

DICLOGESIC

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

Abbreviated Prescribing information for DICLOGESIC [Diclofenac Sodium 50mg and Paracetamol 325mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Nonsteroidal agent with marked analgesic/anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase, (cyclo-oxygenase).

INDICATION: For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

DOSAGE AND ADMINISTRATION: The dosage for the combination should not be used than maximum dosage of individual agent. **Diclofenac sodium:** 75-150mg daily in two or three divided doses (maximum up to 150mg). Children (aged 1-12 years): 1-3mg/kg per day in divided doses.

Paracetamol: Maximum of up to 4gm in 24 hours can be given. Children age 6 to 12 years of age: Maximum of up to 2gm in 24 hours can be given. Children less than 6 years not recommended.

CONTRAINDICATION: Active/history gastric or intestinal ulcer, bleeding or perforation, recurrent peptic ulcer/haemorrhage; Last trimester of pregnancy; Severe hepatic, renal or cardiac failure; NSAIDs is contraindicated in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, aspirin or NSAIDs.

WARNINGS & PRECAUTIONS: Gastrointestinal bleeding effects/history of bleeding; exercise caution while use of drugs which increase the risk of ulceration or bleeding; ulcerative colitis and crohn's disease; abnormal hepatic function; hepatic porphyria; renal failure/impaired renal function; serious skin reactions; systemic lupus erythematosus (SLE) and mixed connective tissue disorders; exercise caution in patients with history of cardiovascular and cerebrovascular disorders; defects of haemostasis, bleeding diathesis or haematological abnormalities; pre-existing asthma; not recommended in female attempting to conceive.

DRUG INTERACTIONS: **Diclofenac sodium:** Interacts with lithium, digoxin, diuretics and antihypertensive agents, anti-coagulants and anti-platelets, corticosteroid, antidiabetic agents, methotrexate, ciclosporin, tacrolimus, quinolone antibiotics, phenytoin, colestipol and cholestyramine, mifepristone and using CYP2C9 inhibitors. **Paracetamol:** Interacts with cholestyramine, metoclopramide, domperidone, chloramphenicol and warfarin.

ADVERSE REACTIONS: Headache, dizziness, cerebrovascular accident, cardiac failure, myocardial infarction, vertigo, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, transaminases increased, rash, liver dysfunction/failure, hematological reaction, hypersensitivity/anaphylactoid reaction, renal failure, bleeding/hemorrhagic reaction.

MARKETED BY:



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(Additional information is available on request)