

PRESERVIN

ACECLOFENAC BP

Compositions:

Preservin Tablet: Each film coated tablet contains Aceclofenac BP 100 mg. Each sustained release tablet contains Aceclofenac BP 200 mg.

Pharmacology:

Aceclofenac is a non steroidal agent with marked anti-inflammatory and analgesic properties. It is a potent inhibitor of the enzyme cyclooxygenase which is involved in the production of prostaglandin. It also stimulates cartilage matrix synthesis.

Indications:

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

Dosage And Administration:

Adults: The recommended dose is 100 mg twice daily. Children: No clinical data or the use of Aceclofenac in children is available. Elderly: The pharmacokinetics of Aceclofenac is not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency.

Contraindications:

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 this drug.

Warning And Precaution:

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 this drug.

Side Effects:

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.

Use in Pregnancy and Lactation:

There is no information on the use of Aceclofenac during pregnancy. The regular use of NSAIDs during the last trimester of pregnancy may increase uterine tone and contraction. There is no information on the secretion of Aceclofenac to breast milk. The use of Aceclofenac should therefore be avoided in pregnancy and lactation unless the potential benefits to the mother outweigh the possible risks to the fetus.

Drug Interaction:

Lithium and Digoxin: Aceclofenac, like many NSAIDs may increase plasma concentration of Lithium and Digoxin Diuretics: Aceclofenac, like other NSAID; 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.

Overdosage:

<p>It is not considered necessary to modify the dose or dose frequency.</p>

Storage:

Store in a cool (below 30° C) & dry place, protected from light. Keep out of reach of children.

Packing:

Preservin Tablet: Each box contains 5x10 tablets in Alu-Alu blister pack. Preservin SR Tablet: Each box contains 3x10 tablets in Alu-Alu blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.