

AMENDED PACKAGE INSERT

FENAGESIC

Capsule 250MG / Tablet 250MG / Tablet 500MG
Capsule : 250mg of Mefenamic Acid per capsule
Tablet : 250mg or 500mg Mefenamic Acid per tablet

Product Description:

Capsule 250MG : Ivory/blue, size 1 capsule.
Tablet 250MG : Round, yellow, convex, film-coated tablet.
Tablet 500MG : Oval, yellow, convex, film-coated tablet with "P-O" debossed on one side and a single score on the other side.

Pharmacodynamics:

It is a nonsteroidal agent with demonstrated anti-inflammatory, analgesic and antipyretic activity. In animal studies, it was found to inhibit prostaglandin synthesis and to compete for binding at the prostaglandin receptor site. Its exact mode of action is not known.

Pharmacokinetics:

Following a single one gram oral dose, peak plasma level of 10 ug/ml occurred in 2 to 4 hours with a half-life of 2 hours. Following multiple doses, plasma levels are proportional to dose with no evidence of drug accumulation. One gram of Mefenamic Acid given four times daily produces peak blood level of 20 ug/ml by the second day of administration. Following a single dose, sixty-seven percent of the total dose is excreted in the urine as unchanged drug or as one of two metabolites. Twenty to twenty-five percent of the dose is excreted in the faeces during the first three days.

Indication:

Mefenamic Acid is indicated for the treatment of primary dysmenorrhea and the relief of moderate pain when therapy will not exceed one week.

Recommended Dosage:

The recommended regimen in acute pain for adults and children over 14 years of age is 500mg three times daily, usually not to exceed one week.

For the treatment of primary dysmenorrhoea, the recommended dosage is 500mg three times daily, starting with the onset of bleeding and associated symptoms.

Mefenamic Acid should not be used for more than 7 days at a time.

After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

Route of Administration: Oral

Contraindications:

Mefenamic Acid should not be used in patients who have previously exhibited hypersensitivity to it. Because the potential exists for cross-sensitivity to aspirin or other NSAIDs, Mefenamic Acid should not be given to patients in whom these drugs induce symptoms of bronchospasm, allergic rhinitis or urticaria.

Mefenamic Acid is contraindicated in patients with active ulceration or chronic inflammation of either the upper or lower gastrointestinal tract.

Mefenamic Acid should be avoided in patients with pre existing renal disease. Since Mefenamic Acid is eliminated primarily by the kidneys, the drug should not be administered to patients with significantly impaired renal function.

Warnings and Precautions:

Cardiovascular Thrombotic Events

Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events, principally myocardial infarction, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk of an adverse cardiovascular event in patient taking NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration.

There is no consistent evidence that the concurrent use of aspirin mitigates the possible increased risk of serious cardiovascular thrombotic events associated with NSAID use.

Hypertension

NSAIDs may lead to the onset of new hypertension or worsening of the pre-existing hypertension and patients taking antihypertensive with NSAIDs may have an impaired anti-hypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.

Heart Failure

Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.

Severe Skin Reactions

NSAIDs may very rarely cause serious cutaneous adverse events such as exfoliative dermatitis, toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), which can be fatal and occur without warning. These serious adverse events are idiosyncratic and are independent of dose or duration of use. Patients should be advised of the signs and symptoms of serious skin reactions and to consult their doctor at the first appearance of a skin rash or any other sign of hypersensitivity.

Mefenamic Acid should be used with caution in patients with impaired renal function or a history of kidney or liver disease and it may exacerbate asthma and hypertension. Caution should be observed when anti-coagulant is administered concomitantly with nonsteroidal anti-inflammatory drugs (NSAIDs), to be certain that no change in anticoagulation dosage is required. In addition to specific drug interactions that might affect prothrombin time, NSAIDs can inhibit platelet aggregation, and can cause gastrointestinal bleeding, peptic ulceration and /or perforation. Safety and effectiveness in children below the age of 14 have not been established.

Risk of GI Ulceration, Bleeding and Perforation with NSAIDs

Serious GI Toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patient treated with NSAIDs therapy. Although minor upper GI problem (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patient with prior history of serious GI events and other risk factor associated with peptic ulcer disease (e.g alcoholism, smoking and corticosteroid therapy) are at increased risk. Elderly or debilitated patient seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Interactions with Other Medicaments:

Mefenamic Acid may prolong prothrombin time. Therefore, when the drug is administered to patients receiving oral anticoagulant drugs, frequent monitoring of prothrombin time is necessary.

Mefenamic Acid may reduce the excretion of lithium leading to significant increase in the steady-state plasma lithium levels. Hence, increased plasma lithium level monitoring is recommended.

Pregnancy and Lactation:

As there are no adequate and well-controlled studies in pregnant women, this drug should be used only if clearly needed. The use of this drug in late pregnancy is not recommended because of the effects on the foetal cardiovascular system. For the same reason, Mefenamic Acid should not be taken by nursing mothers.

Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation.

Side Effects:

Mefenamic Acid may give rise to occasional gastro-intestinal upsets or rashes. Gastro-intestinal haemorrhage may rarely occur. Other haematological effects include haemolytic anaemia, agranulocytosis, pancytopenia, thrombocytopenia, thrombocytopenic purpura and bone marrow aplasia.

The occurrence of diarrhoea or skin rash is an indication for discontinuing treatment.

Symptoms and Treatment of Overdose:

Symptoms of overdose include diarrhoea, nausea with or without vomiting, abdominal pain, drowsiness, dizziness, nervousness, headache, blurred vision. Mefenamic Acid has a marked tendency to induce tonic-clonic (grand mal) convulsions in overdose. Dyskinesia, acute renal failure and coma have been reported. Overdose has led to fatalities.

Treatment is symptomatic and supportive. The stomach should be emptied by inducing emesis or by careful gastric lavage followed by the administration of activated charcoal. Vital functions should be monitored and supported. Because Mefenamic Acid and its metabolites are firmly bound to plasma proteins, hemodialysis and peritoneal dialysis may be of little value.

Incompatibilities: Reports of incompatibilities are not available.

Effects on Ability to Drive and Use Machine:

The effect of Mefenamic Acid on the ability to drive or use machinery has not been systematically evaluated.

Storage Conditions: Store below 30°C.

Shelf-life: 5 years

	Fenagesic Capsule 250MG		Fenagesic Tablet 250MG		Fenagesic Tablet 500MG	
	Bottle	Blister	Bottle	Blister	Bottle	Blister
Pack sizes	-	10 x 10, 50 x 10 and 100 x 10 capsules per strip	20 tablets	2 x 10, 10 x 10, 50 x 10 and 100 x 10 tablets per strip	-	10 x 10, 50 x 10 and 100 x 10 tablets per strip
Pack sizes (Export only)	-	-	1000 tablets 180 tablets	-	1000 tablets 90 tablets	-

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer:
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