Clofenac®

Diclofenac

COMPOSITION

Clofenac® 50 tablet: Each enteric coated tablet contains Diclofenac Sodium BP 50 mg.
Clofenac® DT : Each tablet contains 46.50 mg of Diclofenac Free Acid equivalent to 50 mg Diclofenac Sodium BP.
Clofenac® SR tablet: Each enteric coated tablet contains Diclofenac Sodium BP 100 mg in a sustained release formulation.
Clofenac® Plus injection: Each 2 ml ampoule contains Diclofenac Sodium BP 75 mg and Lidocaine Hydrochloride USP 20 mg .
Clofenac® 1% Gel : Each gm gel contains 11.6 mg Diclofenac Diethyl ammonium salt equivalent to 10 mg Diclofenac Sodium BP.
Clofenac®12.5 suppository : Each suppository contains Diclofenac Sodium BP 12.5 mg.
Clofenac® 25 suppository : Each suppository contains Diclofenac Sodium BP 25 mg.
Clofenac® 50 suppository : Each suppository contains Diclofenac Sodium BP 50 mg.

PHARMACOLOGY

Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) with marked anit-rheumatic, anti-inflammatory, analgesic and antipyretic action. It also has some uricosuric effect. Diclofenac acts by inhibiting the biosynthesis of prostaglandins. Prostaglandins appear to play a major role in causing inflammation, pain and fever.

INDICATION

Clofenac® tablets, capsule, injection, suppositories, and **Clofenac®** Plus injection contain diclofenac sodium, which is used to relief of pain and inflammation in a wide range of conditions including:

a) Arthritic conditions: Rheumatoid Arthritis, Osteoarthritis, Ankylosing spondylitis, Acute gout.

b) Acute musculoskeletal disorders such as periarthritis (e.g., frozen shoulder), tendinitis, tenosynovitis, bursitis.
c) Other painful conditions resulting from trauma, including fracture, low back pain, sprains, strains, dislocations, orthopaedic, dental and other minor surgery.

Clofenac® Plus injection also contains lidocaine, which acts as a local anaesthetic. Therefore, the possibility of pain at the injection site, which is most likely to occur after intramuscular injection of normal diclofenac, is minimized if Clofenac® Plus Injection is used.

Clofenac® Gel & Emulgel are used for the local symptomatic relief of pain and inflammation in:
a) Trauma of the tendons, ligaments, muscles and joints, e.g, due to sprains, strains and bruises
b) Localized chronic pain like osteoarthritic pain and back pain.

DOSAGE AND ADMINISTRATION

Clofenac® 50 tablet, SR tablet

Adults : 75 - 150 mg daily in 2 to 3 divided doses, preferably after food. Dose should be reduced in long term use. Clofenac® SR: 1 tablet daily, taken whole with liquid, preferably at meal times. If necessary, the daily dose can be increased to 150 mg by supplementation with conventional tablets.
Children: 1-3 mg of diclofenac / kg body wt. daily in divided doses.
Elderly patients: In elderly or debilitated patients, the lowest effective dosage is recommended, although the pharmacokinetics of diclofenac sodium is not impaired to any clinically relevant extent in elderly patients.

Clofenac® DT :

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 daily 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 ½ 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.

Clofenac® Plus injection:

Adults: One ampoule once (or in severe cases, twice) daily by intramuscular injection.
Renal colic: One ampoule once daily intramuscularly. A further ampoule may be administered after 30 minutes, if necessary.
The recommended maximum daily dose of diclofenac is 150 mg, by any route.
The recommended maximum daily dose of lidocaine is 200 mg.
Children: In juvenile chronic arthritis, 1-3 mg of diclofenac / kg body wt. daily in divided doses.
Elderly patients: In elderly or debilitated patients, the lowest effective dosage is recommended, commensurate with age and physical status.

Clofenac® Gel: Depending on the size of the affected site, 2 - 4 gm Gel/Emulgel, 3 - 4 times daily. After application, the hands should be washed unless they are the site being treated.

Clofenac® suppository : Suppository should be administered rectally.
Adults: 25 mg or 50 mg suppository only: 75-150 mg daily in divided doses.
Children (1-12 years): 12.5 mg or 25 mg suppository only: 1-3 mg/kg per day in divided doses.

CONTRA-INDICATIONS

Diclofenac is contra-indicated for those patients who are hypersensitive to diclofenac. In patients with active or suspected peptic ulcer or gastro-intestinal bleeding, or for those patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other NSAIDs possessing prostaglandin synthetase inhibiting activity, diclofenac is also contra-indicated.

SIDE-EFFECT

Side-effects to diclofenac are usually mild and transient. However, if serious side-effects occur, diclofenac should be discontinued.
Gastrointestinal: Occasional: epigastric pain, other gastro-intestinal disorders (e.g., nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia).
Rare: gastro-intestinal bleeding, peptic ulcer (with or without bleeding or perforation), bloody diarrhoea. In isolated cases : lower gut disorders (e.g., non-specific haemorrhagic colitis and exacerbations of ulcerative colitis or Crohn's proctocolitis), pancreatitis, glossitis,constipation, etc.

DRUG INTERACTIONS

Diclofenac Sodium may have the following drug interactions:
Lithium and digoxin: Diclofenac may increase plasma concentrations of lithium and digoxin.
Anticoagulants: There are isolated reports of an 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 effect.
Antidiabetic agents : Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect.
Cyclosporin : Cases of nephrotoxicity have been reported in patients receiving cyclosporin and diclofenac concomitantly.
Methotrexate : Cases of serious toxicity have 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 when considering concomitant therapy of NSAID 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 levels of each is lowered, although no clinical significance is known.

USE IN PREGNANCY & LACTATION

Diclofenac should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used. This type of drugs are 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.

STORAGE CONDITION

Clofenac® 50 tablet, SR tablet : Store below 30°C. Protect from light, and moisture.
Clofenac® Gel: Store below 30°C. Protect from light, and moisture.
Clofenac® Plus injection: Store below 30°C. Protect from light.
Clofenac® Suppositories: Store below 25°C. Protect from light.

HOW SUPPLIED

Clofenac® 50 tablet: Box containing 200 tablets in blister pack.
Clofenac® DT: Box containing 50 tablets in blister pack.
Clofenac® SR tablet: Box containing 100 tablets in blister pack.
Clofenac® Plus injection : Box containing 10 ampoules of 2 ml in blister pack.
Clofenac® 1% Gel: Tube containing 20 gm gel.
Clofenac® 12.5 suppository: Box containing 10 suppositories in blister pack.
Clofenac® 25 suppository: Box containing 10 suppositories in blister pack.
Clofenac® 50 suppository : Box containing 10 suppositories in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH