

DYFENAMIC

	DESCRIPTION	CONTENT
DYFENAMIC CAPSULE 250MG MAL19910013AZ	CAPSULE Capsule Colour : Ivory/Blue Capsule Size : # 1 Granules Colour : White To Off-white	Each Capsule Contains: Mefenamic Acid 250 mg
DYFENAMIC TABLET 250MG MAL19910165AZ	TABLET Colour : Yellow Shape : Round and Biconvex Coating : Film-coated	Each Tablet Contains: Mefenamic Acid 250 mg
DYFENAMIC TABLET 500MG MAL19910166AZ	TABLET Colour : Yellow Shape : Oval, Biconvex and Scored Coating : Film-coated	Each Tablet Contains: Mefenamic Acid 500 mg

PHARMACODYNAMICS:

Analgesic action: It may block out pain impulse generation via a peripheral action which may involve inhibition of the synthesis of prostaglandins, and possibly inhibition of the synthesis or action of other substances which sensitise pain receptors to mechanical or chemical stimulation.

Anti-inflammatory action: It may act peripherally in inflamed tissue, probably by inhibiting the synthesis of prostaglandins and possibly by inhibiting the synthesis and/or actions of other local mediators of the inflammatory response.

PHARMACOKINETICS:

Mefenamic Acid is absorbed from the GIT. Peak concentrations on the circulation occur about 2 hours after ingestion. Mefenamic Acid is extensively bound to plasma proteins. Approximately 50% of a dose may be recovered in the urine within 48 hours, mainly as conjugated metabolites.

INDICATIONS:

Mild to moderate pain such as muscular aches, backaches, dental pain, bursitis, dysmenorrhoea, rheumatic pain, traumatic pain, headaches of most aetiology, postoperative and postpartum pain, rheumatoid arthritis (including Still's disease), osteoarthritis and menorrhagia due to dysfunctional causes.

RECOMMENDED DOSAGE:

Adults: Pain - 500 mg initially, followed by 250 mg every 6 hours as necessary. Treatment should not be continued for longer than 7 days.

Dysmenorrhoea - Medication should be initiated with the onset of bleeding and associated symptoms and should not be necessary for more than 2 to 3 days.

Children with Still's disease: 25 mg/kg body weight daily in divided doses (only for tablet).

All to be taken with some food or after meal.

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

CONTRAINDICATIONS:

Patients hypersensitive to Mefenamic Acid. Patients with ulceration or inflammation of gastrointestinal tract.

PRECAUTIONS:

It should be given with care to patients with bleeding disorders, cardiovascular disease, peptic ulceration or a history of such ulceration, and in those who are receiving coumarin anticoagulants. It should be given with caution to patients with renal impairment and patients with impaired liver function. It may impair the ability to perform activities requiring mental alertness or physical co-ordination. Treatment should not be continued for longer than 7 days in children, except in the treatment of Still's disease. It has marked tendency to induce grand mal convulsions in overdose.

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 antihypertensive 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 ulceration occurs 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 Steven-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.

Serious skin reactions such as Generalised bullous fixed drug eruption (GBFDE) have been reported very rarely in association with the use of Mefenamic Acid. Mefenamic Acid should be discontinued at the first appearance of the skin rash, mucosal lesions or any other sign of hypersensitivity.

WARNINGS:

If acute gastric pain, gastric bleeding, severe diarrhoea or severe skin rashes occur, discontinue the drug and seek medical treatment immediately.

WARNINGS

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor GI problems (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. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

DRUG INTERACTIONS:

Mefenamic Acid may enhance the effects of the coumarin anticoagulants.

PREGNANCY AND LACTATION:

Safety in pregnancy has not been established and because of the effects of drugs in this class on the foetal cardiovascular system, the use of Mefenamic Acid in pregnant women is not recommended.

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.

SIDE EFFECTS/ADVERSE REACTIONS:

Gastrointestinal disturbances. Peptic ulceration and gastrointestinal bleeding. Headache, dizziness, nervousness, skin rash, pruritus, tinnitus, oedema, depression, drowsiness, insomnia, blurred vision.

Hypersensitivity reactions, impairment of renal and liver functions, and diarrhoea may occur.

Skin and subcutaneous tissue disorders:

Generalised bullous fixed drug eruption (GBFDE)

SYMPTOMS AND TREATMENT OF OVERDOSE:

Overdose may cause nausea, vomiting, gastrointestinal disturbances, gastric bleeding. In acute poisoning the stomach should be emptied by aspiration and lavage. Activated Charcoal has been suggested to reduce the absorption of Mefenamic Acid.

PACKING/PACK SIZE(S):

DYFENAMIC CAPSULE 250MG - Blister packs of 50x10's and 100x10's.

DYFENAMIC TABLET 250MG - Blister pack of 100x10's.

DYFENAMIC TABLET 500MG - Blister packs of 1x10's, 10x10's and 100x10's.

**JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN**

MANUFACTURER/PRODUCT REGISTRATION HOLDER:

DYNAPHARM (M) SDN. BHD. 198001011897 (65683-V)

2497, Mk. 1, Lorong Perusahaan Baru 5,

Kawasan Perusahaan Perai 3,

13600 Perai, Pulau Pinang, Malaysia.

PI1PC D002-05
Latest Revision: Aug 2024