FENAGESIC

Fenagesic Tablet 250mg	: Mefenamic Acid Erythrosine Ethylene Glycol Monoethyl Ether HPMC Isopropyl Alcohol Lactose Magnesium Stearate Methylene Chloride Quinoline Yellow Sodium Lauryl Sulphate Starch Talc	250mg	Fenagesic Tablet 500mg	: Mefenamic Acid Calcium Phosphate Erythrosine Lake HPMC Isopropyl Alcohol Lactose Magnesium Stearate PVP Quinoline Yellow Starch Talc Titanium Dioxide Water	500mg
Fenagesic Capsule 250mg	: Mefenamic Acid Allura Red Brilliant Blue Gelatin Magnesium Stearate Quinoline Yellow Starch Titanium Dioxide	250mg	Fenagesic Suspension 125mg/5ml	: Mefenamic Acid Cherry Flavour Deionised Water Glucose Glycerine Propylene Glycol Saccharin Sodium Benzoate Tween 80 Xanthan Gum	125mg/5ml

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 mcg/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 mcg/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.

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

Adverse 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.

Precautions / Warnings:
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 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.

Gastrointestinal Events
All NSAIDs can cause gastrointestinal discomfort and rarely serious, potentially fatal gastrointestinal effects such as ulcers, bleeding and perforation which may increase with dose or duration of use, but can occur at any time without warning. Caution is advised in patients with risk factors for gastrointestinal events e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. When gastrointestinal bleeding or ulcerations occur in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patient about signs and symptoms of serious gastrointestinal toxicity. The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse event.

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.

Pregnancy and Lactation:
As there are no adequate and well-controlled studies in pregnant women, this drug should be used only it 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 dysfuction 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.

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 primaril by the kidneys, the drug should not be administered to patients with significantly impaired renal function.
NSAIDS, including mefenamic acis, are contraindicated for the treatment of peri-operative pain in the setting of coronory artery bypass graft (CABG) surgery.

Dosage:
Oral administration.
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.

Symptoms and treatment of overdosage:
Symptoms of overdosage 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 overdosage. 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.

Drug interactions:
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.

Storage conditions: Store at or below 25ºC.

Shelf-life:
Capsule/250 Tablet/500 Tablet: 5 years.
Suspension: 3 years.

Pack sizes:
Capsule : A bottle of 1000 capsules. Blister pack: 100x10 capsules/strip
250 Tablet : A bottle of 1000 tablets. Blister pack: 100x10 tablets/strip
500 Tablet : A bottle of 1000 tablets.
Suspension : A bottle of 1 litre.
Not all presentations may be locally.

Pack sizes:
Capsule : Size 1 capsule, Ivory / Blue
250 Tablet : Round, yellow, convex, film-coated tablets.
500 Tablet : Oval, yellow, convex, film-coated tablet with "P-O" debossed on one side and single score on the other side.
Suspension : Cloudy, white suspension with cherry flavour.

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

Manufacturer:
Sunward Pharmaceutical Pte. Ltd.
11, Wan Lee Road, Singapore 627943

Revised Date: 03/01/2022
CL629A-R5