AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
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LEAFLET

AGODIC-50

Diclofenac Tablets BP 50 mg.

Appearance:
Brown coloured, circular, biconvex enteric coated Tablets

Composition : Each enteric - coated tablet contains :
Diclofenac Sodium BP 50 mg

Diclofenac is a non-steroidal antiinflammatory agent. It is indicated in the treatment of rheumatoid arthritis, osteoarthritis, low back pain, acute musculoskeletal disorders, trauma, ankylosing spondylitis, acute gout etc.

Clinical Pharmacology :
Diclofenac sodium inhibits prostaglandin synthesis by blocking cyclooxygenase pathway. It thereby acts as antiinflammatory, analgesic and antipyretic. Diclofenac sodium is rapidly absorbed from gastrointestinal tract. It undergoes first pass metabolism. Peak plasma concentrations are achieved within 1 hour. It is 99% bound to plasma proteins. Plasma half life is 1 to 2 hours. Approximately 60% of the dose is excreted via kidney in the form of metabolites and less than 1% is excreted in unchanged form. The remainder of the doses is excreted via bile in metabolite form.

Indications :
Diclofenac is indicated in the treatment of rheumatoid arthritis, osteoarthritis, low-back pain, and acute musculo-skeletal disorders. It is also indicated in the treatment of ankylosing spondylitis, trauma, acute gout it is also indicated in the treatment of dysmenorrhoea and juvenile chronic arthritis.

Dosage and administration :
For adult patients the daily dose is 75 mg to 150 mg daily in 2 to 3 divided doses. In children the daily dose is 1 to 3 mg/kg body weight in divided doses. In elderly patients Diclofenac should be administered in minimum effective doses.

Contraindications, Warning and Precautions :
Diclofenac is contraindicated in patients with known hypersensitivity to diclofenac sodium. It is also contraindicated in patients with peptic ulcer or gastrointestinal bleeding, asthma, urticaria, and acute rhinitis. Caution should be exercised in patients with severe hepatic, cardiac or renal insufficiency. Prolonged use of Diclofenac may cause renal, hepatic and GIT disturbances.

Diclofenac should be withdrawn, if liver function tests become abnormal. Patients must be told to take Diclofenac after meals to avoid GIT irritations.

Use in pregnancy and lactation :
Diclofenac should not be used during pregnancy, unless the benefit justifies the risk. It is detected into breast, hence should be used with caution in nursing mothers.

Drug interaction :
Diclofenac may increase the plasma concentration of lithium and digoxin. It also increases the nephrotoxicity of cyclosporin. Diclofenac also increases the plasma concentrations of methotrexate. Diclofenac inhibits the diuretic actions of hydrochlorothiazide and frusemide.

Side effects :
Diclofenac causes epigastric pain, abdominal cramp, dyspepsia, flatulance, anorexia and peptic ulcer with gastrointestinal bleeding. On central nervous system, it may cause headache, dizziness, vertigo, drowsiness and tiredness. Diclofenac also causes occasional rashes or skin eruptions.

Overdosage :
Management of acute poisoning with Diclofenac essentially consists of supportive and symptomatic measures. Gastric lavage is employed to reduce absorption

Storage : Store under normal storage conditions (15°C - 30°C).
Protect from light. Keep all medicines out of reach of children.

Presentation : A Bulk pack of 1000 tablets
Blister of 10 x 10 tablets
Blister of 10 x 1 x 10 tablets.
Blister of 100 x 10 tablets

AGOG PHARMA LTD.