GENAC Injection

Diclofenac Sodium BP

GENAC injection contains Diclofenac Sodium. Each 3 ml ampoule contains 75 mg Diclofenac Sodium BP.

PHARMACODYNAMICS :

Diclofenac is a potent non-steroidal compound with pronounced antirheumatic, anti-inflammatory, analgesic and anti pyretic properties. Diclofenac inhibits the synthesis of prostaglandins by inhibiting cycloxygenase, an enzyme that catatyzes the formation of prostaglandin precursors (endoperoxides) from arachidonic acid.

PHARMACOKINETICS :

Peak plasma concentrations are achieved within half an hour following injection. 99.7% of diclofenac binds to serum 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 peak plasma values have been reached. The apparent half-life for elimination from the synovial fluid is 3 to 6 hours.

Diclofenac is extensively metabolized to a range of phenolic compounds. About 60% of the administered dose is excreted via the kidneys in the form of metabolities and less than 1% is excreted as uncleamped form. The rest of the dose is eliminated as metabolities through the bile in the faeces.

INDICATIONS :

Diclofenac Sodium, which has got the following therapeutic uses: Rheumatic Arthritis, Osteoarthritis, Low back pain and other acute musculoskeletal disorders such as periarthritis (e.g. frozen shoulder) tendinitis, tenosynovitis, burtitis, sprains, strains and dislocations, Ankylosing spondylitis, Acute gout, Acute trama and fractures, control of pain and inflammation in orthopaedic, dental & other minor surgery. Juvenile chronic arthritis, Post-operative pain, pain of rectal colic and other uses.

DOSAGE AND ADMINISTRATION :

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.

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 & physical status or as prescribed by the physician.

CONTRAINDICATIONS :

Gastric or intestinal ulcer. Known hypersensitivity to the active substance. It is contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other drugs with prostoglandin-synthetase inhibiting activity.

PRECAUTION :

History of gastro-intestinal ulceration, haematemesis or melaena, ulcerative or colitis, Crohn's disease and patients suffering from impaired hepatic function, Cardiac or renal insufficiency should be kept under close surveillance. All patients who are receiving long term treatment with NSAIDs should be monitored as a precautionary measure (e.g. renal, hepatic function & blood counts).

USE IN PREGNANCY AND LACTATION :

It 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 & to lactating mother.

SIDE EFFECTS :

Side-effects to diclofenac are usually mild and transient. However, if serious side effects occur, the injection should be discontinued. Gastro-intestinal discomfort, nausea, diarrhoea and occasionally bleeding may occur. In very rare cases injection site disorders may occur. In isolated cases, abscesses and local nacrosis may occur.

STORAGE CONDITION :

Store in a place which protects from heat & light.

HOW SUPPLIED :

Box containing 2 x 5 ampoules in blister pack..

Manufactured by:

Globe Pharmaceuticals Ltd.

Noakhali, Bangladesh.