Flexi®

Aceclofenac BP

COMPOSITION

Flexi® Tablet : Each film-coated tablet contains Aceclofenac BP 100 mg.
Flexi® SR Tablet : Each sustained release tablet contains Aceclofenac BP 200 mg.

PHARMACOLOGY

Flexi® SR (Aceclofenac) is a non-steroidal agent with marked anti-inflammatory and analgesic properties. It is a potent inhibitor of the enzyme cycloxygenase which is involved in the production of prostaglandin.

Pharmacokinetics: After oral administration, Aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3.00 hours following ingestion. Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein-bound (>99%). Aceclofenac circulates mainly as unchanged drug, 4-hydroxy aceclofenac is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

Pharmacodynamics: Aceclofenac has multi-factor mechanism of action. Outside the inflammatory cell, Aceclofenac is metabolized to 4'-hydroxyaceclofenac. The parent drug and the metabolite penetrate the inflammatory cells and then hydrolyzed to the active metabolites diclofenac and 4'-hydroxydiclofenac, which inhibit IL-1 and TNF released by the inflammatory cells and therefore suppress production of PGE2 at the site of inflammation. Aceclofenac prevents neutrophil adhesion and accumulation at the inflammatory site in the early phase and thus blocks the pro-inflammatory actions of neutrophils.

INDICATION

For the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

DOSAGE AND ADMINISTRATION

Flexi® Tablet :
Adults : The recommended dose is 100 mg, twice daily.
Children : There are no clinical data on the use of Aceclofenac in children.
Elderly : The pharmacokinetics of Aceclofenac is not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency.
Flexi® SR Tablet : The recommended dose is 200 mg, once daily.

CONTRAINDICATION AND PRECAUTION

Aceclofenac should not be administered to patients with active or suspected peptic ulcer or gastro-intestinal bleeding. It should not be given to patients with moderate to severe renal impairment. Close medical surveillance is also imperative in patients suffering from severe impairment of hepatic function. It should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used. Aceclofenac should not be administered to patients previously sensitive to Aceclofenac or in whom aspirin or NSAIDs precipitate attacks of asthma, acute rhinitis or urticaria or who are hypersensitive to these drugs.

SIDE EFFECT

The majority of side-effects observed have been reversible and of a minor nature and include gastro-intestinal disorders (dyspepsia, abdominal pain, nausea and diarrhea) and occasional occurrence of dizziness. Dermatological complaints including pruritus and rash and abnormal hepatic enzyme levels and raised serum creatinine have occasionally been reported.

OVER DOSAGE

There are no human data available on the consequences of Aceclofenac over dosage. If over dosage is observed, therapeutic measures should be taken according to symptoms; supportive and symptomatic treatment should be given for complications such as hypotension, gastro-intestinal irritation, respiratory depression, and convulsions.

DRUG INTERACTION

Lithium and Digoxin : Aceclofenac, like many NSAIDs may increase plasma concentrations of lithium and Digoxin.
Diuretics : Aceclofenac, like other NSAIDs, may interact the activity of diuretics.
Anticoagulants : Like other NSAIDs, Aceclofenac may enhance the activity of anticoagulant. Close monitoring of patients on combined anticoagulants and Aceclofenac therapy should be undertaken.
Methotrexate : Caution should be exercised if NSAIDs and Methotrexate are administered within 24 hours of each other, since NSAIDs may increase Methotrexate plasma levels, resulting in increased toxicity.

USE IN PREGNANCY AND LACTATION

The use of Aceclofenac should be avoided in pregnancy and lactation unless the potential benefits to the mother outweigh the possible risks to the fetus.

STORAGE CONDITION

Keep at a cool and dry place, protected from light and moisture.

HOW SUPPLIED

Flexi® Tablet : Each box contains 100 tablets in blister pack.
Flexi® SR Tablet : Each box contains 30 tablets in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Pabna, Bangladesh

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