

Acenac Aceclofenac

COMPOSITION:

Acenac Tablet: Each film coated tablet contains Aceclofenac BP 100 mg.

PHARMACOLOGY:

Acenac (Aceclofenac) is a non-steroidal agent with anti-inflammatory and analgesic properties. Its mode of action is largely based on inhibition of prostaglandin synthesis. **Acenac** is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins. It also stimulates cartilage matrix (glycosaminoglycans) synthesis.

INDICATION:

Acenac is indicated for the relief of pain and inflammation in both acute and chronic pain like osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, dental pain, post-traumatic pain, low back pain, gynaecological pain etc.

DOSAGE AND ADMINISTRATION:

Adults: The maximum recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

Children: There is no clinical data on the use of aceclofenac in children.

Elderly: The pharmacokinetics of aceclofenac are not altered in elderly patients, therefore it is not considered necessary to modify the dose and dose frequency.

Renal insufficiency: There is no evidence that the dosage of aceclofenac needs to be modified in patients with mild renal impairment.

Hepatic insufficiency: The dose of aceclofenac should be reduced in patients with hepatic impairment. An initial daily dose of 100 mg should be administered.

CONTRAINDICATION:

Aceclofenac is contraindicated in patients previously sensitive to aceclofenac or aspirin or other NSAIDs. It should not be administered to patients with active or suspected peptic ulcer or gastrointestinal bleeding and moderate to severe renal impairment.

SIDE EFFECTS:

Generally aceclofenac is well tolerated. The majority of side effects observed have been reversible and of a minor nature and include gastrointestinal disorders (dyspepsia, abdominal pain, nausea and diarrhoea) and occasional occurrence of dizziness. Dermatological side effects including pruritus and rash. Abnormal hepatic enzyme levels and raised serum creatinine have occasionally been reported.

PRECAUTIONS:

Aceclofenac should be administered with caution to patients with symptoms indicative of gastrointestinal disorders, with a history of peptic ulceration, ulcerative colitis, Crohn's disease, hepatic porphyria, and coagulation disorders. Patients suffering from severe hepatic impairment must be monitored.

USE IN PREGNANCY AND LACTATION:

Pregnancy: There is no information on the use of aceclofenac during pregnancy. Aceclofenac should not be administered during pregnancy, unless there are compelling reasons for doing so. The lowest effective dose should be administered.

Lactation: There is no information on the secretion of aceclofenac in breast milk. The use of aceclofenac should therefore be avoided during lactation unless the potential benefits to the mother outweigh the possible risks to the children.

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.

PHARMACEUTICAL PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED:

Acenac Tablet: Each box contains 5x10 tablets in blister pack.

Manufactured by:



MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh