when antiplatelet is combined with NSAIDs.
- Cyclosporine
  Concurrent use of NSAIDs may increase nephrotoxicity with cyclosporine
- Diuretics
  NSAIDs may reduce effect of diuretics
- Methotrexate
  NSAID administration may result in increased plasma levels of methotrexate.
- Corticosteroids
  Concurrent use with NSAIDs may increase gastrointestinal bleeding and ulceration.
- Antacids
  Concomitant ingestion of antacids containing magnesium hydroxide has been shown to significantly increase the rate and extent of mefenamic acid absorption.

ADVERSE DRUG REACTIONS:
Side effects are neglible at recommended dosage. Gastric irritation is occasional and maybe minimized by taking medication during meals, long term continuous administration of mefenamic acid in daily doses of 2000 mg or more is not recommended. These doses are greater than those required for analgesia. Diarrhea may occur on long term continuous medication.

OVERDOSE AND TREATMENT:
Symptoms of acute NSAID over dosage have been limited to nausea, vomiting, epigastric pain, lethargy and drowsiness, which can be reversible with supportive care. Gastrointestinal bleeding has occurred. Manage patients with symptomatic and supportive care following NSAID over dosage. There are no specific antidotes. Consider emesis, activated charcoal and osmotic cathartics in symptomatic patients seen with a large overdose. The stomach should be emptied immediately by including emesis or by gastric lavage, followed by 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 the plasma proteins.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.
Keep out of reach of children.

AVAILABILITY:
Mefenamic Acid (Lezpain) 500 mg - Blister Pack x 10's (Box of 100's)

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

ADR REPORTING STATEMENT:
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph".
Seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:
Mefenamic Acid (Lezpain) 500 mg: DR-XY21758

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06 August 1996

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17 March 2021
Revision 2

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