MAMIC FORTE TABLETS

(Mefenamic Acid 500 mg)

COMPOSITION

Each tablet contains Mefenamic Acid BP 500 mg. Excipients: as per the approved product formulation.

DESCRIPTION AND PHARMACOLOGY

Mefenamic acid is a non-steroidal anti-inflammatory drug (NSAID) of the fenamate group with analgesic, anti-inflammatory and antipyretic effects. It inhibits cyclo-oxygenase-mediated prostaglandin synthesis. Prostaglandins contribute to inflammation, pain and menstrual cramps.

INDICATIONS

Symptomatic relief of mild to moderate pain including musculoskeletal, dental, traumatic and postoperative pain; primary dysmenorrhoea; and painful inflammatory conditions such as osteoarthritis and rheumatoid arthritis. It may be used for heavy menstrual bleeding when an appropriate diagnosis has been established, according to the prescribing physician and approved local labeling.

DOSAGE AND ADMINISTRATION

Adults: One 500 mg tablet orally three times daily, where this regimen is prescribed for the approved indication. Use the lowest effective dose for the shortest possible duration. Take with or after food. For menstrual pain, begin at onset of symptoms and continue only as directed. Important: Other references describe a 500 mg initial dose followed by 250 mg every six hours; this cannot be delivered accurately using an unsplittable 500 mg tablet. Do not assume tablets can be divided unless the approved tablet specification permits it. Do not exceed prescribed dosage.

CHILDREN AND ELDERLY

Not routinely recommended in children younger than 12 years for this 500 mg tablet formulation. Elderly patients are more susceptible to gastrointestinal bleeding, kidney problems and cardiovascular events; use particular caution and close monitoring.

CONTRAINDICATIONS

Hypersensitivity to mefenamic acid, aspirin or other NSAIDs, including prior NSAID-associated asthma, urticaria or allergic reactions; active or recurrent peptic ulceration or gastrointestinal bleeding; prior NSAID-associated gastrointestinal bleeding or perforation; severe heart, liver or renal failure; inflammatory bowel disease; pain associated with coronary artery bypass graft (CABG) surgery; and the third trimester of pregnancy.

IMPORTANT WARNINGS

Cardiovascular risk: NSAIDs may increase the risk of heart attack, stroke and serious thrombotic events, sometimes without warning. Gastrointestinal risk: Potentially fatal ulceration, bleeding or perforation can occur at any time, particularly with increasing dose or duration and in older people. Stop treatment and seek urgent medical attention for chest pain, breathlessness, sudden weakness, vomiting blood or black stools.

PRECAUTIONS

Use with caution in hypertension, cardiovascular disease, oedema, dehydration, kidney or liver impairment, asthma, coagulation disorders, epilepsy and systemic lupus erythematosus. Monitor renal function, blood pressure and signs of blood loss when clinically indicated. Stop if a severe rash, mucosal lesion, persistent diarrhoea, unexplained bruising or allergic reaction develops. NSAIDs may mask fever or infection. Avoid prolonged treatment unless medically supervised.

DRUG INTERACTIONS

Avoid combined use with other NSAIDs, including selective COX-2 inhibitors. Aspirin, anticoagulants (e.g. warfarin), antiplatelets, corticosteroids and SSRIs can increase bleeding risk. ACE inhibitors, ARBs and diuretics may increase renal risk or have reduced antihypertensive effect. Mefenamic acid can increase toxicity of lithium and methotrexate; caution with ciclosporin, tacrolimus and other nephrotoxic medicines. Consult a physician about concomitant drugs.

PREGNANCY AND LACTATION

Avoid in pregnancy unless clearly necessary and prescribed, particularly after 20 weeks because of potential fetal renal effects. Contraindicated in the third trimester due to risk of premature ductus arteriosus closure and other fetal/maternal complications. Mefenamic acid may impair fertility. Consult a physician during breastfeeding; alternative analgesics may be preferred.

ADVERSE REACTIONS

Common effects include nausea, vomiting, abdominal discomfort, heartburn, diarrhoea, dyspepsia, dizziness, headache and rash. Serious events include gastrointestinal ulceration/bleeding, severe skin reactions (including Stevens-Johnson syndrome), bronchospasm or anaphylaxis, kidney injury, liver dysfunction, blood disorders, fluid retention, hypertension and cardiovascular thrombotic events. Seek medical help for severe or persistent symptoms.

OVERDOSAGE

Overdose may cause nausea, vomiting, abdominal pain, dizziness, drowsiness, seizures, gastrointestinal bleeding, acidosis or kidney injury. Obtain urgent medical attention. Management is symptomatic and supportive; no specific antidote is known. Do not induce vomiting unless directed by a medical professional.

EFFECTS ON DRIVING

Dizziness, drowsiness or visual disturbance may occur. Do not drive or use machinery if affected.

STORAGE

Store below 30°C in a dry place, protected from heat, moisture and direct sunlight, unless otherwise stated on the approved pack. Keep out of the reach of children.

PRESENTATION

10 × 10 tablets (100 tablets).

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.