CLOTAN

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

Abbreviated Prescribing information for CLOTAN (Tolfenamic acid 200mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: NSAID with anti-inflammatory, analgesic, and antipyretic effects. Tolfenamic acid is a prostaglandin synthesis inhibitor and a leukotriene synthesis inhibitor.

INDICATION: Acute migraine.

DOSAGE AND ADMINISTRATION: Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms. To be taken preferably with or after food. *Adult:* 200mg when the first symptoms of migraine appear. The treatment can be repeated once after 1-2 hours if a satisfactory response is not obtained.

CONTRAINDICATION: Hypersensitivity to tolfenamic acid or other NSAIDs or to any of the excipients; Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding); severe heart failure, hepatic failure and renal failure; History of GI performation/bleeding related to previous NSAID use; Last trimester of pregnancy.

WARNINGS & PRECAUTIONS: Elderly patients; Respiratory disorders (current/history of bronchial asthma), Cardiovascular, renal and hepatic impairment; Increased risk of arterial thrombotic events (MI, stroke), Uncontrolled hypertension, CHF, cerebrovascular disease, GI bleeding/perforation, SLE and mixed connective tissue disease (may develop aseptic meningitis), Impaired female fertility thus not recommended in women attempting to conceive.

DRUG INTERACTIONS: NSAIDs increase risk of bleeding; Anti-hypertensive and diuretics effect diminished; Anti-coagulants increased risk of bleeding; Corticosteroid increased risk of GI ulceration/bleeding; It interacts with Cardiac glycoside, lithium, methotrexate, ciclosporin, tacrolimus, mifepristone, SSRIs, Quinolones, Zidovudine.

ADVERSE REACTIONS: Hypersensitivity reaction (including allergic reaction, affecting respiratory tract etc), GI hemorrhage and bleeding, rash, pruritus, serious skin/dermatological reaction (SJS, TEN), edema, hypertension, cardiac failure, Thrombocytopenia, renal failure, nephrotoxicity, Abnormal liver function, hepatitis and jaundice, Visual disturbances, optic neuritis, headaches, paraesthesia.

MARKETED BY:

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(Additional information is available on request)