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: Rheumatoid arthritis, osteo arthritis, ankylosing spondylitis and related conditions associated with pain. Additional indication of migraine.

DOSAGE AND ADMINISTRATION: Migraine - acute attacks: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. For oral administration. To be taken preferably with or after food.

CONTRAINDICATION: Hypersensitivity to tolfenamic acid to any of the excipients; NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs; 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 perforation/bleeding related to previous NSAID use; Last trimester of pregnancy.

WARNINGS & PRECAUTIONS: The use of Tolfenamic acid with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients. The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy. When GI bleeding or ulceration occurs in patients receiving Tolfenamic acid, the treatment should be withdrawn. GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events. In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis. Tolfenamic acid should be discontinued at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity. The use of Tolfenamic acid may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Tolfenamic acid should be considered.

DRUG INTERACTIONS: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects. Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs. NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels. The effect of lithium may be increased due to decreased elimination of lithium. Decreased elimination of methotrexate. Increased risk of nephrotoxicity with ciclosporin. NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone. Increased risk of gastrointestinal ulceration or bleeding with corticosteroids. NSAIDs may enhance the effects of anti-coagulants, such as warfarin. In patients treated with anti-coagulants, close monitoring of blood coagulation is recommended. Increased risk of gastrointestinal bleeding with anti-platelets and SSRI. Increased risk of haematological toxicity when NSAIDs are given with zidovudine.

ADVERSE REACTIONS: Peptic ulcers, perforation or GI bleeding, nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis,

exacerbation of colitis, crohn's disease, pancreatitis, hypersensitivity, anaphylaxis, respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, oedema, hypertension, cardiac failure, increased risk of arterial thrombotic events (for example myocardial infarction or stroke), nephritis, nephrotic syndrome, renal failure, dysuria, abnormal liver function, hepatitis, jaundice, visual disturbances, optic neuritis, headaches, paraesthesia, reports of aseptic meningitis (especially in patients with existing auto-immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), stiff neck, disorientation, depression, confusion, hallucinations, tinnitus, vertigo, tremor, euphoria, dizziness, malaise, fatigue, drowsiness, thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia, haemolytic anaemia, and bullous reactions including stevens johnson syndrome and toxic epidermal necrolysis.

MARKETED BY:

TORRENT PHARMA

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(Additional information is available on request)