

FENAGESIC SUSPENSION

Fenagesic Suspension 125mg/5ml	: Mefenamic Acid Cherry Flavour Deionised Water Glucose Glycerine Propylene Glycol Saccharin Sodium Benzoate Tween 80 Xanthan Gum	125mg/5ml
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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 events.

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 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.

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. NSAIDs, including Mefenamic Acid, are contraindicated for the treatment of peri-operative pain in the setting of coronary 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 as an initial dose followed by 250mg every 6 hours as needed, usually not to exceed one week. For the treatment of primary dysmenorrhoea, the recommended dosage is 500mg as an initial dose followed by 250mg every 6 hours, 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 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.

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.

Pack sizes	Storage conditions
A bottle of 60ml, 100ml and 120ml.	Store at or below 30°C.
A bottle of 1 litre.	Store at or below 25°C.

Shelf-life: 3 years.

Descriptions: Cloudy, white suspension with cherry flavour.

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

Manufactured by:
Sunward Pharmaceutical Sdn. Bhd.
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Imported by:
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Revised Date: 07/01/2022
SL311A-R2

For manufactured in Singapore and imported by Malaysia.