

FlexivanTM

Aceclofenac

COMPOSITION

FlexivanTM: Each film coated tablet contains Aceclofenac BP 100 mg.

FlexivanTM EK: Each extended release tablet contains Aceclofenac BP 200 mg.

PHARMACOLOGY

Aceclofenac is a non-steroidal drug with anti-inflammatory and analgesic properties. It is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandin. After oral administration, it is rapidly and completely absorbed an unchanged drug.

INDICATION

Aceclofenac is indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, toothache, trauma and lumbago.

DOSAGE AND ADMINISTRATION

FlexivanTM

Adults : Recommended dose is 100 mg, twice daily.

FlexivanTM EK

The recommended dose in adults is one tablet daily.

CONTRAINDICATION

Aceclofenac is contraindicated in patients with known hypersensitivity to it or in whom aspirin or NSAIDs precipitate attacks of asthma.

WARNING AND PRECAUTION

Caution should be exercised to patients with active or suspected peptic ulcer or gastro-intestinal bleeding moderate to severe hepatic impairment and cardiac or renal impairment. Caution should also be exercised in patients suffering from dizziness or urticaria.

SIDE EFFECTS

Majority of side effects are minor in nature and reversible. These are dyspepsia, abdominal pain, nausea, rash and urticaria.

USE IN PREGNANCY AND LACTATION

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

USE IN CHILDREN

There are no clinical data on the use of Aceclofenac in children.

DRUG INTERACTION

Lithium and Digoxin : May increase plasma concentration of lithium and digoxin.

Diuretics : May interact the activity of diuretics.

Anticoagulants : May enhance the activity of anticoagulant.

Methotrexate : May increase the plasma level of methotrexate.

OVERDOSE

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal irritation, gastrointestinal bleeding, rarely diarrhea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting and convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

STORAGE CONDITION

Keep in a cool & dry place below 30°C temperature, protected from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

FlexivanTM : Each box contains 50 tablets in Alu-PVDC blister pack.

FlexivanTM EK: Each box contains 50 tablets in Alu-PVDC blister pack.