Clofenac® DT

Diclofenac

Analgesic & Anti-inflammatory

COMPOSITION

Clofenac® DT : Each Dispersible Tablet (DT) contains 46.5 mg of Diclofenac Free Acid, which is equivalent to 50 mg of Diclofenac Sodium BP.

PHARMACOLOGY

Clofenac® DT contains 46.5 mg of Diclofenac Free Acid, which is equivalent to 50 mg of Diclofenac Sodium BP. Diclofenac has anti-rheumatic, anti-inflammatory, analgesic and antipyretic action. Diclofenac inhibits cyclooxygenase activity with a reduction in the tissue production of prostaglandins that play a major role in inflammation, pain and fever. Clofenac® DT has a rapid onset of action and is suitable for the treatment of acute painful and inflammatory conditions. As Clofenac® DT is a dispersible tablet, it is also suitable for those who have difficulty in swallowing tablets. Anti-inflammatory and analgesic properties of Clofenac® DT elicit a clinical response characterised by marked relief from signs and symptoms such as pain at rest, pain on movement, morning stiffness and swelling of the joints, as well as improvement in function in rheumatic diseases.

Absorption: Diclofenac from Clofenac® DT is absorbed immediately after administration. A mean peak plasma concentration of about 1 µgm/ml is observed witnin 1 hour after ingestion of one Clofenac® DT tablet in empty stomach. Ingestion of dispersible tablets together with or immediately after a meal does not delay the onset of absorption. It is highly bound to plasma protein that amounts to about 99.7%.

Elimination: About 60% drug of the dose is metabolised and excreted mainly in urine. Less than 1% is excreted as unchanged substance. The rest of the dose is eliminated as metabolites through the bile in the faeces. The half-life in plasma is 1-2 hours. In patients suffering from renal impairment, no accumulation of the unchanged active substance can be inferred from the single dose kinetics when applying the usual dosage schedule. At a creatinine clearance of <10 ml/min, the calculated steady-state plasma levels of hydroxy metabolites are about 4 times higher than in normal subjects. However, the metabolites are ultimately cleared through bile. In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of Diclofenac are the same as in patients without liver disease.

Clofenac® DT

INDICATION

Rheumatoid arthritis, osteoarthritis, low back pain, and other acute musculoskeletal disorders such as tendinitis, tenosynovitis, bursitis, sprains, strains, dislocation, ankylosing spondylitis, acute gout, control of pain and inflammation in orthopedics, dental and other minor surgery, post operative pain, juvenile chronic arthritis and pain of renal colic.

DOSAGE AND ADMINISTRATION

Adults: The recommended daily dosage is 2-3 tablets and the maximum daily dose is 150 mg. In milder cases, 2 tablets of Clofenac® DT per day are sufficient. Clofenac® DT should preferably be taken before meals.
Children: Diclofenac is not recommended in children for other indications except juvenile rheumatoid arthritis where the recommended dose is 1-3 mg/kg body weight.

Clofenac® DT is to be dropped into a half-glass of water and the liquid is to be stirred to aid dispersion before swallowing. There is no information on the use of Clofenac® DT for more than 03 months.

CONTRAINDICATION AND PRECAUTION

Diclofenac is contraindicated in peptic ulcer. Known hypersensitivity to Diclofenac is also a contraindication. Like other NSAIDs, Diclofenac is also contraindicated in patient in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other drugs with prostaglandin synthetase inhibiting activity.

Diclofenac should be used with caution in peptic ulcer, hepatic and renal impairment, pregnancy and allergic disorders. Like other NSAIDs, Diclofenac may temporarily inhibit platelet aggregation. Patients with defects of hemostasis should be carefully monitored, when they are having treatment with Diclofenac.

SIDE EFFECT

Side effects are generally mild and infrequent but include gastrointestinal discomfort or occasional bleeding, nausea, hypersensitivity reaction, headache, vertigo and hearing disturbances such as tinnitus. Severe adverse effects such as peptic ulcer, perforation of peptic ulcer, blood dyscrasias may rarely occur.

DRUG INTERACTION

Lithium & digoxin: Diclofenac may increase plasma concentration of lithium & digoxin.

Anticoagulants: There are isolated reports of an increased risk of hemorrhage with the combined use of Diclofenac and Anticoagulant therapy.

Antidiabetic agents: Clinical studies have shown that Diclofenac can be given together with oral antidiabetic agents without influencing their clinical effects.

Cyclosporin: Cases of nephrotoxicity have been reported in patients receiving concomitant cyclosporin and NSAIDs.

Methotrexate: Cases of serious toxicity have been reported when methotrexate and NSAIDs are given within 24 hours of each other.

Diuretics: Various NSAIDs are liable to inhibit the activity of diuretics.

USE IN PREGNANCY AND LACTATION

Diclofenac should not be prescribed during pregnancy unless there is some compelling reasons. Following oral doses of 50 mg administered every 8 hours, the active substance passes into the breast milk, but in quantities so small that no undesirable effects are to be expected.

HOW SUPPLIED

Clofenac® DT: Box containing 5 x 10 Clofenac® DT in blister pack.