# Diclonac TR

Diclofenac Sodium BP 100 mg

**COMPOSITION**

Each capsule contains Diclofenac Sodium BP 100 mg in a sustained release formulation.

**PHARMACOLOGY**

**Diclonac TR** contains Diclofenac sodium which is a potent non-steroidal anti-inflammatory Drug (NSAID) with marked analgesic and antipyretic properties. It has also some uricosuric effects. The actions of Diclofenac appear to be associated principally with the inhibition of prostaglandin synthesis by inhibiting cyclo-oxygenase, the enzyme that catalyzes the formation of prostaglandin precursors (Endoperoxides) from arachidonic acid. Following oral administration, Diclofenac is rapidly absorbed from the gastro-intestinal tract. Diclofenac is 99.7% bound to plasma proteins and plasma half-life for the terminal elimination phase is 1-2 hours. Diclofenac enters the synovial fluid where maximum concentrations are measured 2-4 hours after the peak plasma values have been obtained. The apparent half-life for elimination from the synovial fluid is 3-6 hours. About 60% of the administered dose is excreted via the kidney in the form of metabolites and less than 1% in unchanged form. The remainder is excreted via the bile in metabolized form.

**INDICATIONS**

Pain and inflammations in a wide range of conditions including: *Arthritic condition:* Rheumatoid arthritis, osteoarthritis, ankylosing spondilitis and acute gout. *Acute musculoskeletal disorders:* Peri-arthritis (e.g. frozen shoulder), tendinitis, tenosynovitis and bursitis. *Other painful conditions resulting from trauma:* Low back pain, sprains, strains, dislocations, and orthopaedic, dental & other minor surgery.

**DOSAGE AND ADMINISTRATION**

**Diclonac TR:** 1 capsule daily, preferably with food. Children: Not recommended.

**CONTRAINDICATION AND PRECAUTION**

Diclofenac is contra-indicated for those patients who are hypersensitive to active or in suspected peptic ulcer or gastrointestinal bleeding or for those patients with asthma, urticaria or acute rhinitis.
Patients with severe hepatic, or renal insufficiency or the elderly should be kept under close surveillance as the use of NSAIDs may result in deterioration of renal function. The lowest efective dose should be used and renal function should be monitored.
If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (Eosinophilia, rash), Diclofenac should be discontinued. All patients who are receiving long term treatment with NSAIDs should be monitored as a precautionary measure (e.g. renal, hepatic function and blood counts).

**SIDE-EFFECTS**

Side-effects of Diclofenac are usually mild and transient. However, if serious side-effects occur, Diclofenac should he discontinued.
Gastrointestinal Side-effects: Occasionally epigastric pain, other gastro-intestinal disorders (e.g. nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia). Rarely gastro-intestinal bleeding, peptic ulcer (with or without bleeding or perforation), bloody diarrhoeal. In isolated cases: Lower gut disorders (e.g. non-proctocolitis), pancreatitis, glossitis, constipation, etc.

**DRUG INTERACTIONS**

All dosage forms may have the following drug interactions. Lithium and digoxin: Diclofenac may increase plasma concentrations of Lithium and Digoxin. Anticoagulants: There are isolated reports and increased risk of haemorrhage with the combined use of Diclofenac and anticoagulant therapy. Although clinical investigations do not appear to indicate any influence on anticoagulant effects. 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 Cyclosporin and Diclofenac concomitantly. Methotrexate: Case of serious toxicity has been reported when Methotrexate and NSAIDs are given within 24 hours of each other. Quinolone antimicrobials: Convulsions may occur due to an interaction between Quinolones and NSAIDs. Therefore, caution should be exercised while considering concomitant therapy of NSAIDs and Quinolones. Other NSAIDs and steroids: Co-administration of Diclofenac with other systemic NSAIDs and steroids may increase the frequency of unwanted effects. With aspirin, the plasma level of each is lowered although no clinical significance is known. Diuretics: Various NSAIDs are liable to inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels. So, serum potassium should be monitored.

**USE IN PREGNANCY AND LACTATION**

Diclofenac should not be prescribed during pregnancy unless there are compelling reasons for doing so and the lowest effective dosage should be used. This type of drug is not recommended during the last trimester of pregnancy. Very small quantities of Diclofenac may be detected in breast milk, but no undesirable effects on the infant are to be expected. Since no experience has been acquired with Diclofenac in pregnancy or lactation, it is not recommended for use in these circumstances.

**STORAGE CONDITION**

Store in a cool and dry place, protected from light.

**PACKAGING**

Each box contains 5x10's capsules in blister pack.

*Manufactured by*

ZISKA PHARMA

**Ziska Pharmaceuticals Ltd.**
Kaliakoir, Gazipur, Bangladesh