XAMIC MF

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for Xamic MF (Tranexamic acid 500 mg and mefenamic acid 250 mg Tablet) [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: ***Tranexamic acid:*** Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At much higher concentrations it is a non- competitive inhibitor of plasmin. ***Mefenamic acid:*** It is a non-steroidal anti-inflammatory agent with analgesic and anti- pyretic properties. **INDICATION:** For the treatment of primary dysmanorrhoea and relief of mild to moderate pain associated with menorrhagia in women. **DOSAGE AND ADMINISTRATION:** ***Tranexamic acid:*** The recommended dosage is 2 tablets 3 times daily for as long as needed, but for a maximum of 4 days. The dosage may be increased but total dose of 4 g daily (8 tablets) should not be exceeded. ***Mefenamic acid:*** The recommended dose is 500 mg three times daily started with the onset of bleeding and associated symptoms. **CONTRAINDICATION:** Contraindicated in patients with thromboembolic risk and hypersensitivity to tranexamic acid and mefenamic acid, inflammatory bowel disease, history of gastrointestinal bleeding or perforation related to previous NSAIDs therapy, history of recurrent peptic ulcer/haemorrhage, severe heart failure, hepatic failure, renal failure, during last trimester of pregnancy and treatment of pain after coronary artery bypass graft (CABG) surgery. **WARNINGS & PRECAUTIONS**: Caution should be required for thromboembolic risk due to concomitant use of hormonal contraceptives, use of factor IX complex concentrates or anti-inhibitor coagulant and with all-trans retinoic acid. Cautions should be required for ocular effects, severe allergic reaction, subarachnoid hemorrhage and ligneous conjunctivitis. Precaution should be taken in patients suffering from dehydration and renal disease, particularly the elderly. Cautions required for respiratory disorders, hepatic impairment, cardiovascular and cerebrovascular effects, gastrointestinal bleeding, ulceration and perforation, SLE and mixed connective tissue disease, skin reactions, impair female fertility and epilepsy. **DRUG INTERACTIONS:** ***Tranexamic Acid:*** concomitant use of hormonal contraception and Tranexamic Acid may further exacerbate the increased thrombotic risk associated with combination hormonal contraceptives. Tissue plasminogen activators decrease the efficacy of both tranexamic acid and tissue plasminogen activators. Tranexamic Acid is contraindicated with Factor IX complex concentrates or anti-inhibitor coagulant concentrates, All-Trans Retinoic Acid (Oral Tretinoin). Mefenamic acid interact with anticoagulant such as warfarin, lithium, anti-platelet agents, SSRIs, antihypertensives and diuretics drugs, ACE inhibitors and angiotensin-II-receptor antagonists, aminoglycosides, cardiac glycosides, ciclosporin, corticosteroids, oral hypoglycaemic agents, methotrexate, mifepristone, probenecid, quinolone antibiotics, tacrolimus and zidovudine. **ADVERSE REACTIONS:** Headache, nasal and sinus symptoms, back pain, abdominal pain, musculoskeletal pain, arthralgia, muscle cramps and spasms, migraine, anemia, fatigue, dyspnea, tightening of throat, facial flushing, nausea, vomiting, and diarrhea, allergic skin reactions, anaphylactic shock and anaphylactoid reactions (severe allergic reaction), thromboembolic events, impaired color vision and other visual disturbances and dizziness. Peptic ulcers, perforation or GI bleeding, flatulence, constipation, dyspepsia, melaena, haematemesis, ulcerative stomatitis, cholestatic jaundice and exacerbation of colitis and Crohn's disease. Mild hepatotoxicity, hepatitis, hepatorenal syndrome, haemolytic anaemia, hypoplasia bone marrow, haematocrit decreased, thrombocytopenic purpura, leukopenia, hypersensitivity, glucose intolerance in diabetic patients, hyponatraemia, confusion, depression, hallucinations, nervousness, optic neuritis, drowsiness, eye irritation, ear pain, tinnitus, oedema, hypertension,

cardiac failure, asthma, erythema multiforme, bullous reactions including Lyell's syndrome (toxic epidermal necrolysis), Stevens-Johnson syndrome, allergic glomerulonephritis, acute interstitial nephritis, dysuria, haematuria, malaise, multi-organ failure and pyrexia.

MARKETED BY:

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