

DICLOGESIC TH

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

Abbreviated Prescribing information for DICLOGESIC TH 4/8 [Diclofenac Sodium 50mg, Thiocolchicoside 4mg/8 mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Diclofenac is a nonsteroidal anti-inflammatory drug with analgesic and antipyretic properties. Thiocolchicoside (TCC) is thio-methyl derivative of colchicoside used clinically for its muscle relaxant, anti-inflammatory, and analgesic properties. **INDICATION:** Indicated for the symptomatic treatment of painful muscle cramps **DOSAGE AND ADMINISTRATION:** Tablet should be taken on a full stomach. It should be given 2 tablets bid for severe muscle cramps. The maximum recommended dose of thiocolchicoside is 16mg daily in divided dose, hence the dosage should not be exceeded the maximum recommended dose.

CONTRAINDICATION: Contraindicated in hypersensitivity to the active substance or any of the excipients, previously shown hypersensitivity reactions (e.g. asthma, angioedema, urticaria or acute rhinitis) to ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs, history of, or active, gastro-intestinal ulcers, bleeding or perforation, severe hepatic, renal and heart failure, during the last trimester of pregnancy, history of gastrointestinal bleeding or perforation, relating to previous NSAID therapy, acute porphyria.

WARNINGS & PRECAUTIONS: Use with cautions if patient with concomitant NSAIDs including cyclo-oxygenase-2-selective inhibitors, elderly patients, gastro-intestinal disorders, with a history suggestive of gastro-intestinal ulceration, with ulcerative colitis or with Crohn's disease, haematemesis, melaena, ulceration or perforation, impairment of hepatic, renal or cardiac function, hypersensitivity reactions, defects of haemostasis, bleeding diathesis or haematological abnormalities, respiratory disorders (bronchial asthma, uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease), serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis. Diclofenac may impair female fertility and is not recommended in women attempting to conceive. It should not be used in patient of severe renal failure.

ADVERSE REACTIONS: Anaemia, hypersensitivity, anaphylactic and anaphylactoid reactions, disorientation, depression, insomnia, headache, dizziness, somnolence, drowsiness, tiredness, visual disturbance, vision blurred, diplopia, vertigo, tinnitus, palpitations, chest pain, hypertension, vasculitis, asthma, alveolitis, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain or cramps, flatulence, anorexia, gastritis, gastrointestinal haemorrhage or bleeding, haematemesis, diarrhoea haemorrhagic/bloody, melaena, gastrointestinal ulcer, with or without bleeding or perforation, colitis, transaminases increased, rash, skin eruptions, urticaria, bullous eruptions/dermatoses, eczema, erythema, erythema multiforme, stevens-johnson syndrome, toxic epidermal necrolysis, interstitial fibrosis, acute renal failure or insufficiency, oedema and impotence.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/ DICLOGESIC TH 4,8mg/Feb-2015/01/AbPI

(Additional information is available on request)